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Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS–NOP–09–0074; NOP–09–01FR]

RIN 0581–AC96

National Organic Program (NOP); Sunset Review (2012); Correction

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Correcting amendments.

SUMMARY: This document contains a correction to the final regulations published on June 6, 2012 (77 FR 33290). These regulations pertain to the 2012 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). A technical error was inadvertently published in the final rule and requires correction. This document corrects the final regulations by revising the listing for ''colors'' at 7 CFR 205.606(d).

DATES: Effective on July 30, 2012.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION: On June 6, 2012, the Agricultural Marketing Service (AMS) published a final rule (77 FR 33290) to address the 2012 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List).

This rule amended the restrictive annotation to the listing for colors at 7 CFR 205.606(d). As published, the modification to the introductory text for this listing for colors at § 205.606(d) inadvertently removed paragraphs (d)(1) through (d)(19). These paragraphs are necessary to identify the specific nonorganic colors that can be used as ingredients in processed products labeled as ''organic'' if organic forms are not commercially available. This document corrects the final regulations by reinserting paragraphs (d)(1) through (19).

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

Accordingly, 7 CFR part 205 is corrected by making the following correcting amendments:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

■ 2. In § 205.606, revise paragraph (d) to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic.''

* * * * *

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Annatto extract color (pigment CAS #1393–63–1)—water and oil soluble.

(2) Beet juice extract color (pigment CAS #7659–95–2).

(3) Beta-carotene extract color, derived from carrots (CAS #1393–63–1).

(4) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(5) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(6) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(7) Carrot juice color (pigment CAS #1393–63–1).

(8) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(9) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(10) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(11) Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(12) Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(13) Paprika color (CAS #68917–78–2)—dried, and oil extracted.

(14) Pumpkin juice color (pigment CAS #127–40–2).

(15) Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(16) Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(17) Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

(18) Saffron extract color (pigment CAS #1393–63–1).

(19) Turmeric extract color (CAS #458–37–7).

* * * * *

Dated: July 20, 2012.

Ruihong Guo,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2012–18511 Filed 7–27–12; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0765; Directorate Identifier 2012–CE–028–AD; Amendment 39–17130; AD 2012–15–01]

RIN 2120–AA64

Airworthiness Directives; Various Aircraft Equipped With Rotax Aircraft Engines 912 A Series Engine

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for various aircraft equipped with Rotax Aircraft Engines 912 A series engine. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a deviation in the manufacturing process of fuel hoses installed on the pressure side of part number 893114 fuel pumps. The fuel hoses may not be fuel resistant, which could lead to detachment of particles from the fuel hose and cause irregularities in the carburetor function and possibly result in rough engine operation, engine misfire, in-flight engine shutdown, and forced landing. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective August 14, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 14, 2012.

We must receive comments on this AD by September 13, 2012.

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

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

For service information identified in this AD, contact BRP–Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; Internet: *http://www.rotax-aircraft-engines.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket 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: Sarjapur Nagarajan, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4145; fax: (816) 329–4090; email: *sarjapur.nagarajan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2012–0097R1, dated June 1, 2012 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Reports from the field confirmed a non-compliance of pressure side fuel hoses installed on certain P/N 893114 fuel pumps, which may have resulted in a latent defect on a limited number of engines. The affected fuel hoses may not be fuel resistant in accordance with the specification.
>
> This condition, if not corrected, could lead to detachment of particles from the fuel hose and irregularities in the carburettor function, possibly resulting in in-flight engine shutdown and forced landing, damage to the aeroplane and injury to occupants.
>
> To address this potential unsafe condition, EASA issued Emergency AD 2012–0093–E to require the replacement of the pressure side fuel hose on certain fuel pumps, identified by P/N 893114. That AD also prohibited installation of an affected engine on an aeroplane, unless the fuel pump installation of that engine had been corrected as required by the AD.
>
> Since that AD was issued, the relevant BRP–Powertrain Alert Service Bulletin (ASB) ASB–912–061 has been revised (R1) to correct the list of affected P/N 893114 fuel pumps, identified by s/n. As some of these pumps (including potentially defective hoses) have been delivered as spares, they could also be installed on other engines than those specified by s/n in BRP–Powertrain ASB–912–061R1.
>
> For the reasons described above, this AD retains the requirements of EASA Emergency AD 2012–0093–E, which is superseded, expands the Applicability to all Rotax 912 series engines and corrects Table 1—Affected P/N 893114 fuel pumps. In addition, 2 aeroplane types have been removed from the Applicability of this AD: Aeromot AMT 300 Turbo Super Ximango and Stemme S10 VT have a Rotax 914 engine installed, not a Rotax 912.
>
> This AD has been revised to correct Table 1 of the Required Action(s) and Compliance Times(s) section, which did not contain all affected s/n fuel pumps.

This AD requires replacement of the pressure side fuel hose on the part number (P/N) 893114 fuel pump. This AD also prohibits the installation of an affected engine unless the pressure side fuel hose on the P/N 893114 fuel pump has been replaced. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Rotax Aircraft Engines BRP has issued Alert Service Bulletin ASB–912–061R1, dated May 31, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the 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 this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because detachment of particles from the fuel hose on the pressure side of the fuel pump could cause engine damage and result in in-flight engine shutdown. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–0765; Directorate Identifier 2012–CE–028–AD'' at the beginning of your comments. We specifically invite comments on the

overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Costs of Compliance

We estimate that this AD will affect 50 products of U.S. registry. We also estimate that it will take about 3 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $300 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $27,750, or $555 per product.

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

For the reasons discussed above, I certify that this AD:

(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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 AD:

2012–15–01 Various Aircraft: Amendment 39–17130; Docket No. FAA–2012–0765; Directorate Identifier 2012–CE–028–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective August 14, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all serial numbers of the airplanes listed in table 1 to paragraph (c) of this AD, that are:

(1) Equipped with a Rotax Aircraft Engines 912 A series engine, with a part number (P/N) 893114 fuel pump installed; and

(2) certificated in any category.

TABLE 1 TO PARAGRAPH (C)—AFFECTED AIRPLANES

Type certificate holder	Aircraft model	Engine model
Aeromot-Indústria Mecânico-Metalúrgica Ltda	AMT–200	912 A2
Diamond Aircraft Industries	HK 36 R ''SUPER DIMONA''	912 A
DIAMOND AIRCRAFT INDUSTRIES GmbH	HK 36 TS and HK 36 TC	912 A3
Diamond Aircraft Industries Inc.	DA20–A1	912 A3
HOAC-Austria	DV 20 KATANA	912 A3
Iniziative Industriali Italiane S.p.A.	Sky Arrow 650 TC	912 A2
SCHEIBE-Flugzeugbau GmbH	SF 25C	912 A2

(d) Subject

Air Transport Association of America (ATA) Code 73: Engine Fuel and Control.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a deviation in the manufacturing process of fuel hoses installed on the pressure side of P/N 893114 fuel pumps. The fuel hoses may not be fuel resistant, which could lead to detachment of particles from the fuel hose and cause irregularities in the carburetor function. We are issuing this AD to prevent failure of the fuel hose on the pressure side of the P/N 893114 fuel pump, which could result in rough engine operation, engine misfire, in-flight engine shutdown, and forced landing.

(f) Actions and Compliance

Unless already done, do the following actions in accordance with Rotax Aircraft Engines BRP Alert Service Bulletin ASB–912–061R1, dated May 31, 2012.

(1) Before further flight after August 14, 2012 (the effective date of this AD), replace the pressure side fuel hose on the P/N 893114 fuel pump.

(2) As of August 14, 2012 (the effective date of this AD), do not install a P/N 893114 fuel pump on any engine, unless the pressure side fuel hose of that fuel pump has been replaced as required in paragraph (f)(1) of this AD.

(3) As of August 14, 2012 (the effective date of this AD), do not install on any airplane a Rotax 912 A series engine, unless the fuel pump installation of that engine has been corrected as required in paragraph (f)(1) of this AD.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Sarjapur Nagarajan, Aerospace

Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4145; fax: (816) 329–4090; email: *sarjapur.nagarajan@faa.gov*. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2012–0097R1, dated June 1, 2012; and Rotax Aircraft Engines BRP Alert Service Bulletin ASB–912–061R1, dated May 31, 2012, for related information.

(i) Material Incorporated by Reference

(1) You must use Rotax Aircraft Engines BRP Alert Service Bulletin ASB–912–061R1, dated May 31, 2012, to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact BRP–Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; Internet: *http://www.rotax-aircraft-engines.com*.

(3) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on July 17, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–18149 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–1164; Directorate Identifier 2010–NM–057–AD; Amendment 39–17135; AD 2012–15–06]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Astra SPX, 1125 Westwind Astra, and Gulfstream 100 airplanes. This AD was prompted by a report indicating that sponge rubber padding was found between wheel well fuel lines and electrical harnesses. This AD requires inspecting for the presence of sponge rubber padding and for proper separation of the fuel lines and electrical harnesses in the wheel well area, and corrective actions if necessary. We are issuing this AD to detect and correct corrosion or chafing of the fuel lines, which could result in fuel leakage and possible fire in the wheel well area.

DATES: This AD becomes effective September 4, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 4, 2012.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Groves, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1503; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on December 8, 2010 (75 FR 76317). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Sponge rubber padding used to provide separation between wheel well fuel lines and electrical harnesses was discovered during fleet maintenance. Use of this type of padding for this purpose is not approved as it is liable to cause corrosion of the fuel lines. Unless steps are taken to remove this padding and install approved separation means, fuel lines may be damaged by corrosion and/or chafing resulting in an unsafe condition due to fuel leakage[, which could result in a fire] in the wheel well area.

Corrective actions include installing loop clamps to correct improper separation and removing sponge rubber padding, and repair or replacement of any corroded or chafed fuel lines found after sponge rubber padding removal. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comments received.

Requests To Include Additional Inspection Area

Gulfstream Aerospace Corporation (Gulfstream) requested that the inspection area be expanded to include tube assemblies outside of the wheel well area that have also been found to have sponge rubber padding and corrosion beneath the padding. Gulfstream stated that the padding with corrosion beneath has been found on four tube assemblies outside of the wheel well area specified in the NPRM (75 FR 76317, December 8, 2010) and Gulfstream Service Bulletin 100–28–297, dated January 21, 2010. These four tube assemblies are part of, or an extension of, the tube assemblies identified by part number in that service bulletin, and terminate in the wing root area.

John R. Dunn, a private citizen, stated that, upon further investigation after discovering instances of sponge rubber

in the left wheel well, foam (sponge rubber padding) was found wrapped around tubes in the forward wing root areas of two airplanes along with wire harnesses alongside the affected tubes. Corrosion was also found on those tubes. John R. Dunn stated that neither of the affected wing root areas are mentioned in Gulfstream Service Bulletin 100–28–297, dated January 21, 2010.

We partially agree. We agree to investigate reports of sponge rubber padding use, and any subsequent corrosion, that occurs outside of the wheel well area specified in Gulfstream Service Bulletin 100–28–297, dated January 21, 2010. Depending on the results of the investigation, we will work with the airplane manufacturer to develop appropriate service information and might consider additional rulemaking to address these areas. We do not agree to change this AD to include the additional areas outside of the wheel well areas, since that would expand the scope of this AD and therefore require additional public review. We do not yet have sufficient information to justify delaying this AD to include those tubes. We have not changed the AD in this regard.

Request To Revise Wording in Paragraph (g) of NPRM (75 FR 76317, December 8, 2010)

Gulfstream requested that the NPRM (75 FR 76317, December 8, 2010) be revised to state that ''all'' tubes in the wheel well areas be inspected for the sponge rubber padding and corrosion conditions. Gulfstream stated that it has received reports where tube part numbers other than those called out in the service information have sponge rubber padding.

We disagree to revise the wording in paragraph (g) of this AD to add the word ''all.'' Gulfstream Service Bulletin 100–28–297, dated January 21, 2010, already specifies a detailed inspection in the wheel well area for the presence of sponge rubber padding without specifying part numbers. As noted in paragraph 4.A. of the Accomplishment Instructions of that service bulletin, this inspection is not limited to the fuel line part numbers identified in that service bulletin. The Accomplishment Instructions of that service bulletin note that if fuel lines other than those with part numbers identified in that service bulletin are found to have sponge rubber padding, then the padding must be removed and those affected tubes must also be inspected for corrosion. We have not revised the AD in this regard.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (75 FR 76317, December 8, 2010) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (75 FR 76317, December 8, 2010).

Differences Between This AD and the MCAI or Service Information

Where Gulfstream Service Bulletin 100–28–297, dated January 21, 2010, specifies to submit a photo of any sponge rubber padding that is found to the manufacturer, this AD does not require that action.

Gulfstream Service Bulletin 100–28–297, dated January 21, 2010, instructs operators to contact Gulfstream if technical assistance is required. However, any deviation from the instructions provided in that service bulletin and mandated by this AD must be approved as an alternative method of compliance (AMOC) under the provisions of paragraph (h)(1) of this AD.

Costs of Compliance

We estimate that this AD will affect 130 products of U.S. registry. We also estimate that it will take about 25 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $100 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $289,250, or $2,225 per product.

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

For the reasons discussed above, I certify that this AD:

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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 the NPRM (75 FR 76317, December 8, 2010), 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 AD:

2012–15–06 Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.): Amendment 39–17135. Docket No. FAA–2010–1164; Directorate Identifier 2010–NM–057–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 4, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Astra SPX, 1125 Westwind Astra, and Gulfstream 100 airplanes, serial numbers 002 through 158 inclusive, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28: Fuel.

(e) Reason

This AD was prompted by a report indicating that sponge rubber padding was found between wheel well fuel lines and electrical harnesses. We are issuing this AD to detect and correct corrosion or chafing of the fuel lines, which could result in fuel leakage and possible fire in the wheel well area.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Actions

Within 24 months after the effective date of this AD, inspect for the presence of sponge rubber padding on the fuel lines in the wheel well area and inspect the fuel lines and electrical harnesses in the wheel well area for proper separation, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 100–28–297, dated January 21, 2010.

(1) If any sponge rubber padding is found, before further flight, remove all sponge rubber padding from the fuel lines, inspect the fuel lines that were covered with the rubber padding for any corrosion and repair or replace as applicable any corroded or chafed fuel lines, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 100–28–297, dated January 21, 2010.

(2) If any fuel lines and electrical harnesses are found to not have proper separation, before further flight, install loop clamps in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 100–28–297, dated January 21, 2010.

(3) If proper separation is found, and no sponge rubber padding is found, no further action is required by this paragraph.

(h) 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: Tom Groves, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1503; 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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(i) Related Information

Refer to MCAI Israeli Airworthiness Directive 28–10–02–01, dated February 22, 2010; and Gulfstream Service Bulletin 100–28–297, dated January 21, 2010; for related information.

(j) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part:

(i) Gulfstream Service Bulletin 100–28–297, dated January 21, 2010.

(ii) Reserved.

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, Georgia 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* Internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 17, 2012.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–18153 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0488; Directorate Identifier 2008–SW–20–AD; Amendment 39–17126; AD 2012–14–12]

RIN 2120–AA64

Airworthiness Directives; Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Arrow Falcon Exporters, Inc. (previously Utah State University); Firefly Aviation Helicopter Services (previously Erickson Air-Crane Co.); California Department of Forestry; Garlick Helicopters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC (previously Western International Aviation, Inc.); International Helicopters, Inc.; Precision Helicopters, LLC; Robinson Air Crane, Inc.; San Joaquin Helicopters (previously Hawkins and Powers Aviation, Inc.); S.M.&T. Aircraft (previously US Helicopters, Inc., UNC Helicopter, Inc., Southern Aero Corporation, and Wilco Aviation); Smith Helicopters; Southern Helicopter, Inc.; Southwest Florida Aviation International, Inc. (previously Jamie R. Hill and Southwest Florida Aviation); Tamarack Helicopters, Inc. (previously Ranger Helicopter Services, Inc.); US Helicopter, Inc. (previously UNC Helicopter, Inc.); West Coast Fabrication; and Williams Helicopter Corporation (previously Scott Paper Co.) Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P Helicopters; and Southwest Florida Aviation Model UH–1B (SW204 and SW204HP) and UH–1H (SW205) Helicopters. This AD requires

inspecting each affected tail rotor blade (blade) forward tip weight retention block (tip block) and the aft tip closure (tip closure) for adhesive bond voids and removing any blade with an excessive void from service. This AD also requires modifying certain blades by installing shear pins and tip closure rivets. This AD was prompted by reports of missing tip blocks or tip closures, resulting in minor to substantial damage to blades installed on Bell Model 212 and 412 helicopters. The actions are intended to prevent loss of a tip block or tip closure, loss of a blade, and subsequent loss of control of the helicopter.

DATES: This AD is effective September 4, 2012.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of September 4, 2012.

ADDRESSES: For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/*. You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* 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 AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

On May 13, 2010, at 75 FR 26889, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to Arrow Falcon Exporters, Inc. (previously Utah State University); Firefly Aviation Helicopter Services (previously Erickson Air-Crane Co.); California Department of Forestry; Garlick Helicopters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC (previously Western International Aviation, Inc.); International Helicopters, Inc.; Precision Helicopters, LLC; Robinson Air Crane, Inc.; San Joaquin Helicopters (previously Hawkins and Powers Aviation, Inc.); S.M.&T. Aircraft (previously US Helicopters, Inc., UNC Helicopter, Inc., Southern Aero Corporation, and Wilco Aviation); Smith Helicopters; Southern Helicopter, Inc.; Southwest Florida Aviation International, Inc. (previously Jamie R. Hill and Southwest Florida Aviation); Tamarack Helicopters, Inc. (previously Ranger Helicopter Services, Inc.); US Helicopter, Inc. (previously UNC Helicopter, Inc.); West Coast Fabrication; and Williams Helicopter Corporation (previously Scott Paper Co.) Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P Helicopters; and Southwest Florida Aviation Model UH–1B (SW204 and SW204HP) and UH–1H (SW205) Helicopters. This NPRM proposed to require inspecting each applicable blade tip block and tip closure for voids and removing any blade with an excessive void from service. The NPRM also proposed to require modifying certain blades by installing shear pins and tip closure rivets. The proposed requirements were intended to prevent loss of a tip block or tip closure, loss of a blade, and subsequent loss of control of the helicopter.

AD 2002–09–04, Amendment 39–12737 (67 FR 22349, May 3, 2002), was issued for the Bell Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters and contained the same requirements as those in this AD. AD 2007–22–02, Amendment 39–15238 (72 FR 60760, October 26, 2007), superseded AD 2002–09–04 to expand the applicability to include other part- and serial-numbered blades. Some of the blades in the applicability of AD 2007–22–02 are eligible for installation on helicopters included in this AD, which may have an FAA-approved modification that increases the helicopter's power rating to the equivalent of the Bell Model 205B or the 212 helicopter. The Bell Model 205B and 212 helicopters are addressed in AD 2007–22–02. Consequently, the inspections and modifications required by AD 2007–22–02 are mandated for the blades installed on helicopters included in this AD.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed except we have revised the estimated costs of complying with this AD to reflect ten hours for inspection instead of three hours, and minor editorial changes. These minor editorial changes are consistent with the intent of the proposals in the NPRM and will not increase the scope of the AD.

Related Service Information

We have reviewed Bell Helicopter Textron Alert Service Bulletin No. 212–00–111, Revision D, dated March 18, 2005 (ASB), which describes procedures for inspecting and modifying certain tail rotor blades. The ASB was issued as a result of an investigation of an in-flight loss of a blade tip block, part number (P/N) 212–010–750–105. The investigation revealed the countersunk screws retaining the tip block were installed incorrectly, resulting in inadequate tip block retention. Reports have also been submitted about loss of the tip closures from other blades possibly because of inadequate adhesive bonding in this area.

Costs of Compliance

We estimate that this AD will affect 716 helicopters of U.S. registry, and 25 of those helicopters will have the increased power rating. Labor costs will average an estimated $85 per work hour. Based on these assumptions, we expect the following costs:

- About 1 work hour to review the helicopter records for a labor cost of $85 per helicopter, $60,860 for the U.S. fleet.
- About 10 work hours to inspect the affected blades, install the shear pins and tip closure rivets, reidentify, and dynamically balance the blade. Required supplies will cost about $45, for a total cost of $895 per helicopter. We assume that the blade sets are installed on 25 helicopters with the FAA-approved modification that will need to be inspected and repaired.

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

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

For the reasons discussed above, I certify that this AD:

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

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

(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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2012–14–12 Arrow Falcon Exporters, Inc. (previously Utah State University); Firefly Aviation Helicopter Services (previously Erickson Air-Crane Co.); California Department of Forestry; Garlick Helicopters, Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC (previously Western International Aviation, Inc.); International Helicopters, Inc.; Precision Helicopters, LLC; Robinson Air Crane, Inc.; San Joaquin Helicopters (previously Hawkins and Powers Aviation, Inc.); S.M.&T. Aircraft (previously US Helicopters, Inc., UNC Helicopter, Inc., Southern Aero Corporation, and Wilco Aviation); Smith Helicopters; Southern Helicopter, Inc.; Southwest Florida Aviation International, Inc. (previously Jamie R. Hill and Southwest Florida Aviation); Tamarack Helicopters, Inc. (previously Ranger Helicopter Services, Inc.); US Helicopter, Inc. (previously UNC Helicopter, Inc.); West Coast Fabrication; and Williams Helicopter Corporation (previously Scott Paper Co.) Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P Helicopters; and Southwest Florida Aviation Model UH–1B (SW204 and SW204HP) and UH–1H (SW205) Helicopters: Amendment 39–17126; Docket No. FAA–2010–0488; Directorate Identifier 2008–SW–20–AD.

(a) Applicability

(1) This AD applies to Model HH–1K, TH–1F, TH–1L, UH–1A, UH–1B, UH–1E, UH–1F, UH–1H, UH–1L, and UH–1P helicopters, and Southwest Florida Aviation Model UH–1B series (SW204 series and SW204HP) and UH–1H series (SW205 series) helicopters, with a tail rotor blade (blade), part number (P/N) 212–010–750–009 through –129, all serial numbers except serial numbers with a prefix of ''A'' or ''AFS,'' and the number 11926, 13351, 13367, 13393, 13400, 13402, 13515, 13540, 13568, 13595 through 13602, 13619, and subsequent larger numbers, installed, certificated in any category.

(2) A blade inspected and modified by following either AD 2002–09–04 (67 FR 22349, May 3, 2002) or AD 2007–22–02 (72 FR 60760, October 26, 2007), for the Bell Helicopter Textron (Bell) Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters satisfies the requirements of this AD.

(b) Unsafe Condition

This AD defines the unsafe condition as adhesive bond voids. This condition could result in loss of the forward tip weight retention block (tip block) or aft tip closure (tip closure), loss of the blade, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective September 4, 2012.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 100 hours time-in-service:

(1) Inspect the tip block and tip closure of each blade for voids. Remove from service any blade with a void in excess of that allowed by the applicable maintenance or Component Repair and Overhaul Manual limitations.

(2) Inspect the tip block attachment countersink screws in the four locations to determine if the head of each countersunk screw is flush with the surface of the abrasion strip. The locations of these four screws are depicted on Figure 1 of Bell Alert Service Bulletin 212–00–111, Revision D, dated March 18, 2005 (ASB). If any of these screws are set below the surface of the abrasion strip or are covered with filler material, install shear pins by following the Accomplishment Instructions, Part A, Shear Pin Installation paragraphs, of the ASB.

(3) Install the tip closure rivets on each blade, re-identify the modified blade by adding an ''FM'' after the P/N, and dynamically balance the tail rotor hub assembly by following the Accomplishment Instructions, Part B, Aft Tip Closure Rivet Installation paragraphs, of the ASB.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, may approve AMOCs for this AD. Send your proposal to: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail Rotor Blades.

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Bell Helicopter Textron Alert Service Bulletin No. 212–00–111, Revision D, dated March 18, 2005.

(ii) Reserved.

(3) For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/*.

(4) You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(5) You may also review a copy of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Fort Worth, Texas, on July 10, 2012.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–17607 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1251; Directorate Identifier 2011–NM–017–AD; Amendment 39–17132; AD 2012–15–03]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Embraer S.A. Model ERJ 190 airplanes. This AD was prompted by a report of damage on the rod end of the retracting actuator rod of the main landing gear (MLG). This AD requires performing a one-time general visual inspection to determine if a certain part number is installed on the MLG retraction actuator; if necessary, performing a general visual inspection for discrepancies between the actuator rod end and shock strut lug of the MLG retraction actuator; and corrective actions if necessary. We are issuing this AD to detect and correct breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.

DATES: This AD becomes effective September 4, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 4, 2012.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Cindy Ashforth, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2768; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on November 28, 2011 (76 FR 72855). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> It has been found the occurrence of damage on the rod end of the Main Landing Gear (MLG) retraction actuator. The ANAC [Agência Nacional de Aviação Civil] is issuing this AD to prevent breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.
>
> * * * * *

Required actions include a one-time general visual inspection to determine if a certain part number is installed on the left-hand and right-hand MLG retraction actuator, and if necessary, a general visual inspection for discrepancies (such as cracks, damage, and movement) between the actuator rod end and shock strut lug of the MLG retraction actuator. The corrective actions include: If any discrepancy is found during any inspection, including any movement between the actuator rod-end and shock strut lug, replace the MLG retraction actuator, and as applicable, replace the anti-rotation pin and the attachment bolt with a new pin and bolt; replace the actuator with a new actuator having a certain part number, and modify the attachment points. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

Request To Use Additional Service Bulletins

EMBRAER requested that we revise the NPRM (76 FR 72855, November 28, 2011) to include EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes); and EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011 (for Model 190–100 ECJ airplanes); as additional service information for the inspection and replacement of the MLG retraction actuator, bolt, and anti-rotation pin.

We agree with EMBRAER's request to add additional service information to this AD. EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes), provides procedures for doing the inspection; and EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011 (for Model 190–100 ECJ airplanes, provides procedures for the replacement. The procedures to do the inspection and replacement are essentially the same as those specified in EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010 (for Model ERJ 190 airplanes); and EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010 (for Model ERJ 190 airplanes). We have revised this AD accordingly.

Request To Allow Flight After Damage Is Found

EMBRAER requested that we revise the NPRM (76 FR 72855, November 28, 2011) to allow further flight within 500 flight cycles after any damage is found on the airplane. EMBRAER stated that EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes); EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011 (for Model 190–100 ECJ airplanes); and Brazilian Airworthiness Directive 2011–02–01, dated February 12, 2011; allows replacement of the MLG retraction actuator, the attachment bolt, and the anti-rotation pin within the next 500 flight cycles if any discrepancy is found. EMBRAER stated that the NPRM requires that any discrepancy found be replaced before further flight.

We disagree with EMBRAER's request to allow further flight within 500 flight cycles after any damage is found on the airplane. Our policy requires repair of known cracks or damage before further flight (though we might make

exceptions to this policy in certain cases of unusual need). This policy is based on the fact that such damaged airplanes do not conform to the FAA-certificated type design and, therefore, are not airworthy until a properly approved repair is made.

We consider the compliance times in this AD adequate, allowing operators to acquire parts to have on hand in the event that any crack or damage is detected during inspection. Therefore, we have determined that, due to the safety implications and consequences associated with such cracking and damage, any subject MLG retraction actuator that is found to be cracked or damaged must be repaired or modified before further flight. We have not changed the final rule regarding this issue.

Change in Product Identification

We have revised the applicability of the existing NPRM (76 FR 72855, November 28, 2011) to identify model designations as published in the most recent type certificate data sheet for the affected models.

Explanation of Redesignated Note

We have redesignated Note 1 of the existing NPRM (76 FR 72855, November 28, 2011) as paragraph (g)(3) of this AD, respectively.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously—except for minor editorial changes. We have determined that these changes:

- Are consistent with the intent that was proposed in the NPRM (76 FR 72855, November 28, 2011) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (76 FR 72855, November 28, 2011).

Costs of Compliance

We estimate that this AD will affect 73 products of U.S. registry. We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $6,205, or $85 per product.

In addition, we estimate that any necessary follow-on actions would take about 6 work-hours and require parts costing $0, for a cost of $510 per product. We have no way of determining the number of products that may need these actions.

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

For the reasons discussed above, I certify that this AD:

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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 the NPRM (76 FR 72855, November 28, 2011), 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 AD:

2012–15–03 Embraer S.A.: Amendment 39–17132. Docket No. FAA–2011–1251; Directorate Identifier 2011–NM–017–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 4, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model ERJ 190–100 STD, –100 LR, –100 ECJ, and –100 IGW airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes; certificated in any category; all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 32: Landing Gear.

(e) Reason

This AD was prompted by a report of damage on the rod end of the retracting actuator rod of the main landing gear (MLG). We are issuing this AD to detect and correct breakage of the MLG retracting actuator rod, which may result in MLG extension with no hydraulic damping and consequent damage to the locking mechanism and collapse of the MLG.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) One-Time General Visual Inspection

Within 30 days after the effective date of this AD, do a one-time general visual inspection to determine if part number (P/N) 190–70980–403 is installed on the left-hand and right-hand MLG retraction actuator. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the MLG retraction actuator can be conclusively determined from that review.

(1) No further action is required by paragraph (g) of this AD if no MLG retraction actuator having P/N 190–70980–403 is found.

(2) If any MLG retraction actuator having P/N 190–70980–403 is found, do a GVI of the actuator and bolt (P/N 2821–0028) for discrepancies (such as cracks, damage, and movement between the actuator rod end and shock strut lug of the MLG retraction actuator), in accordance with ''Part I'' of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010 (for all Model ERJ 190 airplanes); or EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes); within the applicable compliance time specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD. Repeat the inspection, thereafter, at intervals not to exceed 3,500 flight cycles, until the actions required by paragraph (j) of this AD are done.

(i) For any MLG retraction actuator that has accumulated fewer than 3,500 total flight cycles as the effective date of this AD, do the GVI of the actuator before the accumulation of 4,500 total flight cycles on the MLG retraction actuator.

(ii) For any MLG retraction actuator that has accumulated 3,500 total flight cycles or more as of the effective date of this AD, do the GVI of the actuator within 1,000 flight cycles after the effective date of this AD.

(3) For the purpose of this AD, a general visual inspection (GVI) is: ''A visual examination of an interior or exterior area, installation or assembly to detect obvious damage, failure or irregularity. This level of inspection is made from within touching distance, unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight or droplight, and may require removal or opening of access panels or doors. Stands, ladders or platforms may be required to gain proximity to the area being checked.''

(h) Corrective Actions

If any discrepancy is found during any inspection required by paragraph (g)(2) of this AD, including any movement between the actuator rod-end and shock strut lug: Before further flight, replace the MLG retraction actuator, and as applicable the anti-rotation pin and the attachment bolt, in accordance with ''Part II'' and ''Part III,'' as applicable, of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010 (for all Model ERJ 190 airplanes), or EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes); except where EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010 (for all Model ERJ 190 airplanes), or EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011 (for Model 190–100 ECJ airplanes), specifies to contact the manufacturer, before further flight repair, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or Agência Nacional de Aviação Civil (or its delegated agent).

(i) Replacement for MLG Retraction Actuator Having P/N 190–70980–403

Before any MLG retraction actuator having P/N 190–70980–403 accumulates 12,000 total flight cycles or within 1,000 flight cycles after the effective date of this AD, whichever occurs later, replace the actuator with new a actuator having P/N 190–70980–405, and modify the attachment points, in accordance with ''Part I'' and ''Part II,'' as applicable, of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010 (for all Model ERJ 190 airplanes); or EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011 (for Model 190–100 ECJ airplanes).

(j) Replacement for All Actuators

For all actuators: Within 20,000 flight cycles or within 96 months after the effective date of this AD, whichever occurs first, do the replacement and modification, as applicable, in accordance with ''Part III'' of the Accomplishment Instructions of EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010 (for all Model ERJ 190 airplanes); or EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011 (for Model 190–100 ECJ airplanes). Doing the actions in this paragraph terminates the action for the requirements specified in paragraphs (g), (h), and (i) of this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, 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: Cindy Ashforth, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2768; 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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(l) Related Information

Refer to MCAI Brazilian Airworthiness Directive 2011–02–01, dated February 12, 2011, and the service information in paragraph (l)(1) through (l)(4) of this AD; for related information.

(1) EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010.

(2) EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010.

(3) EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011.

(4) EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise.

(i) EMBRAER Service Bulletin 190–32–0036, dated October 4, 2010.

(ii) EMBRAER Service Bulletin 190–32–0037, dated October 6, 2010.

(iii) EMBRAER Service Bulletin 190LIN–32–0014, dated February 10, 2011.

(iv) EMBRAER Service Bulletin 190LIN–32–0015, dated February 10, 2011.

(3) For service information identified in this AD, contact Embraer S.A., Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227–901 São Jose dos Campos—SP—BRASIL; telephone +55 12 3927–5852 or +55 12 3309–0732; fax +55 12 3927–7546; email *distrib@embraer.com.br;* Internet *http://www.flyembraer.com.*

(4) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 13, 2012.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–17957 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONATICS AND SPACE ADMINISTRATION

14 CFR Part 1275

[Docket Number NASA–0031]

RIN 2700–AD84

Research Misconduct

AGENCY: National Aeronautics and Space Administration.

ACTION: Direct final rule.

SUMMARY: The NASA Research Misconduct rule describes procedures to

be used by NASA for the handling of allegations of research misconduct. This direct final rule makes non-substantive changes to the policy governing the handling of allegations of research misconduct and updates to reflect organizational changes that have occurred in the Agency. The revisions to this rule are part of NASA's retrospective plan under EO 13563 completed in August 2011. NASA's full plan can be accessed at: *http://www.nasa.gov/open/.*

DATES: This direct final rule is effective on September 28, 2012, unless adverse comment is received by August 29, 2012. If adverse comment is received, NASA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Comments must be identified with RN 2700–AD84 and may be sent to NASA via the Federal E-Rulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitted comments. Please note that NASA will post all comments on the Internet with changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Teresa Fryberger, Office of the Chief Scientist, NASA Headquarters, telephone (202) 358–1982.

SUPPLEMENTARY INFORMATION:

Direct Final Rule and Significant Adverse Comments

NASA has determined this rulemaking meets the criteria for a direct final rule because it involves nonsubstantive changes dealing with NASA's procedures for dealing with research misconduct. NASA expects no opposition to the changes and no significant adverse comments. However, if NASA receives a significant adverse comment, the Agency will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background

The NASA Research Misconduct Rule was created in accordance with the ''Federal Policy on Research Misconduct'' issued by the Office of Science and Technology Policy on December 6, 2000. The proposed rule, published July 25, 2003 (68 FR 43982), was created to establish a new research misconduct policy for NASA and requested public comments on the proposed action. Details of the proposed rule can be found at *http://www.gpo.gov/fdsys/pkg/FR-2003-07-25/pdf/03-18982.pdf.* The proposed rule was changed to address public comments, and the final rule was published on July 14, 2004 (69 FR 42102). Details on how the comments were addressed can be found at *http://www.gpo.gov/fdsys/pkg/FR-2004-07-14/pdf/04-15432.pdf.*

NASA's research mission involves the advancement of research in the fields of aeronautics, space science, Earth science, biomedicine, biology, engineering, and physical science. NASA fulfills this objective through intramural research performed by NASA researchers and through extramural contracts, cooperative agreements, grants, and Space Act agreements with external entities, including the private sector; nonprofit and academic and educational organizations; and with other governmental entities. Because of this multiplicity of research arrangements, allegations of research misconduct could arise in any number of ways. While there is some overlap in the actions that may be pursued by Federal agencies and research institutions, this rule provides procedures and criteria for the interaction of NASA with its research partners in dealing with the various contingencies that could arise in the processing of research misconduct allegations.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113(a), authorizes the Administrator of the National Aeronautics and Space Administration (NASA) to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 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, reducing costs, harmonizing rules, and promoting flexibility. This final rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

It has been certified that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act Statement

This final rule does not contain an information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 14 CFR Part 1275

Administrative practice and procedure, Grant programs, Investigations, Research, Science and technology, Scientists.

Accordingly, 14 CFR part 1275 is amended as follows:

PART 1275—RESEARCH MISCONDUCT

■ 1. The authority citation for part 1275 continues to read as follows:

Authority: Pub. L. 85–568, 72 Stat. 426, 42 U.S.C. 2473.

■ 2. Section 1275.100 is amended by revising paragraphs (d) and (e) to read as follows:

§ 1275.100 Purpose and scope.

* * * * *

(d) A determination that research misconduct has occurred must be accompanied by recommendations on appropriate administrative actions. However, the administrative actions themselves may be imposed only after further procedures described in applicable Federal acquisition and NASA regulations concerning contracts, cooperative agreements, grants, Space Act agreements, or other transactions, depending on the type of agreement used to fund or support the research in question. Administrative actions involving NASA civil service employees may be imposed only in compliance with all relevant Federal laws and policies.

(e) Allegations of research misconduct concerning NASA research may be transmitted to NASA in one of the

following ways: By mail address to the Office of Inspector General (OIG), National Aeronautics and Space Administration, 300 E Street SW., Washington, DC 20546–0001 via the NASA OIG Hotline at 1–800–424–9183, or cyber hotline at *http://oig.nasa.gov/hotline.html.*

■ 3. Section 1275.101 is amended by revising paragraphs (a) and (m) to read as follows:

§ 1275.101 Definitions.

(a) Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. Research as used in this part includes all basic and applied research as defined in OMB Circular A–11 in all fields of science, engineering, and mathematics, including, but not limited to, research in space and Earth sciences, economics, education, linguistics, medicine, psychology, social sciences, statistics, and biological and physical research (ground based and microgravity), including research involving human subjects or animals.

* * * * *

(m) NASA Adjudication Official is the NASA Associate Administrator of a Mission Directorate, Chief Technologist, or Chief Engineer, depending on the research area involved in the misconduct allegation (as described in the list of NASA research disciplines and their associated directorates contained in the Appendix to this part).

* * * * *

■ 4. The Appendix to Part 1275 is revised to read as follows:

Appendix to Part 1275—Research Misconduct

NASA Research Disciplines and Respective Associated Directorates

1. Aeronautics Research—Aeronautics Research Mission Directorate
2. Space Science Research—Science Mission Directorate
3. Earth Science Research and Applications—Science Mission Directorate
4. Biomedical Research—Human Exploration and Operations Mission Directorate
5. Fundamental Biology—Human Exploration and Operations Mission Directorate
6. Fundamental Physics—Human Exploration and Operations Mission Directorate
7. Research for Exploration Systems not covered by the disciplines above—Human Exploration and Operations Mission Directorate
8. Research for the International Space Station not covered by the disciplines above—Human Exploration and Operations Mission Directorate
9. Other engineering research not covered by disciplines above—NASA Chief Engineer
10. Other technology research not covered by disciplines above—NASA Chief Technologist

Charles F. Bolden, Jr.,

Administrator.

[FR Doc. 2012–18435 Filed 7–27–12; 8:45 am]

BILLING CODE P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 50

RIN 3038–AD60

Swap Transaction Compliance and Implementation Schedule: Clearing Requirement Under Section 2(h) of the CEA

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is adopting regulations to establish a schedule to phase in compliance with the clearing requirement under new section 2(h)(1)(A) of the Commodity Exchange Act (CEA or Act), enacted under Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). The schedule will provide additional time for compliance with this requirement. This additional time is intended to facilitate the transition to the new regulatory regime established by the Dodd-Frank Act in an orderly manner that does not unduly disrupt markets and transactions.

DATES: The rules will become effective September 28, 2012.

FOR FURTHER INFORMATION CONTACT: Sarah E. Josephson, Deputy Director, 202–418–5684, *sjosephson@cftc.gov;* Brian O'Keefe, Associate Director, 202–418–5658. *bokeefe@cftc.gov;* or Peter Kals, Attorney-Advisor, 202–418–5466, *pkals@cftc.gov*, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

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I. Background

Section 723(a)(3) of the Dodd-Frank Act amended the CEA to provide, under new section 2(h)(1)(A) of the CEA, that it shall be unlawful for any person to engage in a swap unless that person submits such swap for clearing to a derivatives clearing organization (DCO) that is registered under the CEA or a DCO that is exempt from registration under the CEA if the swap is required to be cleared (the Clearing Requirement).[1] Section 2(h)(2) charges the Commission with the responsibility for determining whether a swap is required to be cleared (a Clearing Requirement determination), through one of two avenues: (1) Pursuant to a Commission-initiated review; or (2) pursuant to a submission from a DCO of each swap, or any group, category, type, or class of swaps that the DCO ''plans to accept for clearing.'' [2] The Commission is proposing its first Clearing Requirement determination concurrently with its adoption of this compliance schedule rule. The finalization of that proposal will trigger the compliance schedule provided for under this adopting release.

On September 20, 2011, the Commission published proposed § 39.5(e) [3] to phase in compliance of the Clearing Requirement upon the Commission's issuance of a Clearing Requirement determination pursuant to § 39.5(b) or (c).[4] That notice of proposed rulemaking (NPRM) also included an implementation schedule for the requirement pursuant to amended section 2(h)(8)(A), which requires a swap subject to the Clearing

[1] Section 2(h)(7) of the CEA provides an exception to the Clearing Requirement when one of the counterparties to a swap (i) is not a financial entity, (ii) is using the swap to hedge or mitigate commercial risk, and (iii) notifies the Commission how it generally meets its financial obligations associated with entering into a non-cleared swap.

[2] Under section 2(h)(2)(B)(ii), the Commission must consider swaps listed for clearing by a DCO as of the date of enactment of the Dodd-Frank Act.

[3] Commission regulations referred to herein are found at 17 CFR Ch. 1.

[4] *See* 76 FR 58186 (Sept. 20, 2011).

Requirement to be executed on a designated contract market (DCM) or swap execution facility (SEF), unless no SEF or DCM makes the swap available to trade (the Trade Execution Requirement). The Commission is hereby adopting proposed § 39.5(e), as newly designated § 50.25, to establish a schedule for compliance only for the Clearing Requirement. A separate rulemaking will promulgate the final implementation schedule for the Trade Execution Requirement.[5]

The compliance schedule for the Clearing Requirement is based on the type of market participants entering into a swap subject to the Clearing Requirement. The compliance schedule balances several goals. First, the Commission believes that some market participants, such as certain managed accounts, referred to under § 50.25 as ''Third-Party Subaccounts,'' may require additional time to bring their swaps into compliance with the Clearing Requirement. Pursuant to § 39.5(e) (finalized as § 50.25), these market participants would be afforded additional time to clear their swaps so that they will be able to document new client clearing arrangements, connect to market infrastructure such as DCOs, and prepare themselves and their customers for the new regulatory requirements.

Another goal of the compliance schedule is to have adequate representation of market participants involved at the outset of implementing a new regime for requiring certain swaps to be cleared. The Commission believes that having a cross-section of market participants involved at the outset of formulating and designing the rules and infrastructure under which the Clearing Requirement is implemented will best meet the needs of all market participants.

The compliance schedule set forth in § 50.25 defines three categories of market participants: Category 1 Entities,[6] Category 2 Entities,[7] and all other market participants. As described in § 50.25(b), a swap between two Category 1 Entities must comply with the Clearing Requirement no later than 90 days after the publication of the Clearing Requirement determination in the **Federal Register**.[8] A swap between a Category 2 Entity and a Category 1 Entity or another Category 2 Entity must comply within 180 days, and all other swaps must be submitted for clearing no later than 270 days after the Clearing Requirement determination is published in the **Federal Register**. To clarify, the swap is subject to the latest compliance date for one of the counterparties. In other words, if a Category 1 Entity enters into a swap with a Category 2 Entity, both parties have 180 days to submit the swap for clearing. However, the counterparty entitled to the later compliance date may elect to clear the swap earlier, and in that event, its counterparty is required to oblige.

II. Comments on the Notices of Proposed Rulemaking

The Commission received 26 comments during the six-week public comment period following publication of the NPRM. The Commission considered each of these comments in formulating the final regulation, § 39.5(e) (finalized as § 50.25).

A. Comment Period

The Commission published the NPRM in the **Federal Register** on September 20, 2011, and the public comment period closed on November 4, 2011.

Financial Services Roundtable (FSR) comments that the public should be able to comment on an implementation schedule for each swap subject to the Clearing Requirement because the characteristics of one particular swap may necessitate a very different schedule from another.

Pursuant to § 39.5(b)(5) in the case of swap submissions and § 39.5(c)(2) in the case of Commission-initiated reviews, the public will have an opportunity to comment on each of the Commission's proposed Clearing Requirement determinations, and to comment on whether the Commission should employ the compliance schedule for that determination. In this manner, the public will have an opportunity to comment on whether use of the compliance schedule is appropriate for a given Clearing Requirement determination covering particular swaps.

B. Harmonization

The NPRM reflects consultation with the staff of the Securities and Exchange Commission (SEC), prudential regulators, and international regulatory authorities. With respect to the latter, the Commission is mindful of the benefits of harmonizing its regulatory framework with that of its counterparts in foreign countries. The Commission therefore has monitored global advisory, legislative, and regulatory proposals, and has consulted with foreign regulators in developing the final regulations.

Vanguard, the Federal Home Loan Banks (FHLBs), and the Investment Company Institute (ICI) each recommend that the Commission coordinate the compliance schedule for the Clearing Requirement, as well as implementation schedules concerning other Dodd-Frank Act requirements, with the SEC, the prudential regulators, and international regulators to avoid market disruption and avoid regulatory arbitrage. The American Council of Life Insurers (ACLI) urges the Commission to coordinate with the SEC and international regulators to achieve reductions in compliance costs. A joint letter by the Futures Industry Association, the International Swaps and Derivatives Association, and the Securities Industry and Financial Markets Association (FIA/ISDA/SIFMA) urges the Commission to coordinate implementation schedules with those introduced by the SEC, the National Futures Association, self-regulatory organizations, and market infrastructure providers.

In addition to the regulators referenced above, the Commission has consulted with other U.S. financial regulators including: (1) The Board of Governors of the Federal Reserve System; (2) the Office of the Comptroller of the Currency; and (3) the Federal Deposit Insurance Corporation. Staff from each of these agencies has had the opportunity to provide oral and/or written comments to this adopting release, as well as to the proposal.

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[5] The Commission will address the proposed compliance schedules for trading documentation and margining under section 4s of the CEA, 76 FR 58176 (Sept. 20, 2011), at the same time that it finalizes the underlying documentation and margin rules.

[6] A Category 1 Entity is defined under § 50.25(a) to include a swap dealer; security-based swap dealer; major swap participant; major security-based swap participant; or active fund (also defined by § 50.25(a)).

[7] A Category 2 Entity is defined under § 50.25(a) to include a commodity pool; a private fund as defined in section 202(a) of the Investment Advisers Act of 1940 other than an active fund; or a person predominantly engaged in activities that are in the business of banking, or in activities that are financial in nature as defined in section 4(k) of the Bank Holding Company Act of 1956, provided that, in each case, the entity is not a Third-Party Subaccount. As proposed, this category contained employee benefit plans under the Employee Retirement Income and Security Act of 1974, but under the final rule, these plans will not be included in Category 2. *See* below for further discussion.

[8] As proposed, the rule required compliance within 90, 180, or 270 days after the effective date set by the Commission for a Clearing Requirement determination. In order to clarify precisely when the compliance period will commence, the Commission has modified the rule to indicate that the compliance periods begin as of the date of publication of final Clearing Requirement determination rules in the **Federal Register**. From this point, market participants have either 90, 180, or 270 days to come into compliance.

C. Cross-Border and Affiliate Transactions

The NPRM did not differentiate between domestic and foreign swap dealers (SDs), major swap participants (MSPs) or their counterparties, and did not address affiliate transactions.

MarkitSERV and the Alternative Investment Management Association (AIMA) each comment that the NPRM, as well as other proposals setting forth implementation schedules for complying with Dodd-Frank Act requirements, should clarify the status of cross-border transactions. Better Markets states that trading relationships between an SD or MSP and its affiliate or an international counterparty should not be treated any differently than any other trading relationship. FIA/ISDA/SIFMA comments that the Commission should publish guidance concerning the extraterritorial application of Title VII prior to the commencement of any implementation schedule.

The Commission separately has issued guidance on the cross-border application of Title VII, including the Clearing Requirement.[9] With regard to inter-affiliate transactions, the Commission will be considering this issue in an upcoming proposal.

D. Comprehensive Implementation Schedule

This adopting release pertains exclusively to the implementation of the Clearing Requirement.

The Coalition for Derivatives End-Users (CDE), a joint letter by the Edison Electric Institute, the National Rural Electric Cooperative Association, and the Electric Power Supply Association (Joint Associations); ICI; and MarkitSERV each argue that the Commission should create an implementation plan addressing all of its final Dodd-Frank rules and that the Clearing Requirement compliance schedule should be part of that comprehensive schedule. CDE comments further that a comprehensive schedule is important to end-users, particularly in the areas of recordkeeping and reporting. The Joint Associations also comment that a comprehensive schedule should detail compliance dates, both specific and market-wide, for each registered entity and that the Commission should request further comment on this subject as more final rules are published.

Vanguard comments that in implementing Title VII, the Commission should focus first on systemic risk issues and then issues relating to transparency and trade practices. Implementation schedules should be organized by type of participant and asset class. The schedules should also allow for voluntary compliance.

ACLI argues that the Commission has not provided sufficient guidance concerning new rules and effective dates in order for market participants to conduct a prudent review of resource planning. ACLI maintains that complying with only some rules creates a risk that documents will have to be renegotiated when other rules are phased in.

In this adopting release, the Commission is focused on providing additional time to market participants that may require more time to comply with one of the key elements of the Dodd-Frank Act—the Clearing Requirement. The compliance schedule that is the subject of this adopting release was proposed at the same time as three other compliance schedules—schedules for the Trade Execution Requirement and two important requirements under section 4s of the CEA, documentation and margin for uncleared swaps. Each of these proposed compliance schedules responded to particular concerns from market participants, especially those that are not required to register with the Commission. The Commission also has published compliance dates for phasing in implementation in nearly all of its final rules.[10] In addition, the Commission has twice published on its Web site general schedules regarding the sequence and timing for its own consideration of final rules.[11]

In response to ACLI, as discussed further below, the Commission has finalized all the documentation requirements necessary for compliance with the Clearing Requirement.[12] With regard to Vanguard's comment, the Commission intends to implement the Clearing Requirement based on specific classes of swaps, beginning with those asset classes that are currently being cleared. The Commission believes that implementation of the Clearing Requirement will serve to reduce systemic risk by mitigating counterparty credit risk through the use of the marking-to-market, margining, and risk mutualization provided by central counterparties. The adoption of this compliance schedule is an important step toward implementing that requirement. In addition, the compliance schedule expressly allows for voluntary clearing prior to the required compliance date, and market participants currently are free to clear all swaps offered for clearing by DCOs on a voluntary basis.

E. Prerequisite Rules

The preamble to the NPRM stated that prior to requiring compliance with any Clearing Requirement determination, the Commission must publish the following final rules: Definitions of swap, SD, and MSP; End-User Exception to Mandatory Clearing of Swaps; and Protection of Cleared Swaps Customer Collateral.

The FHLBs comment that the rule text of an implementation rule should state that the compliance schedule will not take effect until the Commission has published applicable final rules. The FHLBs believe that it is insufficient for the preamble to make this point.

The Joint Associations state that they cannot comment on the adequacy of either the compliance schedule for the Clearing Requirement or other implementation schedules until various final rules have been published, including the definitions of swap, SD, and MSP. The Joint Associations want to see how many of their comments to these rules have been adopted because this will affect how long it will take their members to comply with Title VII requirements. ICI comments that parties cannot prepare for centralized clearing until the Commission publishes the final rule concerning the definition of swap.

Citadel, FHLBs, and FIA/ISDA/SIFMA each recommend that the Commission publish final rules related to clearing, such as customer clearing documentation, timing of acceptance for clearing, and clearing member risk management, prior to phasing in the Clearing Requirement. FHLBs state that the prior publication of the Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management rules is important so that market participants can fully appreciate risks and not have to renegotiate documentation.

The Committee on Investment of Employee Benefit Assets (CIEBA) recommends that the Commission not impose the Clearing Requirement until full physical segregation is available for margin of cleared swaps. CIEBA also

[9] *See* Cross-Border Application of Certain Swaps Provisions of the Commodity Exchange Act, 77 FR 41213 (July 12, 2012).

[10] *See, e.g.,* Swap Data Recordkeeping and Reporting Requirements, 77 FR 2136, 2195–2196 (Jan. 13, 2012); Business Conduct Standards for Swap Dealers and Major Swap Participants with Counterparties, 77 FR 9734, 9803 (Feb. 17, 2012); and Derivatives Clearing Organization General Provisions and Core Principles, 76 FR 69334, 69408 (Nov. 8, 2011).

[11] *See http://www.cftc.gov/LawRegulation/DoddFrankAct/index.htm.*

[12] *See* Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management, 77 FR 21278 (April 9, 2012).

comments that if the Commission publishes final segregation rules for cleared swaps customer collateral at the same time that it phases in the Clearing Requirement, then market participants' limited resources would be overwhelmed. ICI comments that parties cannot prepare for centralized clearing until the Commission publishes the final rule concerning the Protection of Cleared Swaps Customer Collateral. ICI also argues that the documentation requirements under section 4s(i) of the CEA must be finalized before market participants are required to comply with mandatory clearing.

CME recommends that the Commission finalize the DCO Conflicts of Interest rules prior to requiring compliance with the Clearing Requirement.

The American Bankers Association (ABA) believes that end-user banks not be required to comply with the Clearing Requirement until 180 days after the Commission determines whether end-user banks will be exempt from the Clearing Requirement.

AIMA believes the Commission should publish final rules concerning the Margin Requirement, as well as customer collateral protection rules, prior to phasing in the Clearing Requirement.

The Commission has finalized all four of the rules identified in the NPRM that it needed to be completed prior to requiring compliance with the Clearing Requirement (namely, the End-User Exception to Mandatory Clearing of Swaps; [13] Protection of Cleared Swaps Customer Collateral; [14] the Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant''; [15] and the Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping).[16] In addition, the Commission has finalized rules related to Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management.[17] Finalizing these rules addresses the FHLBs' concerns about having to revise documentation more than once and provides certainty as to swap processing requirements and expectations regarding risk management for clearing members. On the other hand, in response to CME's comment, the Commission does not believe it is necessary for final DCO Conflicts of Interest rules to be in effect before requiring compliance with the Clearing Requirement because these rules do not relate directly to the clearing process, customer connectivity, clearinghouse risk management, or other matters that would affect the implementation of the Clearing Requirement.

In response to the FHLBs' request that the implementation rule text include a provision that the rule is not effective until the definitions of SD, MSP, and swap are finalized, the Commission reiterates that all of the pre-requisite rules for the Clearing Requirement have been adopted. With regard to CIEBA's comment about full physical segregation, the Commission published its final rule concerning Protection of Cleared Swaps Customer Collateral on February 7, 2012.[18] In that rulemaking, the Commission indicated that it may address issues related to collateral held in third-party safekeeping accounts at some point in the future. However, given that a fully operational segregation regime is required to be in place by November 8, 2012, the Commission does not believe that it is necessary for this additional matter to be resolved prior to requiring compliance with the Clearing Requirement.

In response to ICI's comment, the Commission clarifies that finalization of the swap trading relationship documentation requirements for SDs and MSPs under section 4s(i) of the CEA is not required for compliance with the Clearing Requirement because the documentation that is the subject of those rules relates primarily to bilaterally-executed, uncleared swap transactions, and none of the provisions in proposed § 23.504 pertain directly to the Clearing Requirement. Similarly, in response to AIMA's comment, final margin rules for uncleared swaps are not required to be finalized prior to requiring compliance with the Clearing Requirement as these are related, but distinct, provisions under the Dodd-Frank Act.

F. Definitions

Under § 39.5(e)(1), the Commission proposed definitions of the terms ''Category 1 Entity,'' ''Category 2 Entity,'' ''Active Fund,'' and ''Third-Party Subaccount.'' The definitions set forth in proposed § 39.5(e) (now § 50.25) would apply specifically to provisions contained in part 39 (now part 50) and only those other rules that explicitly cross-reference these definitions. The Commission is adopting the definitions as proposed, with the exceptions discussed below.

1. Active Fund

As proposed under § 39.5(e)(1), ''any private fund as defined in section 202(a) of the Investment Advisers Act of 1940, that is not a third-party subaccount and that executes 20 or more swaps per month'' would be defined as an ''Active Fund'' and subject to the shortest implementation schedule for compliance with the Clearing Requirement.

Numerous commenters, such as Better Markets, Chris Barnard, and AIMA, agree with the Commission that using a market participant's average monthly trading volume would be an appropriate proxy for determining an entity's ability to comply with the Clearing Requirement and would be better than a proxy based on notional volume or open interest. AIMA agrees with the NPRM's proposal that Active Funds be subject to the 90-day deadline.

Other commenters express concerns about solely relying on monthly volumes as a proxy, especially without further defining the types of swaps that would be included in the calculation. ACLI states that the frequency of trading is not an appropriate indicator of a market participant's experience or resources. The Association of Institutional Investors (AII) states that the definition should specify the type of swaps that count towards the threshold. CDE recommends a minimum average monthly notional threshold to avoid capturing smaller end-users. CDE also states that hedges and inter-affiliate swaps should be excluded from this monthly average threshold. Managed Funds Association (MFA) similarly requests clarification regarding those swaps that would be included in the monthly swap calculation. Specifically, MFA requests clarification as to whether novations, amendments, or partial tear-ups would be included.

Commenters also focus on the average monthly threshold of 20 swaps per

[13] End-User Exception to the Clearing Requirement for Swaps, adopted by the Commission on July 10, 2012, available at *www.cftc.gov.*

[14] Protection of Cleared Swaps Customer Contracts and Collateral; Conforming Amendments to the Commodity Broker Bankruptcy Provisions, 77 FR 6336 (Feb. 7, 2012).

[15] Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant,'' 77 FR 30596 (May 23, 2012).

[16] Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, Section VII, adopted by the Commission on July 10, 2012, available at *www.cftc.gov.*

[17] Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management, 77 FR 21278, (April. 9, 2012).

[18] 77 FR 6336 (Feb. 7, 2012).

month for the preceding 12 months. FIA/ISDA/SIFMA proposes that the threshold be an average of 200 trades per month. Vanguard proposes a similar threshold. Both AII and MFA think the proposed threshold was overly inclusive. MFA also highlights its belief that the proposed definition would be difficult to administer, while unnecessarily creating another tier of market participants for the purposes of the implementation schedules.

In response to these comments, the Commission is increasing the average monthly threshold to 200 swap trades per month for the preceding 12 months. The Commission believes that monthly trading volume is a suitable proxy for determining the appropriate implementation schedule for a swap counterparty. By increasing the threshold to 200, as recommended by FIA/ISDA/SIFMA, as well as Vanguard, the risk of capturing smaller, less experienced swap counterparties should be substantially diminished. The market participants engaging in this level of swap activity should be able to access the resources necessary to meet the 90-day implementation schedule. In light of the number of transactions currently being cleared on a voluntary basis by funds, the Commission does not believe that an increase in the threshold of monthly swap trades will negatively impact the goal of broad market participation in the implementation of the Clearing Requirement. The Commission believes this increase in the average monthly threshold also addresses CDE's concerns about smaller market participants using swaps only to hedge risk.

Further, by maintaining the concept of Active Fund, the Commission believes that it will continue to ensure adequate representation across the spectrum of market participants during the first phase of the implementation of the Clearing Requirement. As a result of this participation, processes and infrastructure will be established to serve all segments of the market, not just SDs and MSPs, which are included in the initial phase of the compliance schedule for the Clearing Requirement.

In response to AII and MFA, the Commission clarifies that the average monthly threshold of swaps applies to new swaps that the entity enters into, and it does not apply to novations, amendments, or partial tear-ups. In addition, the Commission clarifies that the 200 swap threshold includes any swap, as defined under the CEA and § 1.3, and not just those swaps that would be subject to the relevant Clearing Requirement determination and attendant compliance schedule.

2. Third-Party Subaccount

Under § 39.5(e) (finalized herein as § 50.25), Third-Party Subaccounts are excluded from the definitions of Category 1 Entity and Category 2 Entity, with the effect that such subaccounts will have 270 days, the longest period, in which to comply with the Clearing Requirement. The NPRM defined Third-Party Subaccounts as ''a managed account that requires the specific approval by the beneficial owner of the account to execute documentation necessary for executing, confirming, margining, or clearing swaps.'' The purpose of excluding Third-Party Subaccounts from the defined categories was to ensure that investment managers, who may be faced with bringing numerous accounts into compliance, would have adequate time to do so.

Commenters question whether the definition was broad enough to provide sufficient time for Third-Party Subaccounts to comply with the Clearing Requirement. ICI noted that Third-Party Subaccounts, whether subject to the specific execution authority of the beneficiary or not, require managers to work closely with clients when entering into trading agreements on the customer's behalf. As such, ICI feels that no distinction should be made based on specific execution authority or lack thereof. ICI comments that all Third-Party Accounts should be uniformly classified and be given 270 days to comply. AII similarly states that the definition is too narrow given the administrative work required to manage an account, regardless of the execution authority. Further, AII states that execution authority is not an industry standard. The term, as proposed, therefore divides the universe of managed accounts inappropriately. FIA/ISDA/SIFMA recommends that all accounts managed by third parties, regardless of the execution authority, should be given the most time to comply with the Clearing Requirement.

Based on the comments received, the Commission is revising the definition of Third-Party Subaccount to mean ''an account that is managed by an investment manager that (1) is independent of and unaffiliated with the account's beneficial owner or sponsor, and (2) is responsible for the documentation necessary for the account's beneficial owner to clear swaps.'' In modifying this definition, the Commission is taking into account the point made by AII, FIA/ISDA/SIFMA, and ICI that all investment managers will need additional time to comply with a Clearing Requirement regardless of whether they have explicit execution authority. However, the definition retains the nexus between the investment manager and the documentation needed for clearing swaps. In other words, if the investment manager has no responsibility for documenting the clearing arrangements, then that account would be required to clear its swaps subject to required clearing within 180 days. For those accounts under the revised definition, however, the Commission believes that the 270-day deadline is more appropriate. Given the general notice investment managers have had about the Dodd-Frank Act's Clearing Requirement since the enactment of the statute in July, 2010, managers should have been able to consider and plan the infrastructure and resources that are necessary for all of their accounts, including Third-Party Subaccounts, to comply with the Clearing Requirement. Thus, the 180- and 270-day deadlines should provide adequate time to accommodate all managed accounts.

3. Category 1 and Category 2 Entities

The compliance schedule is organized according to the type of market participant. To the extent that the Commission determines that a compliance schedule is warranted in connection with a Clearing Requirement determination (*i.e.* to comply with the Clearing Requirement) a market participant defined as a Category 1 Entity will have 90 days to comply, a Category 2 Entity will have 180 days, and all others will have 270 days. According to the proposed definitions, a Category 1 Entity includes an SD, a security-based swap dealer, an MSP, a major security-based swap participant, or an Active Fund. A Category 2 Entity includes a commodity pool, a private fund, as defined by the Investment Advisers Act of 1940, an ERISA plan, or a person predominantly engaged in banking or other financial activities, as defined by section 4(k) of the Bank Holding Company Act. A Category 2 Entity would not include an Active Fund or a Third-Party Subaccount.

Encana Marketing (USA) Inc. (Encana) and the Joint Associations comment that non-financial end users should be expressly included in the category with the longest timeframe. CDE argues that financial end-users should be treated identically to non-financial end-users because they do not pose systemic risk, and, therefore, should be given the most time to comply with the Clearing Requirement, and not included in Category 2. ICI seeks clarification that a market participant can determine whether it is an MSP for purposes of the compliance schedule for the Clearing

Requirement at the same time that it is required to review its status as an MSP under other Commission and SEC rules.

CIEBA states that in-house ERISA funds should be in the group with the longest compliance time, and not Category 2 Entities. CIEBA notes that such funds do not pose systemic risk, and they typically rely upon third-party managers for some portion of their fund management. Splitting in-house and external accounts (*i.e.* those accounts meeting definition of Third-Party Subaccount and permitted 270 days) of the same ERISA plan will impact risk management given different implementation schedules. CIEBA also states that this distinction will cause pension funds to bear the costs of compliance because they will need to comply prior to their third-party managers, who would be better positioned to provide insight and service in this regard.

The Commission believes that the definitions of Category 1 Entity should be finalized as proposed, but that the definition of Category 2 Entity should be modified by removing the reference to ERISA plans. In response to Encana and the Joint Associations, non-financial end users are adequately addressed in § 39.5(e)(2)(iii) (now § 50.25(b)(3))—unless the swap transactions are eligible to claim the exception from the Clearing Requirement under section 2(h)(7) of the CEA, the parties are given 270 days to comply with the Clearing Requirement. With respect to issues raised by CDE regarding those financial entities included in Category 2, based on numerous meetings with participants in the swap market, the Commission believes that financial entities are capable of complying with the Clearing Requirement 90 days sooner than non-financial entities. Accordingly, the compliance schedule has correctly situated Category 2 Entities based upon their ability to meet the requirements of the underlying regulations. Moreover, the distinction between financial and non-financial entities has a statutory basis in section 2(h)(7) of the CEA.

The Commission recognizes the concerns raised by CIEBA regarding splitting in-house and external accounts (*i.e.,* those accounts meeting the definition of Third-Party Subaccount and permitted 270 days) of the same ERISA plan. In response to these concerns, the Commission is removing the reference to employee benefit plans as defined in paragraphs (3) and (32) of section 3 of the Employee Retirement Income and Security Act of 1974. As a result, these ERISA plans will be afforded the longest compliance period (270 days).

With regard to ICI's comment, a potential MSP can review its obligation to register as an MSP at the same time it is reviewing where it fits under the Clearing Requirement compliance schedule. In many instances, MSPs will have to review their registration obligations ahead of complying with the Clearing Requirement. However, if an entity discovers that it has crossed the threshold established under the MSP rules and is required to register during the 90-day period for Category 1 Entities, the Commission would consider allowing that entity to petition for additional time to come into compliance with the Clearing Requirement.[19]

G. Compliance Schedule for the Clearing Requirement

As mentioned above, § 39.5(e)(2) provides that when the Commission determines that an implementation schedule is appropriate in connection with a given Clearing Requirement determination, market participants within the definition of Category 1 will have 90 days to comply, those within the definition of Category 2 will have 180 days, and all others 270 days to implement the Clearing Requirement.

4. Application to All Swap Types

The Clearing Requirement compliance schedule is based upon the nature of a given swap market participant, considering the participant's risk profile, compliance burden, resources, and expertise. The schedule does not contemplate different implementation timeframes based upon the characteristics of particular swaps.

AIMA states that it does not believe further implementation schedules are necessary based on the nature of the swap itself. Better Markets, Citadel, and MFA comment that the compliance schedule should apply, however, to all swaps within a ''group'' or ''class,'' as defined by the Commission's Clearing Requirement determination.

Commenters such as CDE state that the Commission should publish an implementation schedule specific to the characteristics of a particular type of swap. CDE comments that because it is unlikely that end-users, and other entities relied upon by end-users, will be able to meet the requirements necessary to comply with clearing determinations for all swap products at the same time, the Commission should phase in implementation deadlines by swap type, according to the amount of systemic risk posed by a particular swap.

MarkitSERV asserts that all Dodd-Frank Act requirements should be phased-in by asset class, taking into account that different asset classes have various levels of product standardization, electronification, volumes, and types of counterparties. FIA/ISDA/SIFMA also states that there should be a separate compliance schedule for each asset class. FIA/ISDA/SIFMA also states that the Commission should require credit default swaps and interest rate swaps to be cleared first because those products are already being cleared. Commodity and equity swaps, according to FIA/ISDA/SIFMA, should be required to be cleared later because the marketplace is currently clearing fewer of those products.

AIMA, CDE, ICI, and MarkitSERV state that the compliance schedule should require the Commission to phase in each Clearing Requirement determination as set forth in § 39.5(e). FHLB and ICI comment that the Commission should have the flexibility to extend clearing implementation dates, but not shorten them. Citadel counters that the compliance schedule should only be triggered when a determination is issued for a new category of swaps.

This rule affords the Commission discretion to determine whether to apply the compliance schedule in connection with a particular Clearing Requirement determination. The Commission agrees that while the schedule may be necessary in connection with some Clearing Requirement determinations, especially those covering new classes of swaps, there also may be determinations that are sufficiently similar to prior ones that no compliance schedule is necessary. As such, the Commission will determine whether or not to apply the § 39.5(e) (now § 50.25) compliance schedule as part of its analysis in connection with each Clearing Requirement determination.

Further, it remains the Commission's intention that those swaps currently being cleared will be subject to the first Clearing Requirement determinations. As a result, market participants initially will comply with the Clearing Requirement using established platforms and technology. This should limit a market participant's burden in transitioning to clearing, as the use of existing infrastructure will mean less time and expense necessary to develop independent programs, technology, or platforms to clear such transactions.

[19] Similarly, the Commission would consider allowing entities to petition for additional time to comply to the extent that they discover that they have exceeded the *de minimis* threshold under the swap dealer definition and are required to register during the 90-day period for Category 1.

5. Timing of Implementation Schedules

Citadel and Better Markets comment that they agree with the proposed compliance schedule because market participants have had notice of the movement towards clearing for one to three years, and the clearing infrastructure already exists with regard to interest rate and credit default swap products. Citadel and Tradeweb believe the proposed schedule correctly staggers compliance according to category of market participant. Citadel does not support extending the 270-day timeframe because 270 days would grant sufficient time to market participants without providing so much time as to engender a material, competitive advantage or regulatory arbitrage. AIMA believes the proposed schedule grants sufficient time to each category of market participant so that they will be able to comply with the Clearing Requirement. Similarly, the Joint Associations and The Westpac Group (Westpac) generally agree with phasing in implementation with the Clearing Requirement according to category of participant.

CIEBA states that because SDs, MSPs, and Active Funds will be the first focus for all third party vendors, ERISA plans will be competing for these resources only after the first implementation deadline has passed, leaving only 90 days for a crowded market place to comply. With limited resources, such a tight timeframe may lead to inadequate agreements and/or increased risk exposure. Further, inadequate agreements caused by lack of resources and rushed documentation will create even further cost disparity for clearing between U.S. pension plans and European ones that will not be required to clear swaps. As such, CIEBA recommends that Category 2 Entities have more than 180 days to comply. Likewise, FIA/ISDA/SIFMA note that the compliance schedule should be lengthened and that buy-side entities, which may currently be categorized as Category 1 Entities, should not be required to commence clearing until the second quarter of 2013 at the earliest.

CDE argues that SDs and MSPs should comply before establishing other end-user deadlines. CDE believes that if Category 1 Entities cannot comply, then that will compound problems for Category 2 and 3 Entities. If an implementation schedule must be set, the CDE recommends one year for end-users, in light of their limited internal resources and the competition for external resources.

ACLI comments that complex issues will surface as market participants try to combine the agency framework presently existing in the futures markets (*i.e.,* customer-futures commission merchant) with the principal-to-principal framework that has existed in the over-the-counter swaps market. In addition to executing the necessary agreements, insurers will want to ensure they enter into agreements with parties that serve them best. The combination of these factors means that timeframes are too short and may result in smaller firms accepting unfavorable agreements with fewer counterparties, possibly concentrating risk. ACLI also highlights that insurers face an additional burden in ensuring that compliance with the Clearing Requirement is consistent with their state regulatory obligations.

Vanguard argues that additional time will be required to enter into the new agreements necessitated by the move to a cleared derivatives market. Vanguard highlights the large volume of such agreements and the lack of market standards. ICI also finds the compliance schedule to be too short in light of the needs to build and test new systems, adapt to new regulatory requirements, and educate customers about these changes.

Mastercard Worldwide urges the Commission to give non-bank firms at least 270 days to comply with the Clearing Requirement in respect of their foreign currency hedging activities, even if the firm is covered by section 4(k) of the Bank Holding Company Act. Westpac comments that Category 1 Entities should have at least 180 days to comply with the Clearing Requirement, noting that not all SDs, particularly smaller ones, are currently DCO members. Regional Banks also request that small SDs have at least 180 days to comply with the Clearing Requirement in light of their relative lack of resources and experience, as compared to larger SDs.

ACLI and FSR believe that the compliance schedule for the respective entity categories should run consecutively rather than concurrently. For example, the 180 days given to Category 2 Entities to comply with the Clearing Requirement should begin only after the expiration of the 90 days given to Category 1 Entities.

FSR does not believe there are sufficient resources, either internally, at market participants, or externally, at third party vendors, for the compliance schedule to run concurrently. If the schedule were to run concurrently, then resources would be allocated sequentially to the detriment of entities in the later implementation groups. ACLI, Joint Associations, and the Coalition of Physical Energy Companies (COPE) each express concern that the proposed compliance schedule does not provide sufficient time for the software companies and other vendors, upon which many smaller market participants rely, to develop, test, and debug the software and other technology that will be needed to ensure compliance with the Clearing Requirement. The Joint Associations and COPE each suggests the Commission take affirmative steps to solicit feedback from these software makers, particularly from vendors that provide ''position and trade capture software,'' in order to determine the amount of time market participants will need to implement software necessary to comply with the Clearing Requirement.

The Commission is finalizing the compliance schedule for the Clearing Requirement as proposed, except for the changes described above for ERISA plans and Third-Party Subaccounts. The Commission believes that the 90-, 180-, and 270-day implementation periods will give market participants sufficient time to comply with the Clearing Requirement. The Commission agrees with commenters such as Citadel and Better Markets that the move to required clearing has been proceeding for two years under the Dodd-Frank Act. This period should have allowed parties to contemplate and design implementation plans and to identify the resources needed to execute those plans. With the Commission's decision to focus on those swaps that are currently cleared when considering its initial Clearing Requirement determinations, market participants will be working with clearing offerings that are seasoned and established, justifying the timeframes provided for in the compliance schedule. For these reasons, the Commission also declines to change the concurrent nature of the compliance schedule.

Given the final rules for the definitions of swap dealers, and the threshold used in terms of annual notional volume of swaps for such swap dealers, the Commission does not believe it necessary to further distinguish between larger swap dealers and smaller ones for purposes of the implementation periods related to Clearing Requirements.[20] Similarly, the Commission does not believe it practicable to make distinctions between entities covered by section 4(k) of the Bank Holding Company Act for the purpose of establishing a 180-day

[20] Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant,'' 77 FR 30596 (May 23, 2012).

implementation period as compared to a 270-day period.

In response to CDE, the Commission also notes that certain swaps would not be subject to the Clearing Requirement under section 2(h)(7) of the CEA when one of the counterparties to a swap (i) is not a financial entity, (ii) is using the swap to hedge or mitigate commercial risk, and (iii) notifies the Commission how it generally meets its financial obligations associated with entering into a non-cleared swap. If a market participant can claim an exemption, the Clearing Requirement will not be applicable. In all other cases, the implementation schedule for a Clearing Requirement would provide for up to 180 or 270 days for such market participants.

In response to concerns that state regulatory obligations for insurance companies might create obstacles to compliance with implementation schedules as suggested by ACLI, the Commission observes that those insurers would have a minimum of six months to work with their state regulators to address the matter. If no solution could be found within that time period, an affected insurer would be able to petition the Commission for specific relief.

The Commission also has taken affirmative steps to ensure that external providers of services to derivative market participants, such as derivatives software providers, have been included in the dialogue concerning implementation scheduling. At the May 2011 Implementation Roundtable, these vendors voiced their opinions with respect to how an implementation schedule could provide sufficient time for market participants relying on ''off-the-shelf'' derivatives tracking software to deploy such software such that they could comply with the Clearing Requirement. The Commission will continue to develop its understanding of technology issues and will solicit comment on this issue in forthcoming proposed Clearing Requirement determinations.

III. Cost-Benefit Considerations

A. Pre-Dodd-Frank Context

Prior to the enactment of the Dodd-Frank Act,[21] swaps were not subject to required clearing. However, the limited market data that is available suggests that over-the-counter (OTC) swap markets have been migrating into clearing over the last few years in response to natural market incentives as well as in anticipation of the Dodd-Frank Act's clearing requirement. LCH.Clearnet data, for example, shows that the outstanding volume of interest rate swaps cleared by LCH has grown steadily since at least November 2007, as has the monthly registration of new trade sides. Together, those facts indicate increased demand for LCH clearing services related to interest rate swaps, a portion of which preceded the Dodd-Frank Act.[22] Data available through CME and TriOptima indicate similar patterns of growing demand for interest rate swap clearing services, though their publicly available data does not provide a picture of demand prior to the passage of the Dodd-Frank Act in July 2010.[23] The trend toward increased clearing of swaps is likely to continue as the Commission begins determining that certain swaps are required to be cleared (Clearing Requirement determination). In fact, the Tabb Group estimates that 60–80% of the swaps market measured by notional amount will be cleared within five years of the time that the Dodd-Frank Act is implemented.[24]

B. Dodd-Frank Act Section 723(a)(3)

In the wake of the financial crisis of 2008, Congress determined, among other things, that swaps shall be cleared upon Commission determination. Specifically, section 723(a)(3) of the Dodd-Frank Act amended section 2(h)(1)(A) of the CEA to make it ''unlawful for any person to engage in a swap unless that person submits such swap for clearing to a derivatives clearing organization that is registered under this Act or a derivatives clearing organization that is exempt from registration under this Act if the swap is required to be cleared.'' [25] The statutory swap clearing requirement is designed to standardize and reduce counterparty risk associated with swaps, and, in turn, mitigate the potential systemic impact of such risks and reduce the likelihood for swaps to cause or exacerbate instability in the financial system.[26] It reflects a fundamental premise of the Dodd-Frank Act: The use of properly functioning central clearing can reduce systemic risk.

C. Final Rule

The rule contained in this adopting release addresses one aspect of required swap clearing under section 2(h) of the CEA: Implementation scheduling following a Commission determination that a class of swaps is required to be cleared. In other words, is immediate clearing required or is implementation subject to some delay. On September 20, 2011, the Commission published a NPRM.[27] The Commission proposed a phased-in compliance schedule for swaps subject to Clearing Requirement determinations that distinguishes among Category 1 Entities, Category 2 Entities, and all other entities (referred to for purposes of this section III as ''Category 3 Entities''); those entities, respectively, would have 90 days, 180 days, and 270 days, from the date of the Clearing Requirement determination to comply with the Clearing Requirement.[28] The NPRM also requested comment with respect to the costs and benefits of the proposed schedule, including, specifically, data, assumptions, calculations, or other information to quantify its costs and benefits, as well as alternatives to it. The Commission received 26 comment letters in response, none of which provided quantitative analysis regarding the costs or benefits of the proposed compliance schedule.[29]

These comments touch upon a variety of issues, and include a number that supported the Commission's approach as proposed. Others note certain areas of concern about costs or benefits under

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[21] Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111–203, 124 Stat. 1376 (2010).

[22] *See http://www.lchclearnet.com/swaps/volumes/.*

[23] *See http://www.cmegroup.com/trading/interest-rates/cleared-otc/index.html#data* and *http://www.trioptima.com/repository/historical-reports.html.*

[24] *See* Tabb Group, ''Technology and Financial Reform: Data, Derivatives and Decision Making.''

[25] Section 2(h)(2) of the CEA charges the Commission with responsibility for determining whether a swap is required to be cleared (a Clearing Requirement determination).

[26] When a bilateral swap is moved into clearing, the clearinghouse becomes the counterparty to each of the original participants in the swap. This standardizes counterparty risk for the original swap participants in that they each bear the same risk attributable to facing the clearinghouse as counterparty. In addition, clearing mitigates counterparty risk to the extent that the clearinghouse is a more creditworthy counterparty relative to those that each participant in the trade might have otherwise faced. This is because a clearinghouse benefits from netting with counterparties and may compel counterparties to post additional initial margin as collateral or force them to reduce their outstanding positions when markets move against them. Clearinghouses have demonstrated resilience in the face of past market stress. Most recently, they remained financially sound and effectively settled positions in the midst of turbulent events in 2007–2008 that threatened the financial health and stability of many other types of entities.

[27] *See* 76 FR 58186.

[28] The schedule contained in the NPRM, like the one contained in this adopting release, can be used at the option of the Commission when issuing Clearing Requirement determinations.

[29] ACLI provides an estimate for one member's information technology and legal costs to comply with all Title VII requirements. The estimate does not include any calculations and does not separate out any costs they believe are directly attributable to this rule.

the rule as proposed, and either expressly propose alternatives or raise issues that have caused the Commission to consider alternatives to it. Among other things, commenters responded to the phased approach, the entities included in Category 1, Category 2, and Category 3, the amount of time that the schedule provides for entities in each category, and the optionality of the schedule.

In the absence of this rule, market participants would be required to comply with the Clearing Requirement immediately upon issuance of a Clearing Requirement determination by the Commission. Pursuant to the rule, however, when the Commission deems it appropriate, market participants will be provided additional time as prescribed in the rule's schedule to comply with Clearing Requirement determinations. Category 1 entities, which include, among others, SDs, MSPs, and Active Funds,[30] will have 90 days from the date that a Clearing Requirement determination is published in the **Federal Register** to comply. Category 2 Entities, which include commodity pools; private funds as defined by the Investment Advisers Act of 1940, other than Active Funds; and banks; but not Third-Party Subaccounts, will have 180 days to comply with a new Clearing Requirement determination. Category 3 Entities are those with Third-Party Subaccounts, as well as any other entity not eligible to claim an exception under section 2(h)(7) of the CEA, including ERISA plans, and they will have 270 days to comply with a Clearing Requirement determination once it is published in the **Federal Register**.

The discussion that follows considers the costs and benefits of, and alternatives to, the rule in this adopting release.

D. Statutory Mandate To Consider the Costs and Benefits of the Commission's Action: CEA Section 15(a)

Section 15(a) of the CEA [31] requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

In this rulemaking the Commission is not imposing clearing requirements, but is exercising its discretion to stagger required clearing implementation according to a particular schedule and subject to the conditions specified in these rules. For purposes of this analysis, the Commission considers the costs and benefits attributable to its choices in this rulemaking—*e.g.,* to stagger the implementation of clearing requirements and to do so in the manner prescribed—against those that would arise absent this Commission action—*i.e.,* if implementation of the Dodd-Frank Act's Clearing Requirement for those swaps that the Commission separately determines to be subject to clearing was not staggered according to the rule's schedule.

For reasons discussed in more detail below, the cost and benefits associated with requiring clearing immediately upon the Clearing Requirement determination for a swap class, or after some longer versus shorter period of delay, are not susceptible to meaningful quantification. As described above, these are not the costs and benefits of implementing Clearing Requirement determinations, but rather the costs and benefits of implementing them more slowly than would be required in the absence of this rule. The Commission is not aware of any analog to either an immediate or delayed requirement to establish the capability to clear that would produce data that the Commission could use to estimate the difference in costs and benefits between the two. Moreover, any data that might be gleaned from the experiences of an individual market participant establishing a relationship with a futures commission merchant (FCM) during normal market conditions would not reflect the influence of a number of effects that are likely to result from the simultaneous implementation of many market participants in a series of three waves. This coordinated movement creates both costs and benefits that cannot be quantified using data drawn from current market conditions. Notwithstanding these limitations, the Commission identifies and considers the costs and benefits of this rule in qualitative terms.

E. Costs and Benefits of This Rule

Determining whether to implement required clearing immediately upon Commission determination or after some period of delay necessarily involves cost and benefit tradeoffs. On the one hand, delaying required clearing implementation also delays the benefits of clearing of certain swaps, including reduced counterparty risk and increased stability in the financial system. These benefits are substantial, and any delay in their realization represents a cost to the market and the public. On the other hand, requiring implementation immediately or within a very compressed timeframe creates certain costs for industry participants. Reducing these costs—enumerated below—by extending the implementation schedule represents a benefit.

First, to meet pressing timelines, some firms will need to contract additional staff or hire vendors to handle some necessary tasks or projects. Additional staff hired or vendors contracted in order to meet more pressing timelines represent an additional cost for market participants. Moreover, a tightly compressed timeframe raises the likelihood that more firms will be competing to procure services at the same time; this could put firms that conduct fewer swaps at a competitive disadvantage in obtaining those services, making it more difficult for them to meet required timelines.[32] In addition, it could enable service providers to command a pricing premium when compared to times of ''normal'' or lesser competition for similar services. That premium represents an additional cost when compared to a longer implementation timeline.

Second, if entities are not able to comply with Clearing Requirement determinations by the required date, they may avoid transacting swaps that are required to be cleared until such a time as they are able to comply. In this event, liquidity that otherwise would result from those foregone swaps would be reduced, making the swaps more expensive for market participants taking the other side. Moreover, firms compelled to withdraw from the market pending implementation of required clearing measures will either leave certain positions un-hedged—potentially increasing the firm's own default risk, and therefore the risk to their counterparties and the public. Alternatively, firms compelled to withdraw from the market for a period of time could attempt to approximate

[30] An ''Active Fund'' is any private fund as defined in section 202(a) of the Investment Advisers Act of 1940, that is not a third-party subaccount and that executes 200 or more swaps per month. The Commission does not intend to use the designation for any purpose beyond this rule.

[31] 7 U.S.C. 19(a).

[32] *See* letter from CIEBA.

their foregone swap hedges using other, likely more expensive, instruments. And to the extent the withdrawing entities are market makers, they will forsake the revenue potential that otherwise would exist for the period of their market absence.

Third, firms may have to implement technological solutions, sign contracts, and establish new operational procedures before industry standards have emerged that address new problems effectively. To the extent that this occurs, it is likely to create costs. Firms may have to incur additional costs later to modify their technology platforms and operational procedures further, and to renegotiate contracts—direct costs that a more protracted implementation schedule would have avoided.[33] Moreover, costs created by the adoption of standards that fail to address certain problems, or attributable to undesired competitive dynamics resulting from such standards, may be longstanding.

Given the factors identified above, this rulemaking aims to strike the optimal cost-balance tradeoff amidst the competing concerns. Shorter timelines will tend to push greater numbers of swaps into clearing more quickly, reducing the counterparty and systemic exposures in ways that were intended by the Dodd-Frank Act—a benefit. But, shorter timelines also increase the costs as discussed above. Longer timelines have the opposite effect, decreasing the costs described above, but increasing the amount of time during which counterparty and systemic exposures that would otherwise be mitigated by required clearing persist.

In theory, the optimal tradeoff between the two is the point at which the marginal cost of an additional one-day delay in implementation equals the marginal benefits of the same incremental delay. But it is not possible, at this stage, to determine the marginal costs or benefits of each day of delay. To estimate such values reliably requires data that does not yet exist—*i.e.,* data gleaned in the midst of the transition process. Therefore, neither the Commission nor commenters are able to assert conclusively that any particular schedule is more or less advantageous relative to all others that the Commission might have considered. Thus, in the face of these practical limitations, the Commission has relied on qualitative considerations, informed by commenters, to guide the necessary tradeoff determinations.

The Commission, informed by its consideration of comments and alternatives, discussed in the sections above and below, believes that the approach contained in this adopting release is reasonable and appropriate in light of the tradeoffs described above. The schedule established here gives the Commission the opportunity to provide additional time to entities in ways that generally align with: (1) Their resources and expertise, and therefore their ability to comply more quickly; and (2) their level of activity in the swap markets, and therefore the possible impact of their swap activities on the stability of the financial system. Entities with the most expertise in, and systems capable to transact, swaps also are likely to be those whose swaps represent a significant portion of all transactions in the swap markets. They are more likely to be able to comply quickly, and the benefits of requiring them to do so are greater than would be the case for less active entities. On the other hand, entities with less system capability and in-house swap expertise may need more time to comply with Clearing Requirement determinations, but it is also likely that their activities represent a smaller proportion of the overall market, and therefore are less likely to create or exacerbate shocks to the financial system.[34] The Commission believes that Category 1 encompasses entities likely possessing more advanced systems and expertise, and whose swap activities constitute a significant portion of overall swap market transactions, while Categories 2 and 3 encompass those likely to have relatively less developed infrastructure and whose swap activities constitute a less significant proportion of the market.

The Commission notes that clearing of certain swaps, and in particular interest rate and credit default swaps, has been occurring for some time; by implication, this indicates that the requisite technology, contractual terms, and operational standards among clearinghouses, clearing members, and some clients exist.[35] The Commission also notes that it is likely that the degree to which firms have already implemented such technology, contracts, and operational patterns varies considerably, particularly among potential customers of FCMs, and that the legal, technological, and operational changes that are necessary for less frequent swap market participants may be more substantial. However, given the availability of FCMs (through which market participants may clear swaps) as well as the technology and contractual standards necessary to clear swaps, the Commission believes that a number of firms can reduce the costs associated with meeting compliance timelines by forming necessary FCM relationships and contracts, and implementing the necessary technology, before the Commission begins issuing Clearing Requirement determinations.[36] Nonetheless, the Commission considered these concerns, among other issues, when determining to grant Category 2 and Category 3 Entities an extended 180 and 270 days, respectively, rather than requiring them to comply at the same time as Category 1 Entities.

Moreover, use of the schedule contained in this release is at the Commission's discretion; in situations where the Commission determines that the benefits of delayed implementation do not justify the additional costs of such a delay, the Commission may require immediate compliance with Clearing Requirement determinations. Therefore, in situations where the Commission determines that a swap must be cleared, and further believes that clearing the swap will not necessitate significant changes to market participants' technology, legal arrangements, or operational patterns, the Commission is likely to determine that immediate compliance is

[33] *See* e.g., ACLI letter.

[34] OCC data demonstrates that among insured U.S. commercial banks, ''the five banks with the most derivatives activity hold 96 percent of all derivatives, while the largest 25 banks account for nearly 100% of all contracts.'' The report is limited to insured U.S. commercial banks, and also includes derivatives that are not swaps. However, swap contracts are included among the derivatives in the report, constituting approximately 63 percent of the total notional value of all derivatives. These statistics suggest that a relatively small number of banks hold the majority of swap positions that could create or contribute to distress in the financial system. Data is insufficient, however, to generalize the conclusions to non-banking institutions. *See* ''OCC's Quarterly Report on Bank Trading and Derivatives Activities: Fourth Quarter 2011'' at 11. *http://www.occ.treas.gov/topics/capital-markets/financial-markets/trading/derivatives/dq411.pdf.*

[35] For example, CME and ICE both began clearing credit default swaps (CDS) in 2009. As of March 2012, ICE had cleared more than $11 trillion notional in CDS, and had 26 clearing members in CDS. CME began clearing interest rate swaps in 2010 and currently has open interest of $210 billion notional and 15 clearing members in interest rate swaps. Moreover, by March of 2010, 26 of the largest market makers were clearing interest rate derivatives. At that time, ISDA asserted that ''In excess of 90% of new dealer-to-dealer volume in Eligible Trades of Interest Rate Derivative products, and total dealer-to-dealer volume in Eligible Trades of Credit Derivative products is now cleared through CCPs.'' *See http://www.newyorkfed.org/newsevents/news/markets/2010/100301_letter.pdf.*

[36] The Commission understands approximately 2.5 months is sufficient for some market participants to enter into a clearing arrangement with an FCM for purposes of clearing swaps. *See* External Meeting with Blackrock, 4/2/2012. *http://www.cftc.gov/LawRegulation/DoddFrankAct/ExternalMeetings/dfmeeting_040212_1463.*

warranted. In these cases, the benefits of required clearing will be realized immediately.

The discretionary nature of the schedule contained in the adopting release, however, may create some uncertainty for market participants, and consequently may create some costs as market participants take steps to protect themselves from the impact of such uncertainty. For example, if a market participant believes that the Commission may issue a determination that a particular swap must be cleared, but is not certain whether clearing will be required immediately or according to the schedule contained in this release, that entity may begin developing the capacity to clear such a swap prior to a determination by the Commission in order to reduce the risk that it would be forced to stop trading the swap while it comes into compliance. If that participant's belief that the Commission will require the swap to be cleared is incorrect, the participant will have unnecessarily borne the cost of preparing for such a possibility. The Commission considered this cost, but believes that the notice and comment approach that the Commission will use when issuing Clearing Requirement determinations mitigates it. Each proposed Clearing Requirement determination will be published in the **Federal Register** and will be available for public comment for a period of at least 30 days; the Commission anticipates clarifying in each proposed Clearing Requirement determination whether compliance will be required immediately upon the final determination or according to the schedule contained in this rule. This approach will provide market participants with notice regarding the expected timeline for compliance, which will mitigate costs associated with uncertainty about compliance timelines.

F. Consideration of Comments and the Costs and Benefits of Alternatives

Commenters propose or otherwise highlight points that suggest alternatives with respect to various aspects of the NPRM.[37] These aspects, as categorized for discussion below, are: (1) Phased approach; (2) entity categorization; (3) schedule increments; and (4) schedule discretion.

Phased Approach

A number of commenters express support generally for additional time to comply with Clearing Requirement determinations and for a phased approach that distinguishes between various types of entities.[38] Commenters note that the additional clarity provided by the schedule will encourage industry participants to commit resources to overcoming structural and economic barriers that prevent widespread clearing.[39] Some commenters, however, maintain that the phased approach used to implement clearing requirement determinations should not be applied to exchange trade requirements.[40] The AIMA believes that effective required clearing will enable execution of swaps on SEFs and DCMs and that linking the trading and clearing compliance schedules could delay the transition into central clearing. In response to these comments, the Commission has decided to limit the scope of this rule to Clearing Requirement determinations, to retain the phased approach to required clearing, and to address implementation of trade execution in a separate rule.

Some commenters note that a phased approach could complicate implementation for large investor advisor firms that may have multiple funds in separate categories. Specifically, AII expresses concern that it may be difficult for institutional advisers to execute block trades for multiple clients during the implementation period because they will have to consider whether each client must comply with the Clearing Requirement. Nevertheless, AII recommends retaining the phased approach with at least 18 months for entities to comply. The Commission recognizes that such complexities exist and could introduce certain costs for large investor adviser firms. However, it is not clear that delaying the implementation period would alleviate this concern, although prolonging the implementation period likely would exacerbate the issue by extending the time during which such concerns are relevant. Moreover, the Commission notes that the benefits of required clearing are substantial and that further delays create costs borne by market participants and the public. In these circumstances, the Commission considers the latter consideration most compelling and, accordingly, has determined not to delay implementation beyond what is set forth in the schedule in the adopting release.

Finally, relative to the alternative of immediate implementation following a Commission Clearing Requirement determination—the result in the absence of this rule—the Commission believes that the phased approach reflected in this adopting release is superior. The immediate implementation alternative would not mitigate the costs, enumerated above, to market participants and the public. In contrast, while delaying implementation also entails a different set of costs, also discussed above, the Commission has carefully tailored the rule's phased approach to contain and dampen them.

Entity Categorization

Commenters generally agree that some buy-side representation in Category 1 is valuable in order to ensure that buy-side interests are represented as technological and legal standards begin to form,[41] though commenters express varied views about whether Active Funds should play that role, and what entities should be included in that group. Some commenters state their belief that transaction volume is an appropriate proxy for a firm's level of expertise in conducting swaps and, therefore, is a useful criterion for identifying the buy-side entities that are best equipped to make the transition as part of Category 1.[42] Some express concern, however, that as defined in the NPRM, the term ''Active Fund'' could be over-inclusive and recommend raising the threshold number of swaps or excluding swaps that are hedges or have a notional value below $10 million.[43]

The Commission's intent in selecting Active Funds to participate in Category 1 is to identify those market participants that are larger and have significant experience in the swap markets. To ensure that the rule effectively selects for these entities, and in response to commenters, the Commission has raised the threshold number of swaps from a trailing average of 20 swaps per month over the previous twelve months, to a trailing average of 200 swaps per month over the previous twelve months. The Commission, however, believes that

[37] Other commenters raise issues beyond the scope of this rule—*i.e.,* implementation timing of required clearing—that, consequently, are beyond, and not appropriate for Commission consideration in, this rulemaking. Specifically, some commenters request that the Commission establish a comprehensive schedule for implementation of all rules and requirements pursuant to the Dodd-Frank Act. (*See* Barnard, MFA.) Others request a comprehensive schedule of clearing requirement determinations (*See, e.g.,* CDEU), an issue already addressed by the Dodd-Frank Act and the rule regarding the Process for Review of Swaps for Mandatory Clearing. *See* section 2(h)(2)(B)(ii) of the CEA; 76 FR 44473.

[38] *See* letters from Encana, Vanguard, ICI, FSR, MFA, FIA/ISDA/SIFMA, AII, MarkitSERV, and AIMA.

[39] *See* MFA letter.

[40] *See* letters from AIMA and MFA.

[41] *See* AIMA letter.

[42] *See* letters from Barnard and AIMA.

[43] *See* letters from AII and CDEU.

further criteria restricting the swaps that are included against that count would create incremental administrative and operational costs that do not justify the resulting benefit, and therefore has not placed further restrictions on the types of swaps that count against the threshold. However, per commenters' request for clarification, the Commission is clarifying that the average monthly threshold of swaps applies to new swaps that the entity enters into, and it does not apply to novations, amendments, or partial tear-ups.

ACLI maintains that there is diversity among buy-side participants in their use of swaps, and expresses concern that Active Funds may not be able to effectively represent diverse buy-side interests, and those of insurance companies in particular. ACLI, however, does not describe or quantify specific costs that it believes would result from this circumstance.[44] The Commission acknowledges that buy-side market participants are diverse and may have specific needs reflecting concerns or interests unique to individual industries or even individual entities. However, the Commission also notes that the fact of certain differences among firms does not exclude the possibility of remaining similarities. Further, it believes that realizing the benefits provided by some buy-side representation in Category 1 is preferable to a scenario in which these benefits are foregone by removing Active Funds from Category 1 for required clearing implementation. Moreover, in the absence of any input as to how dissimilarities may specifically impact the compliance implementation process, the apparent solution to ACLI's concern would be to include insurance companies in Category 1 to assure representation of their interests earlier in the implementation process. While any Category 2 Entity or any other entity may elect to comply sooner than the schedule requires (and are encouraged by the Commission to do so), the Commission finds no basis to believe that the benefits of requiring all insurance companies to participate in Category 1 warrant the additional costs that such an approach would create for them.

MFA expresses concern that questions related to the term ''Active Fund'' could create an additional burden for fund operations and Commission staff, and proposed that all private funds be placed in Category 2 in order to eliminate this burden.[45] MFA, however, does not specify what these questions are, nor the cost to funds associated with addressing them. In the absence of more specific information about the nature of the potential questions and their associated costs, the Commission has insufficient basis to conclude that costs to clarify Active Fund issues—either for fund operators or itself—are likely to be significant. Accordingly, it believes that the benefits of early-stage, buy-side representation warrant retention of the Category 1 Active-Fund component.

Some commenters express concern about the definition of the term Third-Party Subaccounts. They maintain that the Third-Party Subaccount category should include any managed accounts, regardless of the level of authority granted in the advisory agreement to enter into trading agreements, on grounds that the operational and contractual challenges for moving swaps related to these accounts into clearing will be much the same regardless of whether the accounts' investment management agreements have ''specific approval'' requirements.[46] Similarly, some commenters advocate in favor of including all ERISA plans in Category 3 given their expectations that (1) Category 2 entities will bear more ''start-up'' costs related to required clearing than those in Category 3, and (2) putting some ERISA plans in Category 2 and others in Category 3 will make overlays more difficult and costly.[47] Conversely, AIMA specifically states that making all funds Category 3 Entities is not a suitable approach because it would eliminate buy-side representation during the early stages of implementation, and, consequently, urges the Commission not to adopt this approach.[48]

Furthermore, AIMA and FSR asserted that some Third-Party Subaccounts may be ''private funds'' as defined in the Investment Advisers Act of 1940 that would otherwise qualify as Active Funds; AIMA expresses concern that allowing such funds 270 days to comply with clearing requirements could provide them a competitive advantage relative to other Active Funds that are not Third-Party Subaccounts for the period of time between the compliance dates for Categories 1 and 3. To level this playing field, AIMA proposes placing all Active Funds in Category 1, regardless of whether the funds also meet the criteria for a Third-Party Subaccount. In support of this proposition, AIMA opines that large institutional managers of large numbers of Third-Party Subaccounts are likely to have sufficient resources to make the transition within the 90 days required of Category 1 Entities.

The Commission recognizes that some managed funds that do not require third party sign-off for clearing agreements, nevertheless, may choose to involve their clients in negotiation of relevant documents, and that some costs may result from placing some managed funds and ERISA plans in Category 2 and others in Category 3. After considering the alternatives posed by commenters, the Commission has modified the definition of Third-Party Subaccount to include managed accounts for which the investment manager is responsible for clearing documentation, regardless of whether the investment manager has explicit execution authority. In addition, the Commission has determined not to include ERISA plans in Category 2. The Commission has made these changes despite the fact that commenters do not attempt to quantify the costs associated with these provisions, nor do they recognize that such costs must be considered against the costs of further delaying required clearing implementation by a number of managed funds and ERISA plans. A fundamental premise of the Dodd-Frank Act is that central clearing minimizes risk to counterparties and the financial system as a whole; therefore, further delaying implementation of one or more groups of market participants creates costs associated with prolonged exposure of the financial system to a greater number of un-cleared swaps. Nonetheless, the Commission believes it appropriate to permit certain market participants an additional 90 days to come into compliance with the clearing requirement based on the comments received.

Schedule Increments

Some commenters express the opinion that 90, 180, and 270 days is sufficient for Category 1, 2, and 3 Entities, respectively, to comply with Clearing Requirement determinations.[49] Several other commenters, however, expressed concern that the additional time provided in this rule may not be sufficient for some entities to comply.[50] In that vein, commenters state that the

[44] *See* ACLI letter.

[45] *See* MFA letter.

[46] *See e.g.,* letters from ICI and AII.

[47] *See* CIEBA letter.

[48] *See* AIMA letter.

[49] *See e.g.,* letters from Better Markets and MFA. MFA qualifies its support, stating that certain additional rules should be adopted prior to the schedule becoming effective, and also requests changes to the entities included in each category, but still generally supports the 90-, 180-, and 270-day implementation schedule.

[50] *See e.g.,* letters from AII, CIEBA, ICI, FIA/ISDA/SIFMA, and FSR.

schedules may not be sufficient for contract negotiations to be completed,[51] that pressing timelines could undermine the ability of some entities to negotiate effectively,[52] and that rapid compliance may lead to the creation of industry standards that are not fair or prudent.[53] Some commenters also express concern that entities in Categories 2 and 3 may not be able to find vendors able to provide sufficient support to meet the deadlines effectively.[54]

It is impossible to quantify the costs and benefits of one particular schedule phase-in increment relative to another—*e.g.,* 90 days to comply versus 110—and the permutations of such an exercise would be endless, even if possible. Similarly, as discussed above, whether the schedule included in this adopting release mitigates costs to a greater degree than other increments the Commission might have adopted as an alternative to immediate implementation of required clearing (the result in the absence of this rule) is also a question that cannot be resolved with precision. In light of these limitations, however, the Commission has drawn upon its historical experience monitoring clearing, as well as its consideration of the qualitative feedback offered by market participants, in determining to incorporate the 90-, 180-, and 270-day benchmark features within the schedule adopted in this release. In so doing, the Commission believes that it has selected a reasonable schedule that is appropriate and well-suited to mitigate compliance pressures for market participants, and fairly accommodate the various competing interests involved.

As is stated above, the Commission recognizes that extending the compliance schedule for one or more entities will reduce compliance costs for market participants in a number of different ways, but will also increase the amount of time during which market participants and the public do not benefit from the protections provided by mandatory clearing.

Scheduling Discretion

Some commenters support the Commission's retention of discretion to override the schedule in this release to require immediate clearing when it believes that the benefits do not justify the associated costs.[55] These commenters note that over time market participants will gain experience to enable swifter compliance with later Clearing Requirement determinations, and maintain that, over time, the compliance schedules will not be warranted for Clearing Requirement determinations for new types, groups, or categories of swaps within an asset class that are already subject to a prior Clearing Requirement.[56] Other commenters, however, support application of the schedule to all Clearing Requirement determinations in order to reduce uncertainty and facilitate orderly transitions to compliance.[57]

As discussed below, the Commission believes that the challenges of compliance are likely to vary depending on whether previous Clearing Requirement determinations have been made for other swaps in the same class, how long previous Clearing Requirement determinations for swaps in that class have been in place, the similarities between the swaps addressed by a determination and swaps subject to previous determinations, and a number of other factors. Therefore, the Commission believes that the tradeoff between the costs and benefits of more rapid compliance will vary as well. Where Clearing Requirement determinations pertain to swaps that have important points of similarity with swaps already required to be cleared, it is likely that the costs associated with more rapid compliance will be significantly less, and therefore the balance will shift in favor of a shorter compliance deadline than would be allowed under the schedule contained in this rule. Also, by including the applicable compliance schedule within its public notifications of a proposed Clearing Requirement determination, the Commission will mitigate uncertainty costs that could result.

G. Consideration of Section 15(a) Factors

(1) Protection of Market Participants and the Public

Category 1 includes, among others, SDs as well as MSPs and Active Funds. If SDs were not able to comply immediately with a Clearing Requirement determination, and were not given additional time to comply, they could choose to withdraw from the market as they work toward compliance. Such withdrawal would create lost opportunities for them as they fail to capture business that they would have otherwise conducted during that period. If MSPs or Active Funds choose to withdraw from the market while they work to come into compliance, it could become more costly for them to either effectively create or hedge certain exposures, which could also prompt them to leave certain risks un-hedged that they would otherwise mitigate through the use of swaps. By giving Category 1 Entities an additional 90 days to comply with Clearing Requirement determinations, the schedule contained in this adopting release reduces the likelihood of these entities withdrawing from the swap markets while they work toward compliance; this, in turn, reduces the probability that these Category 1 Entities will bear the potential costs of un-hedged risk exposure.

Moreover, the Commission believes that SDs are an important source of liquidity for swap market participants. If SDs withdraw from the market while they work toward compliance, it could negatively impact swap liquidity, increasing costs for market participants forced to hedge certain risks through less efficient means (or not at all) for a period of time. The costs of not hedging certain risks would be borne not only by the firms that choose such an approach, but by the public in the form of increased counterparty risk throughout the financial system. Again, by providing additional time for SDs to comply with Clearing Requirement determinations, the schedule in the adopting release facilitates an orderly transition and reduces the likelihood that the costs associated with SDs withdrawing from the market for a period of time would materialize. The Commission considered this benefit in light of the cost associated with delayed compliance among Category 1 Entities and believes that an appropriate balance has been struck.

The Commission also anticipates that the staggered compliance schedule contained in this rule will, to some extent, enable Category 2 and 3 Entities to adopt technological, legal, and operational standards developed by Category 1 Entities. To the extent that this occurs, it will reduce the number of entities that are working in parallel to develop solutions to the same problems by allowing Category 2 and 3 Entities some time to wait for Category 1 Entities and vendors to develop viable solutions to technological, legal, and operational challenges. Some of those solutions are likely to be proprietary, while others

[51] *See e.g.,* ACLI letter.

[52] *See* letters from ACLI, AII, and CIEBA.

[53] *See* letters from ACLI and ICI.

[54] *See* letters from ACLI, CDEU, CIEBA, COPE, and EEI. COPE and EEI specifically requested that the Commission determine whether ''off the shelf'' software is available to meet the needs of entities that do not yet have necessary technology. Further conversation clarified that both were concerned about technologies that extend beyond those directly related to Clearing Requirements established by the Act.

[55] *See* letters from Barnard and MFA.

[56] *See* letters from Barnard and MFA.

[57] *See* letters from FHLB and ICI.

will likely relate to non-proprietary standards that must be shared in order to be effective. Both types of advances can reduce costs for Category 2 and 3 Entities. In the case of non-proprietary standards, Category 2 and 3 entities will benefit from the opportunity to adopt them without having to invest in their development. In the case of proprietary solutions, some of them are likely to be owned by vendors marketing them to multiple market participants, thereby spreading the development costs among their clients. Each of these consequences is likely to reduce overall development costs for the industry, and development costs for Category 2 and 3 Entities, in particular.[58]

In weighing the tradeoff between shorter versus longer compliance timelines, the Commission believes Category 2 Entities are likely to be less well-resourced and less active in these markets. Therefore the dynamic between more or less rapid compliance tips in favor of providing additional time for these entities. As stated above, by providing 180 days, it becomes more likely that Category 2 Entities will be able to draw from lessons learned and standards established by Category 1 Entities. It also increases the likelihood that where Category 2 Entities will depend on vendors for help developing and implementing necessary technology, legal agreements, and operational patterns, they will not have to compete as directly with Category 1 Entities for those resources.

The Commission believes that entities with Third-Party Subaccounts have an additional challenge of transitioning hundreds (or in some cases, thousands) of subaccounts into compliance with Clearing Requirement determinations, which may require formalizing new agreements with each of their customers, and educating their customers about how the Clearing Requirement will impact costs and operations. In the Commission's view, this additional challenge justifies additional time for compliance beyond what is allowed for Category 2 Entities.[59]

As described above, the Commission recognizes that delaying implementation creates some additional costs in the form of delayed protections that central clearing of swaps would otherwise provide—standardized and reduced counterparty risk for swaps that are required to be cleared, and associated reductions in the overall level of systemic risk. However, the Commission believes that this approach appropriately balances the tradeoff by requiring firms that are likely to be the most active in these markets to comply first and allowing additional time for those whose positions are less likely to pose significant risk to the financial system as a whole.

(2) Efficiency, Competitiveness, and Financial Integrity of Futures Markets

As suggested above, Category 1 Entities are likely to establish technological, legal, and operational standards that will influence or be adopted by Category 2 and 3 Entities. This will (1) serve to reduce development costs that Category 2 and 3 Entities otherwise would face, (2) focus responsibility for shaping new platforms and standards on those firms that possess greater cleared swap experience, and (3) support the likelihood that new platforms and standards will reflect current best practices. Each of these elements promotes the efficiency and integrity of the markets. Moreover, by reducing the number of entities necessarily working in parallel to develop such standards, and allowing Category 2 and 3 Entities to learn from and build on the solutions developed by Category 1 Entities, the phased schedule contained in this adopting release holds the potential to foster compatibility and interoperability, which reduces the cost and complexity of interconnectedness.

The phased schedule as adopted also will promote an implementation plan in which similar entities (*i.e.,* those that usually compete with one another) generally have the same compliance timelines, thereby protecting competition during the transition period. One commenter states, ''A phased approach to compliance will allow the Commission to balance its goal of obtaining adequate representation at each stage of the regulatory roll-out with the goal of avoiding anti-competitive concerns.'' [60]

That said, however, the Commission also has to balance the goal of maintaining a level playing field with other priorities. In particular, the Commission deems it important to ensure representation of both buy and sell side firms in the earliest stages of compliance. Moreover, the Commission believes that, in certain circumstances, variance in compliance burden among competitors warrants placing them in different implementation categories. Some competitive consequences may result from the need to balance these various priorities. The Commission believes, however, that it has built sufficient flexibility into the phased schedule to mitigate such consequences; specifically, the schedule preserves entities' ability to respond to competitive incentives to move into clearing voluntarily prior to the date required by the compliance schedule. The Commission believes that providing flexibility to allow expression of competitive market incentives is preferable to the alternative of imposing a more compressed compliance schedule for purposes of maintaining a level playing field. As discussed above, a shorter schedule could also increase the likelihood that industry standards established during the implementation period could create and perpetuate undesirable competitive dynamics. In sum, the Commission anticipates that any temporary impacts on competitive dynamics created by the phased implementation approach it is adopting are likely to be less costly than an approach that increases the likelihood of sustained competitive disparities, and therefore has chosen not to shorten the compliance schedule as a remedy to address the risk of competitive advantages that may be conferred on market participants that have later compliance dates.

As discussed above, for the 90-, 180-, and 270-day periods that Clearing Requirements are delayed, the markets are exposed to the risks that the Clearing Requirements would mitigate. However, the Commission has considered this cost for the limited delay durations prescribed in light of the benefits—reduced implementation costs, greater degrees of compatibility and interoperability, and lessened risk of market disturbances from the withdrawal of entities that are not able to comply immediately—and considers the tradeoff reflected in the rules warranted.

(3) Price Discovery

Neither the Commission nor commenters have identified consequences for price discovery that are expected to result from this rule.

(4) Sound Risk Management Practices

An orderly transition for swaps subject to a Clearing Requirement determination promotes sounder risk management practices, particularly during the transition period. As mentioned above, in the absence of the

[58] As indicated in the NPRM, to the extent that Category 1 Entities bear a larger portion of the industry wide ''start-up'' or development costs, the Commission believes this is appropriate since they are likely to be among the most active participants in these markets.

[59] As stated in the NPRM, Category 2 and 3 Entities that want to come into compliance sooner than the 180- and 270-day deadlines are allowed, and encouraged, to do so.

[60] *See* ICI letter.

schedule provided in this rule, some entities might exit swap markets while taking steps to come into compliance. This result could reduce liquidity, particularly if the withdrawing entities are SDs. Reduced liquidity likely would increase the cost of using swaps to manage risk by increasing spreads, and make it more difficult for entities to enter and exit positions in a timely manner. It could also prompt some entities to maintain exposures that they would otherwise use swaps to mitigate, which would elevate the risk profile of those entities and the level of risk that their counterparties bear as a consequence. By providing a timetable for orderly transition, this rule encourages continued participation in the swap markets and use of swaps for risk mitigation purposes during the transition.

Clearing Requirement delay does prolong existing costs associated with not having counterparty credit risk monitored and managed effectively by a DCO. More prompt implementation of Clearing Requirements would have the benefit of preventing losses from accumulating over time through the settlement of variation margin between a DCO's clearing members each day. The settlement of variation margin each day (and in some cases, multiple times per day) reduces the size of exposures a clearinghouse faces should one of its counterparties default, and the mechanisms that a clearinghouse has to ensure its own solvency reduce the probability that it would default on obligations to clearing members. Moreover, more prompt implementation also promotes the use of initial margin as a performance bond against potential future losses such that if a party fails to meet its obligation to pay variation margin, resulting in a default, the DCO may use the defaulting party's initial margin to cover most or all of any loss based on the need to replace the open position. The Commission believes, however, that (1) it has tailored the rule to limit the degree, and thereby these costs attributable to, clearing implementation delay and (2) the benefits afforded by the schedule's operation when the Commission elects to use it warrant the costs of the tailored implementation delay.

(5) Other Public Interest Considerations

The schedule allows market participants to comply with the requirements of the Dodd-Frank Act and provides a sound basis for achieving the overarching Dodd-Frank Act goals of reducing counterparty risk and promoting stability of the financial system.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that agencies consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact.[61] As stated in the NPRM, the subject of this rulemaking provides a compliance schedule for a new statutory requirement, section 2(h)(1)(A) of the CEA, and does not itself impose significant new regulatory requirements.[62] Accordingly, the Chairman, on behalf of the Commission, certified pursuant to 5 U.S.C. 605(b) that the proposed rule would not have a significant economic impact on a substantial number of small entities. The Commission then invited public comment on this determination.

FSR comments that the NPRM failed to evaluate the impact of the proposed compliance schedule for the Clearing Requirement on a substantial number of small entities. FSR argued that small entities may have to bear a more significant burden than larger entities in establishing clearing arrangements with FCMs because larger entities will be able to enter into such arrangements first.

In response, the Commission points out that the compliance schedule for the Clearing Requirement will affect only eligible contract participants (ECPs). Pursuant to section 2(e) of the CEA, only ECPs may enter into swaps, unless the swap is listed on a DCM. The Clearing Requirement will affect only ECPs because all persons that are not ECPs are required to execute their swaps on a DCM, and all contracts executed on a DCM must be cleared by a DCO, as required by statute and regulation; not by operation of any Clearing Requirement.

The Commission has previously determined that ECPs are not small entities for purposes of the RFA.[63] However, in their comment letter, the Joint Associations assert that certain members of the National Rural Electric Cooperative Association (NRECA) may both be ECPs under the CEA and small businesses under the RFA. These members of NRECA, as the Commission understands, have been determined to be small entities by the Small Business Administration (SBA) because they are ''primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and [their] total electric output for the preceding fiscal year did not exceed 4 million megawatt hours.'' [64] Although the Joint Associations do not provide details on whether or how the NRECA members that have been determined to be small entities use the types of swaps that will be subject to the Clearing Requirement, the Joint Associations do state that NRECA members ''engage in swaps to hedge commercial risk.'' [65] Because the NRECA members that have been determined to be small entities would be using swaps to hedge commercial risk, the Commission expects that they would be able to use the end-user exception from the Clearing Requirement and therefore would not be affected to any significant extent by the Clearing Requirement.

Thus, because nearly all of the ECPs that may be subject to the Clearing Requirement are not small entities, and because the few ECPs that have been determined by the SBA to be small entities are unlikely to be subject to the Clearing Requirement, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the rule herein creating the compliance schedule for the Clearing Requirement will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) [66] imposes certain requirements on federal agencies (including the Commission) in connection with conducting or sponsoring any collection of information as defined by the PRA. As stated in the NPRM, this rulemaking will not require a new collection of information from any persons or entities.[67]

V. List of Subjects

List of Subjects in 17 CFR Part 50

Business and industry, Clearing, Swaps.

In consideration of the foregoing, and pursuant to the authority in the Commodity Exchange Act, as amended, and in particular section 2(h) of the Act, the Commission hereby adopts an amendment to Chapter I of Title 17 of the Code of Federal Regulation by adding a new part 50 as follows:

[61] 5 U.S.C. 601 *et seq.*

[62] 76 FR 58192–58193 (Sept. 20, 2011).

[63] *See* 66 FR 20740, 20743 (Apr. 25, 2001).

[64] Small Business Administration, Table of Small Business Size Standards, Nov. 5, 2010.

[65] *See* Joint Associations' comment letter, at 2. The letter also suggests that NRECA members are not financial entities. *See id.,* at note 5, and at 5 (the associations' members ''are not financial companies'').

[66] 44 U.S.C. 3507(d).

[67] 76 FR 58186, 58193 (Sept. 20, 2011).

PART 50—CLEARING REQUIREMENT

Authority: 7 U.S.C. 2 as amended by Pub. L. 111–203, 124 Stat. 1376.

§ 50.25 Clearing requirement compliance schedule.

(a) *Definitions.* For the purposes of this paragraph:

Active Fund means any private fund as defined in section 202(a) of the Investment Advisers Act of 1940, that is not a third-party subaccount and that executes 200 or more swaps per month based on a monthly average over the 12 months preceding the Commission issuing a clearing requirement determination under section 2(h)(2) of the Act.

Category 1 Entity means a swap dealer, a security-based swap dealer; a major swap participant; a major security-based swap participant; or an active fund.

Category 2 Entity means a commodity pool; a private fund as defined in section 202(a) of the Investment Advisers Act of 1940 other than an active fund; or a person predominantly engaged in activities that are in the business of banking, or in activities that are financial in nature as defined in section 4(k) of the Bank Holding Company Act of 1956, provided that, in each case, the entity is not a third-party subaccount.

Third-party Subaccount means an account that is managed by an investment manager that is independent of and unaffiliated with the account's beneficial owner or sponsor, and is responsible for the documentation necessary for the account's beneficial owner to clear swaps.

(b) Upon issuing a clearing requirement determination under section 2(h)(2) of the Act, the Commission may determine, based on the group, category, type, or class of swaps subject to such determination, that the following schedule for compliance with the requirements of section 2(h)(1)(A) of the Act shall apply:

(1) A swap between a Category 1 Entity and another Category 1 Entity, or any other entity that desires to clear the transaction, must comply with the requirements of section 2(h)(1)(A) of the Act no later than ninety (90) days from the date of publication of such clearing requirement determination in the **Federal Register**.

(2) A swap between a Category 2 Entity and a Category 1 Entity, another Category 2 Entity, or any other entity that desires to clear the transaction, must comply with the requirements of section 2(h)(1)(A) of the Act no later than one hundred and eighty (180) days from the date of publication of such clearing requirement determination in the **Federal Register**.

(3) All other swaps for which neither of the parties to the swap is eligible to claim the exception from the clearing requirement set forth in section 2(h)(7) of the Act and § 39.6, must comply with the requirements of section 2(h)(1)(A) of the Act no later than two hundred and seventy (270) days from the date of publication of such clearing requirement determination in the **Federal Register**.

(c) Nothing in this rule shall be construed to prohibit any person from voluntarily complying with the requirements of section 2(h)(1)(A) of the Act sooner than the implementation schedule provided under paragraph (b).

Issued in Washington, DC, on July 24, 2012, by the Commission.

Sauntia Warfield,

Assistant Secretary of the Commission.

Appendices to Swap Transaction Compliance and Implementation Schedule: Clearing Requirement under Section 2(h) of the CEA—Commission Voting Summary and Statements of Commissioners

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Sommers, Chilton, O'Malia and Wetjen voted in the affirmative; no Commissioner voted in the negative.

Appendix 1—Statement of Chairman Gary Gensler

I support the final rule to establish a schedule to phase in compliance with the clearing requirement provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act.

The rule gives market participants an adequate amount of time to comply and helps facilitate an orderly transition to the new clearing requirements for the swaps market. The rule provides greater clarity to market participants regarding the timeframe for bringing their swaps into compliance with the clearing requirement.

[FR Doc. 2012–18383 Filed 7–27–12; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1300

[Docket No. DEA–341F]

RIN 1117–AB31

Classification of Two Steroids, *Prostanozol* and *Methasterone,* as Schedule III Anabolic Steroids Under the Controlled Substances Act

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this Final Rule, the Administrator of the DEA classifies the following two steroids as ''anabolic steroids'' under the Controlled Substances Act (CSA): prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one). These steroids and their salts, esters, and ethers are Schedule III controlled substances subject to the regulatory control provisions of the CSA.

DATES: *Effective Date:* August 29, 2012.

FOR FURTHER INFORMATION CONTACT: Alan G. Santos, Associate Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended (hereinafter, ''CSA''). The implementing regulations for these statutes are found in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances by statute are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR Part 1308.

On November 29, 1990, the President signed into law the Anabolic Steroids Control Act of 1990 (Title XIX of Pub. L. 101–647), which became effective

February 27, 1991. This law established and regulated anabolic steroids as a class of drugs under Schedule III of the CSA. As a result, a new anabolic steroid is not scheduled according to the procedures set out in 21 U.S.C. 811, but is administratively classified as an anabolic steroid through the rulemaking process if it meets the regulatory definition of an anabolic steroid in 21 CFR 1300.01.

On October 22, 2004, the President signed into law the Anabolic Steroid Control Act of 2004 (Pub. L. 108–358), which became effective on January 20, 2005. Section 2(a) of the Anabolic Steroid Control Act of 2004 amended 21 U.S.C. 802(41)(A) by replacing the existing definition of ''anabolic steroid.'' The Anabolic Steroid Control Act of 2004 classifies a drug or hormonal substance as an anabolic steroid if the following four criteria are met: (A) The substance is chemically related to testosterone; (B) the substance is pharmacologically related to testosterone; (C) the substance is not an estrogen, progestin, or a corticosteroid; and (D) the substance is not dehydroepiandrosterone (DHEA). Any substance that meets these criteria is considered an anabolic steroid and must be listed as a Schedule III controlled substance.

Background

In a Notice of Proposed Rulemaking (NPRM) published on November 23, 2011 (76 FR 72355), DEA proposed classification of two steroids as Schedule III anabolic steroids under the CSA: Prostanozol and methasterone. DEA believes that prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) meet this definition of anabolic steroid.

Anabolic steroids are a class of drugs structurally related to the endogenous hormone testosterone that exert androgenic (masculinizing) as well as anabolic (body building) effects. These effects are mediated primarily through binding of the anabolic steroid to the androgen receptor in target tissues (Evans, 2004). Anabolic effects include promotion of protein synthesis in skeletal muscle and bone, while the androgenic effects are characterized by the development of male secondary sexual characteristics such as hair growth, deepening of the voice, glandular activity, thickening of the skin, and central nervous system effects (Kicman, 2008). Anabolic efficacy is characterized by positive nitrogen balance and protein metabolism, resulting in increases in protein synthesis and lean body mass (Evans, 2004). These effects often come at a cost to the healthy individual who experiences clear physical and psychological complications (Trenton and Currier, 2005; Brower, 2002; Hall *et al.,* 2005).

In the United States, only a small number of anabolic steroids are approved for either human or veterinary use. Approved medical uses for anabolic steroids include treatment of androgen deficiency in hypogonadal males, adjunctive therapy to offset protein catabolism associated with prolonged administration of corticosteroids, treatment of delayed puberty in boys, treatment of metastatic breast cancer in women, and treatment of anemia associated with specific diseases (e.g., anemia of chronic renal failure, Fanconi's anemia, and acquired aplastic anemia). However, with the exception of the treatment of male hypogonadism, anabolic steroids are not the first-line treatment due to the availability of other preferred treatment options. DEA is not aware of any legitimate medical use or New Drug Applications (NDA) for the two substances that DEA is proposing to classify by this NPRM as anabolic steroids under the definition set forth under 21 U.S.C. 802(41)(A). Moreover, DEA has been unable to identify any chemical manufacturers currently using these substances as intermediates in their manufacturing processes.

Adverse health effects are associated with abuse of anabolic steroids and depend on several factors (e.g., age, sex, anabolic steroid used, the amount used, and the duration of use) (Hall and Hall, 2005; Quaglio *et al.,* 2009). These include cardiovascular, dermatological, behavioral, hepatic, and gender specific endocrine side effects. Anabolic steroids have direct and indirect impact on the developing adolescent brain and behavior (Sato *et al.,* 2008). Furthermore, adolescent abuse of anabolic steroids may result in stunted growth due to premature closure of the growth plates in long bones.

In adolescent boys, anabolic steroid abuse can cause precocious sexual development. In both girls and women, anabolic steroid abuse induces permanent physical changes such as deepening of the voice, increased facial and body hair growth, menstrual irregularities, and clitoral hypertrophy. In men, anabolic steroid abuse can cause testicular atrophy, decreased sperm count, and sterility. Gynecomastia (i.e., enlargement of the male breast tissue) can develop with the abuse of those anabolic steroids with estrogenic actions. In both men and women, anabolic steroid abuse can damage the liver and may result in high cholesterol levels, which may increase the risk of strokes and cardiovascular heart attacks. Furthermore, anabolic steroid abuse is purported to induce psychological effects such as aggression, increased feelings of hostility, and psychological dependence and addiction (Brower, 2002; Kanayama *et al.,* 2008).

Upon abrupt termination of long-term anabolic steroid abuse, a withdrawal syndrome may appear including severe depression. Additionally, polysubstance abuse is routinely associated with anabolic steroid abuse, where ancillary drugs, including recreational and prescription drugs, are abused in response to unwanted side effects (Hall *et al.,* 2005; Parkinson *et al.,* 2005; Skarberg *et al.,* 2009).

A review of the scientific literature finds adverse health effects including liver toxicity with renal failure reported in conjunction with methasterone abuse (Shah *et al.,* 2008; Jasiurkowski *et al.,* 2006; Singh *et al.,* 2009; Nasr and Ahmad, 2008; and Krishnan *et al.,* 2009). In March 2006, the U.S. Food and Drug Administration (FDA) issued a Warning Letter in response to adverse health effects associated with the product Superdrol (methasterone). In July 2009, FDA issued a warning regarding bodybuilding products containing steroid or steroid-like substances. In this warning, a product containing the THP ether derivative of prostanozol was named in conjunction with other products presenting safety concerns.

Evaluation of Statutory Factors for Classification as an Anabolic Steroid

With the issuance of this Final Rule, DEA classifies prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) as anabolic steroids under the definition set forth under 21 U.S.C. 802(41)(A). As noted previously, a drug or hormonal substance is classified as an anabolic steroid by meeting the following four definitional requirements: (A) The substance is chemically related to testosterone; (B) the substance is pharmacologically related to testosterone; (C) the substance is not an estrogen, progestin, or corticosteroid; and (D) the substance is not DHEA.

(A) Chemically Related to Testosterone

To classify a substance as an anabolic steroid, a substance must be chemically related to testosterone. A structure activity relationship (SAR) evaluation for each substance compared the chemical structure of the steroid to that of testosterone. Substances with a

structure similar to that of testosterone are predicted to possess comparable pharmacological and biological activity.

Prostanozol is also known by the following name: 17β-hydroxy-5α-androstano[3,2-c]pyrazole. DEA determined that the chemical structure of prostanozol is similar to testosterone, differing by only the attachment of a pyrazole ring at carbon 2 (C2) and carbon 3 (C3) positions of the androstane skeleton, replacing the C3-keto group and the lack of a double bond between carbon 4 (C4) and carbon 5 (C5) positions. Similar modifications to testosterone's chemical structure have been documented and, in general, they have been found to be well tolerated, displaying both anabolic and androgenic activity (Fragkaki *et al.,* 2009; Vida, 1969). Clinton and coworkers, in their synthesis of prostanozol, described the modification as a fusion of a pyrazole ring to the androstane steroidal nucleus at C2 and C3 (Clinton *et al.,* 1961). Further analysis finds the chemical structure of prostanozol to be very similar to the anabolic steroid stanozolol. The two structures differ only about a 17α-methyl group (alpha methyl group attached to carbon 17).

Methasterone is known by the following chemical names: 2α,17α-dimethyl-5α-androstan-17β-ol-3-one; 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one; 17α-methyl-drostanolone; methasteron; methyldrostanolone; 2α,17α-dimethyldihydrotestosterone; and 2α,17α-dimethyl-etiocholan-17β-ol-3-one. DEA has determined that the chemical structure of methasterone is chemically related to testosterone. The chemical structure of methasterone differs from testosterone by the following three chemical groups: An alpha methyl group at carbon 17 (C17), an alpha methyl group at C2, and the lack of a double bond between spanning C4 and C5. Removal of the C4–C5 double bond (A-ring) and methylation at the C2 and C17 positions has been shown to increase anabolic activity (Zaffroni, 1960; Fragkaki *et al.,* 2009). Furthermore, methyl group substitution at the C2 and C17 has been reported to impair aromatization, thus, prolonging the anabolic effect (Fragkaki *et al.,* 2009).

(B) Pharmacologically Related to Testosterone

A substance must also be pharmacologically related to testosterone (i.e., produce similar biological effects) to be classified as a Schedule III anabolic steroid. The pharmacology of a steroid, as related to testosterone, can be established by performing one or more of the following androgenic and anabolic activity assays: ventral prostate assay, seminal vesicle assay, levator ani assay, and androgen receptor binding and efficacy assays. These assays are described below.

Ventral Prostate Assay, Seminal Vesicle Assay, and Levator Ani Assay: The classic scientific procedure for evaluating androgenic (masculinizing) and anabolic (muscularizing) effects of a steroid is the ventral prostate assay, seminal vesicle assay, and levator ani assay. This testing paradigm allows for the direct comparison to testosterone. Select male accessory tissues (i.e., the ventral prostate, seminal vesicles, and levator ani muscle) are testosterone sensitive, specifically requiring testosterone to grow and remain healthy. Upon the removal of the testes (i.e., castration), the primary endogenous source of testosterone is eliminated causing the atrophy of the ventral prostate, seminal vesicles, and levator ani muscle (Eisenberg *et al.,* 1949; Nelson *et al.,* 1940; Scow, 1952; Wainman and Shipounoff, 1941). Numerous scientific studies have demonstrated the ability of exogenous testosterone or a pharmacologically similar steroid administered to rats following castration to maintain the normal weight and size of all three testosterone sensitive organs (Biskind and Meyer, 1941; Dorfman and Dorfman, 1963; Dorfman and Kincl, 1963; Kincl and Dorfman, 1964; Nelson *et al.,* 1940; Scow, 1952; Wainman and Shipounoff, 1941). Thus, a steroid with testosterone-like activity will also prevent the atrophy of these three testosterone-dependent organs in castrated rats.

Castrated male rats are administered the steroid for a number of days, then the rats are euthanized and the previously described tissues are excised and weighed. Tissue weights from the three animal test groups are compared, castrated animals alone, castrated animals receiving the steroid, and healthy intact animals (control), to assess anabolic and androgenic activity. A reduction in tissue weights relative to the control group suggests a lack of androgenic and/or anabolic activity. An increase in tissue weights relative to the castrated rats receiving no steroid suggests an androgenic and/or anabolic effect.

Androgen Receptor Binding and Efficacy Assay: Anabolic steroids bind with the androgen receptor to exert their biological effect. Affinity for the receptor is evaluated in the receptor binding assay, while the transactivation (functional) assay provides additional information as to both affinity and ability to activate the receptor. Receptor binding and transactivation studies are valuable tools in evaluating pharmacological activity and drawing comparisons to other substances. A steroid displaying affinity for the androgen receptor and properties of being an agonist in transactivation studies is determined to be pharmacologically similar to testosterone.

Studies used to evaluate anabolic steroids are the androgen receptor binding assay and the androgen receptor transactivation assay. Both are well-established and provide significant utility in evaluating steroids for affinity to their biological target and the modulation of activity. The androgen receptor binding assay provides specific detail as to the affinity of a steroid for the androgen receptor (biological target of anabolic steroids). To assess further whether the steroid is capable of activating the androgen receptor, the androgen receptor transactivation assay evaluates the binding of a steroid to the androgen receptor and subsequent interaction with DNA. In this study, transcription of a reporter gene provides information as to a steroid's ability to modulate a biological event. This activity measurement provides information as to the potency of a steroid to bind to a receptor and either initiate or inhibit the transcription of the reporter gene. The androgen receptor binding assay and androgen receptor transactivation assay are highly valuable tools in assessing the potential activity of a steroid and comparing the activity to testosterone.

Results of the Androgenic and Anabolic Activity Assays: DEA reviewed the published scientific literature, and pharmacological studies were undertaken to collect additional information on prostanozol and methasterone in several different androgenic and anabolic activity assays. Findings from these studies indicate that in addition to being structurally similar to testosterone, prostanozol and methasterone have similar pharmacological activity as testosterone.

Prostanozol

The chemical synthesis and anabolic and androgenic effects of prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) were published in 1961 (Clinton *et al.,* 1961). Clinton and coworkers evaluated the anabolic activity by means of nitrogen balance and androgenic activity based on weight changes of the ventral prostrate of prostanozol upon subcutaneous administration to rats with the reference

standard testosterone propionate. The potency ratio of anabolic activity to androgenic activity for prostanozol was reported to be eight (Clinton *et al.,* 1961). In another study, prostanozol was reported to have approximately the same relative binding affinity for human sex steroid binding protein as testosterone (Cunningham *et al.,* 1981).

To build on these findings, a pharmacological study [1] was conducted to evaluate the anabolic and androgenic effects of prostanozol in castrated male rats. Results were compared to testosterone by a similar protocol. Administration of prostanozol to castrated male rats by subcutaneous injection prevented the atrophy (loss in weight) of the ventral prostate, seminal vesicles, and levator ani muscle.[1] These testosterone sensitive tissues experienced increases in weight comparable to testosterone in castrated male rats. Results from this study support that prostanozol possesses both androgenic and anabolic activity. Additional studies were conducted to further assess prostanozol's anabolic effect. In a competitive binding assay, prostanozol was found to possess affinity for the androgen receptor comparable to testosterone.[1] In the androgen receptor transactivation assay, prostanozol displayed increased activity relative to testosterone.[1] Effects elicited by prostanozol in this transactivation assay were consistent and comparable to those of testosterone. Taken together, data from in vitro and in vivo assays indicate the pharmacology of prostanozol to be similar to testosterone.

Methasterone

The synthesis of methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) was reported in 1956 and the anabolic activity in 1959 (Ringold and Rosenkranz, 1956; Ringold *et al.,* 1959). Methasterone was described as a potent anabolic agent exhibiting weak androgenic activity in the castrated male rat (Ringold *et al.,* 1959). Zaffaroni and coworkers reported methasterone possessed one-fifth the androgenic activity and four times the anabolic activity of the anabolic steroid methyltestosterone, when administered orally to the experimental animal (Zaffaroni *et al.*, 1960).

Additional pharmacological studies were undertaken to further evaluate the androgenic and anabolic effects of methasterone.[1] Methasterone was administered subcutaneously and orally to castrated male rats. By both routes of administration, methasterone prevented the atrophy (loss in weight) of ventral prostate, seminal vesicles, and levator ani muscle. Tissue weight increases for the castrated methasterone-treated animals were comparable to the castrated rats treated with testosterone and methyltestosterone. These results were consistent with earlier findings that methasterone is anabolic and androgenic (Zaffaroni, 1960; Ringold *et al.,* 1959). Functional assays were also undertaken to further evaluate methasterone.[1] Methasterone displayed affinity for the androgen receptor comparable to testosterone in a competitive binding assay.[1] In the androgen receptor transactivation assay, methasterone displayed increased activity relative to testosterone.[1] Effects elicited by methasterone in the androgen transactivation assay were consistent and comparable to those of testosterone. Collectively, in vivo and in vitro results indicate that the pharmacology of methasterone is similar to testosterone.

(C) Not Estrogens, Progestins, and Corticosteroids

DEA has determined that prostanozol and methasterone are unrelated to estrogens, progestins, and corticosteroids. DEA evaluated the SAR for each of the substances. The chemical structure of each substance was compared to that of estrogens, progestins, and corticosteroids, since chemical structure can be related to its pharmacological and biological activity. DEA found that these two substances lack the necessary chemical structures to impart significant estrogenic activity (e.g., aromatic A ring) (Duax *et al.,* 1988; Jordan *et al.,* 1985; Williams and Stancel, 1996), progestational activity (e.g., 17β-alkyl group) (Williams and Stancel, 1996), or corticosteroidal activity (e.g., 17β-ketone group or 11β-hydroxyl group) (Miller *et al.,* 2002). Furthermore, methasterone was reported to display anti-estrogenic activity in mouse assay to assess estrogen stimulated uterine growth (Dorfman *et al.,* 1961). To assess the estrogenic, progestational, and corticosteroid activity of prostanozol and methasterone, these substances were evaluated in receptor binding and functional transactivation assays. Prostanozol and methasterone showed low binding affinity for the estrogen, progesterone, and glucocorticoid receptors. Furthermore, these steroids displayed low to no transactivation mediated by the estrogen receptors, progesterone receptors, or glucocorticoid receptors. Therefore, based on these data, prostanozol and methasterone are not estrogens, progestins, or corticosteroids and these anabolic steroids are not exempt from control on this basis.

(D) Not Dehydroepiandrosterone

Dehydroepiandrosterone, also known as DHEA, is exempt from control as an anabolic steroid by definition (21 U.S.C. 802(41)(A)). Prostanozol and methasterone are not dehydroepiandrosterone and therefore, are not exempt from control on this basis.

Comments Received

On November 23, 2011, DEA published a NPRM (76 FR 72355) to classify prostanozol and methasterone as Schedule III anabolic steroids. The proposed rule provided an opportunity for all interested persons to submit their comments on or before January 23, 2012. In response to the request, DEA received three comments.

Comment: One commenter disagreed that anabolic steroids, and in particular those encountered in dietary supplements, should be placed in Schedule III of the CSA. He indicated that classifying these substances as Schedule III anabolic steroids would force the public to procure other, non-regulated and unsafe substitutes from illicit sources in the future, and that DEA should employ an alternate method of regulation.

DEA Response: DEA disagrees with this comment. As stated in the NPRM and this Final Rule, these substances were found to be similar in structure and pharmacology to testosterone through substantive scientific evaluation and investigation. Further, the United States Food and Drug Administration has issued multiple warnings regarding dietary supplements, especially concerning contamination through novel synthetic steroids that do not qualify as dietary ingredients.

Regarding the commenter's request for alternative regulation of these substances. DEA regulates the manufacture, importation, export, distribution, and sale of controlled substances for medical, scientific, or other legitimate uses pursuant to the CSA. These substances have not been approved as safe for human consumption and, despite the commenter's unsubstantiated and factually inaccurate claims of their benefits, should neither be consumed nor should other unapproved substances ever be sought from any source, illicit or otherwise.

The additional remarks this commenter made regarding a perceived

[1] The study by Bioqual, Inc., Rockville, MD, may be found at *http://www.regulations.gov* in the electronic docket associated with this rulemaking.

disparity between men and women in access to hormonal products, and other perceived problems with the regulation of substances by the government, are not germane to this rulemaking.

Comment: Two separate commenters agreed placement of these two substances under the CSA was appropriate as provided per the Anabolic Steroid Control Act of 2004.

DEA Response: DEA appreciates the support for this rulemaking. As discussed above, prostanozol and methasterone are similar in structure and pharmacology to testosterone and are not approved for human consumption. DEA believes their placement into Schedule III as anabolic steroids will provide the appropriate safeguards to limit their availability to and prevent their abuse by the public.

Conclusion

After evaluation of the statutory factors above and consideration of the comments to the NPRM, DEA concludes that prostanozol and methasterone meet the CSA definition of ''anabolic steroid'' because each substance is: (A) Chemically related to testosterone; (B) pharmacologically related to testosterone; (C) not an estrogen, progestin, or a corticosteroid; and (D) not DHEA (21 U.S.C. 802(41)). Once a substance is determined to be an anabolic steroid, DEA has no discretion regarding the placement of these substances into Schedule III of the CSA.

Impact of Classification as Anabolic Steroids

With the publication of this Final Rule, DEA classifies prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole) and methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one) as Schedule III anabolic steroids subject to the CSA. Any person who manufactures, distributes, dispenses, imports, or exports prostanozol or methasterone, or who engages in research or conducts instructional activities with respect to these two substances, will be required to obtain a Schedule III registration in accordance with the CSA and its implementing regulations.

As of the effective date of this Final Rule, the manufacture, import, export, distribution, or sale of prostanozol or methasterone, except by DEA registrants, is a violation of the CSA that may result in imprisonment and fines (see, *e.g.,* 21 U.S.C. 841 and 960). Possession of these two steroids, unless legally obtained, is also subject to criminal penalties pursuant to 21 U.S.C. 844.

Manufacturers and importers of these two substances will be required to register with DEA and will be permitted to distribute these substances only to other DEA registrants. Only persons registered as dispensers will be allowed to dispense these substances to end users. The CSA defines a practitioner as ''a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' 21 U.S.C. 802(21). At present, there are no approved medical uses for these two substances. Until a manufacturer applies to the FDA and gains approval for products containing these substances, no person may dispense them in response to a prescription.

Additionally, these two substances may only be imported for medical, scientific, or other legitimate uses (21 U.S.C. 952(b)) under an import declaration filed with DEA (21 CFR 1312.18). Importation of these substances will be illegal unless the person importing these substances is registered with DEA as an importer or researcher and files the required declaration for each shipment. Any individual who purchases either of these substances directly from foreign companies and has them shipped to the United States will be considered to be importing even if the steroids are intended for personal use. Illegal importation of these substances will be a violation of the CSA that may result in imprisonment and fines pursuant to 21 U.S.C. 960.

Requirements for Handling Substances Defined as Anabolic Steroids

As of the effective date of this Final Rule, prostanozol and methasterone are subject to CSA regulatory controls and the administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importation, and exportation of a Schedule III controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, or engages in research or conducts instructional activities with a substance defined as an anabolic steroid, or who desires to engage in such activities, will be required to be registered to conduct such activities with Schedule III controlled substances in accordance with 21 CFR Part 1301.

Security. Substances defined as anabolic steroids will be subject to Schedule III security requirements and will be required to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of substances defined as anabolic steroids will be required to comply with the requirements of 21 CFR 1302.03–1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of any substance defined as an anabolic steroid will be required to keep an inventory of all stocks of the substances on hand pursuant to 21 U.S.C. 827 and 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in Schedule III for any substance defined as an anabolic steroid will be required to conduct an inventory of all stocks of the substances on hand at the time of registration.

Records. All registrants will be required to keep records, as generally provided in 21 U.S.C. 827(a) and specifically pursuant to 21 CFR 1304.03, 1304.04, 1304.05, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for these Schedule III substances or for products containing these Schedule III substances, if approved in the future by FDA, will be required to be issued pursuant to 21 U.S.C. 829(b) and 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for these Schedule III compounds or for products containing these Schedule III substances, if authorized for refilling, will be limited to five refills within six months of the date of issuance of the prescription. Controlled substance dispensing via the Internet will have to comply with 21 U.S.C. 829(e).

Importation and Exportation. All importation and exportation of any substance defined as an anabolic steroid will be required to be in compliance with 21 U.S.C. 952(b), 953(e), and 21 CFR Part 1312.

Disposal. Persons who possess substances that become classified as anabolic steroids and who wish to dispose of them rather than becoming registered to handle them should contact their local DEA Diversion field office for assistance in disposing of these substances legally pursuant to 21 CFR 1307.21. The DEA Diversion field office will provide the person with instructions regarding the disposal. A list of local DEA Diversion field offices may be found at *http://www.deadiversion.usdoj.gov.*

Criminal Liability. Any activity with any substance defined as an anabolic

steroid not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act will be unlawful.

Regulatory Analyses

Regulatory Flexibility Act

The Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). This regulation will not have a significant economic impact on a substantial number of small entities. As of March 2010, DEA had identified approximately 75 dietary supplements that were currently or had been promoted for building muscle and increasing strength that purported to contain prostanozol or methasterone. Thirteen dietary supplements were purported to contain prostanozol and 62 dietary supplements were purported to contain methasterone. These dietary supplements are marketed and sold over the Internet.

The manufacturers and distributors of dietary supplements purported to contain prostanozol and methasterone also sell a variety of other dietary supplements. DEA has identified a substantial number of Internet distributors that sell these dietary supplements. However, these distributors also sell a variety of other nutritional products. Without information on the percentage of revenues derived from these dietary supplements, DEA is not able to determine the economic impact of the removal of these dietary supplements alone on the business of the firms. These steroids have been the focus of warning letters issued by the FDA. However, products continue to be marketed despite these warnings. DEA has not been able to identify any chemical manufacturers that are currently using these substances as intermediates in their manufacturing process(es). As of March 2010, DEA had identified 13 chemical manufacturers and distributors that sell at least one of the two steroids. Most of these companies are located in China and sell a variety of other anabolic steroids. DEA notes that, as the vast majority of entities handling these substances are Internet based, it is virtually impossible to accurately quantify the number of persons handling these substances at any given time. DEA has not identified any company based in the United States that manufactures or distributes these substances. DEA notes, upon placement into Schedule III, these substances may be used for analytical purposes. These companies are registered with DEA and are already in compliance with the CSA and DEA implementing regulations regarding the handling of Schedule III substances.

Executive Orders 12866 and 13563

This rulemaking has been drafted in accordance with the principles of Executive Order 12866, 1(b), as reaffirmed by Executive Order 13563. This rule is not a significant regulatory action but has been reviewed by the Office of Management and Budget. As discussed above, the effect of this rule will be to remove products containing these substances from the over-the-counter marketplace. DEA has no basis for estimating the size of the market for these products. DEA notes, however, that virtually all of the substances are imported. According to U.S. International Trade Commission data, the import value of all anabolic steroids in 2009 was $5.9 million. These two substances would be a subset of those imports. The total market for products containing these substances, therefore, is probably quite small. Moreover, DEA believes that the importation of these two substances is for illegitimate purposes.

The benefit of controlling these substances is to remove from the marketplace substances that have dangerous side effects and no legitimate medical use in treatment in the United States. As discussed in detail above, these substances can produce serious health effects in adolescents and adults. If medical uses for these substances are developed and approved, the drugs would be available as Schedule III controlled substances in response to a prescription issued by a medical professional for a legitimate medical purpose. Until that time, however, this action will bar the importation, exportation, and sale of these two substances except for legitimate research or industrial uses.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This rule will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

Paperwork Reduction Act

This rule regulates two anabolic steroids, which are neither approved for medical use in humans nor approved for administration to cattle or other non-humans. Only chemical manufacturers who may use these substances as chemical intermediates for the synthesis of other steroids would be required to register with DEA under the CSA. However, DEA has not been able to identify any chemical manufacturers that are currently using these substances as intermediates in their manufacturing processes. Thus DEA does not expect this rule to impose any additional paperwork burden on the regulated industry.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

List of Subjects in 21 CFR Part 1300

Chemicals, Drug traffic control.

For the reasons set out above, 21 CFR part 1300 is amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).

■ 2. In § 1300.01, the definition of *Anabolic steroid* under paragraph (b) is amended by:
■ A. Redesignating paragraphs (32) through (63) as (33) through (64),
■ B. Adding a new paragraph (32),
■ C. Further redesignating newly designated paragraphs (58) through (64) as (59) through (65), and
■ D. Adding new paragraph (58).

The additions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

Anabolic steroid * * *

(32) Methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one)

* * * * *

(58) Prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole)

* * * * *

Dated: July 13, 2012.

Michele M. Leonhart,

Administrator.

Note: The following appendix will not appear in the Code of Federal Regulations.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0478]

Drawbridge Operation Regulations; Gulf Intracoastal Waterway, Sarasota, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviations from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has issued temporary deviations from the regulations governing the operation of the following four bridges in Sarasota, Florida: The Venice Airport Bridge, mile 54.9, across the Gulf Intracoastal Waterway; the North Manasota Bridge, mile 49.9, across the Gulf Intracoastal Waterway; the Tom Adams Bridge, mile 43.5, across the Gulf Intracoastal Waterway; and the Venice Bridge, mile 56.6, across the Gulf Intracoastal Waterway. The deviations are necessary to allow for participants in the Rev3 Triathlon to traverse the aforementioned bridges without delay. These deviations will result in the bridges remaining in the closed position during the Rev3 Triathlon.

DATES: These deviations are effective from 8 a.m. through 1:30 p.m. on October 28, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2012–0478 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0478 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Michael Lieberum, Seventh District Bridge Branch, Coast Guard; telephone (305) 415–6744, email *Michael.B.Lieberum@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Rev3 Triathlon Director has requested temporary modifications to the operating schedules of the Venice Airport Bridge, the North Manasota Bridge, the Tom Adams Bridge, and the Venice Avenue Bridge in Sarasota, Florida. These deviations will result in the aforementioned bridges remaining in the closed position during the Rev3 Triathlon on October 28, 2012. The Rev3 Triathlon route passes over these four bridges. Any bridge opening during the Rev3 Triathlon would disrupt the race. The temporary deviations will be in effect from 8 a.m. through 1:30 p.m. on October 28, 2012.

The details and regular operating schedule for each bridge are set forth below.

1. *Venice Airport Bridge, mile 54.9.* The vertical clearance of the Venice Airport Bridge, across the Gulf Intracoastal Waterway, is 19 feet, above mean high water. The normal operating schedule for the Venice Airport Bridge is set forth in 33 CFR 117.5. 33 CFR 117.5 requires the bridge to open promptly and fully for the passage of vessels when a request or signal to open is given in accordance with this subpart. As a result of this temporary deviation, the Venice Airport Bridge will remain closed to navigation from 8 a.m. to 9:45 a.m. on October 28, 2012. Tugs and tugs with tows are not exempt from this deviation.

2. *North Manasota Bridge, mile 49.9.* The vertical clearance of the North Manasota Bridge, across the Gulf Intracoastal Waterway, is 26 feet, above mean high water. The normal operating schedule for the North Manasota Bridge is set forth in 33 CFR 117.5. 33 CFR 117.5 requires the bridge to open promptly and fully for the passage of vessels when a request or signal to open is given in accordance with this subpart. As a result of this temporary deviation, the North Manasota Bridge will remain closed to navigation from 8:30 a.m. to 10:50 a.m. on October 28, 2012. Tugs and tugs with tows are not exempt from this deviation.

3. *Tom Adams Bridge, mile 43.5.* The vertical clearance of the Tom Adams Bridge, across the Gulf Intracoastal Waterway, is 26 feet, above mean high water. The normal operating schedule for the Tom Adams Bridge is set forth in 33 CFR 117.5. 33 CFR 117.5 requires the bridge to open promptly and fully for the passage of vessels when a request or signal to open is given in accordance with this subpart. As a result of this temporary deviation, the Tom Adams Bridge will remain closed to navigation from 8:50 a.m. to 10:50 a.m. on October 28, 2012. Tugs and tugs with tows are not exempt from this deviation.

4. *Venice Avenue Bridge, mile 56.6.* The vertical clearance of the Venice Avenue Bridge, across the Gulf Intracoastal Waterway, is 30 feet, above mean high water. The normal operating schedule for the Venice Avenue Bridge is set forth in 33 CFR 117.287 (a–2). 33 CFR 117.287 (a–2) requires the bridge to open on signal, except that from 7 a.m. to 4:30 p.m., Monday through Friday except Federal holidays, the draw need open only at 10 minutes after the hour, 30 minutes after the hour and 50 minutes after the hour and except between 4:35 p.m. and 5:35 p.m. when the draw need not open. As a result of this temporary deviation, the Venice Avenue Bridge will remain closed to navigation from 10:20 a.m. to 1:30 p.m. on October 28, 2012. Tugs and tugs with tows are not exempt from this deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the designated time period. These deviations from the operating regulations are authorized under 33 CFR 117.35.

Dated: July 16, 2012.

B.L. Dragon,

Bridge Program Director, Seventh Coast Guard District.

[FR Doc. 2012–18457 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0432]

RIN 1625–AA00

Safety Zone, Atlantic Intracoastal Waterway; Emerald Isle, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Atlantic Intracoastal Waterway at Emerald Isle, North Carolina. The safety zone is necessary to provide for the safety of mariners on navigable waters during maintenance of the NC 58 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 226, at Emerald Isle, North Carolina. The safety zone will temporarily restrict vessel movement within the designated area.

DATES: This rule is effective from September 12, 2012 until December 12, 2012 and will be enforced from 8 a.m. on September 12, 2012 until 8 p.m. on December 12, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0432]. 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 CWO4 Joseph M. Edge, U.S. Coast Guard Sector North Carolina; telephone 252–247–4525, email *Joseph.M.Edge@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Regulatory History and Information

On June 15, 2012 a Notice of Proposed Rule Making (NRPM) was published in 77 FR 35903. We received no comments on the proposed rule. No public meeting was requested, and none was held.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C.1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1. which collectively authorize the Coast Guard to define regulatory safety zones.

North Carolina Department of Transportation has contracted Marine Contracting Corporation of Virginia Beach, Virginia to perform bridge maintenance on the NC 58 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 226, at Emerald Isle, North Carolina. The contract provides for replacement of the fender system to commence on September 12, 2012 with a completion date of December 12, 2012. The contractor will utilize a 140 foot deck barge with a 40 foot beam as a work platform and for equipment staging. This safety zone will provide a safety buffer for transiting vessels as bridge repairs present potential hazards to mariners and property due to reduction of horizontal clearance. During this period the Coast Guard will require a one-hour notification to the work supervisor at NC 58 Fixed Bridge, Atlantic Intracoastal Waterway crossing, mile 226, Emerald Isle, North Carolina. The notification requirement will be applicable during the maintenance period for vessels requiring a horizontal clearance of greater than 50 feet.

C. Discussion of Comments, Changes and the Final Rule

We received no comments on the proposed rule. No public meeting was requested, and none was held.

The temporary safety zone will encompass the waters directly under the NC 58 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 226, at Emerald Isle, North Carolina (34°40′28″ N, 077°03′56″ W). All vessels transiting this section of the waterway requiring a horizontal clearance of greater than 50 feet will be required to make a one-hour advanced notification to the work supervisor at the NC 58 Fixed Bridge while the safety zone is in effect. This zone will be in effect and enforced from 8 a.m. September 12, 2012 through 8 p.m. December 12, 2012.

D. Regulatory Analyses

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

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 does restrict traffic from transiting a portion of the Atlantic Intracoastal Waterway; it merely imposes a one-hour notification to ensure the waterway is clear of impediment to allow passage to vessels requiring a horizontal clearance of greater than 50 feet.

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 Coast Guard received no comments from the Small Business Administration on this rule. 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 would affect the following entities, some of which may be small entities: The owners or operators of commercial tug and barge companies, recreational and commercial fishing vessels intending to transit the specified portion of Atlantic Intracoastal Waterway from 8 a.m. September 12, 2012 through 8 p.m. December 12, 2012.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons. Although the safety zone will apply to this section of the Atlantic Intracoastal Waterway, vessel traffic will be able to request passage by providing a one-hour advanced notification. Before the effective period, the Coast Guard will issue maritime advisories widely available to the users of the waterway.

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 INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a temporary safety zone. 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; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–0432 to read as follows:

§ 165.T05–0432 Safety Zone; Atlantic Intracoastal Waterway, Emerald Isle, NC.

(a) *Regulated Area.* The following area is a safety zone: This zone includes the waters directly under and 100 yards either side of the NC 58 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 226, at Emerald Isle, North Carolina (latitude 34°40′28″ N, longitude 077°03′56″ W).

(b) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05–0432. In addition the following regulations apply:

(1) All vessels requiring greater than 50 feet horizontal clearance are prohibited from entering this zone, except as authorized by the Coast Guard Captain of the Port North Carolina. All other vessels are required to transit the zone at no wake speeds.

(2) All vessels requiring greater than 50 feet horizontal clearance to safely transit through the NC 58 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 226, at Emerald Isle, North Carolina must contact the work supervisor on VHF–FM marine band radio channels 13 and 16 one hour in advance of intended transit.

(3) All Coast Guard assets enforcing this safety zone can be contacted on VHF–FM marine band radio channels 13 and 16.

(4) The operator of any vessel within or in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign; and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(c) *Definitions.* (1) Captain of the Port North Carolina means the Commander, Coast Guard Sector North Carolina or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port North Carolina to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This section will be enforced from 8 a.m. September 12, 2012 through 8 p.m. December 12,

2012 unless cancelled earlier by the Captain of the Port.

Dated: July 19, 2012.

A. Popiel,

Captain, U.S. Coast Guard Captain of the Port U.S. Coast Guard Sector North Carolina.

[FR Doc. 2012–18562 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0431]

RIN 1625–AA00

Safety Zone, Atlantic Intracoastal Waterway; Oak Island, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Atlantic Intracoastal Waterway at Oak Island, North Carolina. The safety zone is necessary to provide for the safety of mariners on navigable waters during maintenance of the NC 133 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 311.8, at Oak Island, North Carolina. The safety zone will temporarily restrict vessel movement.

DATES: This rule is effective from September 12, 2012 until December 12, 2012 and will be enforced from 8 a.m. on September 12, 2012 until 8 p.m. on December 12, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0431]. 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 CWO4 Joseph M. Edge, U.S. Coast Guard Sector North Carolina; telephone 252–247–4525, email *Joseph.M.Edge@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Regulatory History and Information

On June 15, 2012 a Notice of Proposed Rule Making (NPRM) was published in 77 FR 35906. We received no comments on the proposed rule. No public meeting was requested, and none was held.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; PubLIC LAW 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1. which collectively authorize the Coast Guard to define regulatory safety zones.

North Carolina Department of Transportation has awarded a contract to Marine Contracting Corporation of Virginia Beach, Virginia to perform bridge maintenance on the NC 133 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 311.8, at Oak Island, North Carolina. The contract provides for replacing the fender system to commence on September 12, 2012 with a completion date of December 12, 2012. The contractor will utilize a 140 foot deck barge with a 40 foot beam as a work platform and for equipment staging. The safety zone will provide a safety buffer to transiting vessels as bridge repairs present potential hazards to mariners and property due to reduction of horizontal clearance. During this period the Coast Guard will require a one hour notification to the work supervisor at the NC 133 Fixed Bridge at the Atlantic Intracoastal Waterway crossing, mile 311.8, Oak Island, North Carolina. The notification requirement will be applicable during the maintenance period for vessels requiring a horizontal clearance of greater than 50 feet.

C. Discussion of Comments, Changes and the Final Rule

We received no comments on the proposed rule. No public meeting was requested, and none was held.

The temporary safety zone will encompass the waters directly under the NC 133 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 311.8, at Oak Island, North Carolina (33°55′18″ N/078°04′22″ W). All vessels transiting this section of the waterway requiring a horizontal clearance of greater than 50 feet will be required to make a one hour advanced notification to the work supervisor at the NC 133 Fixed Bridge while the safety zone is in effect. This zone will be in effect and enforced from 8 a.m. September 12, 2012 through 8 p.m. December 12, 2012.

D. Regulatory Analyses

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

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 does restrict traffic from transiting a portion of the Atlantic Intracoastal Waterway; it imposes a one hour notification to ensure the waterway is clear of impediment to allow passage to vessels requiring a horizontal clearance of greater than 50 feet.

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 Coast Guard received no comments from the Small Business Administration on this rule. 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 would affect the following entities, some of which may be small entities: The owners or operators of commercial tug and barge companies, recreational and commercial fishing vessels intending to transit the specified portion of Atlantic Intracoastal Waterway from 8 a.m. September 12, 2012 through 8 p.m. December 12, 2012.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons. Although the safety zone will apply to this section of the Atlantic Intracoastal Waterway, vessel traffic will be able to request passage by providing a one hour advanced notification. Before the

effective period, the Coast Guard will issue maritime advisories widely available to the users of the waterway.

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 INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a temporary safety zone. 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; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–0431 to read as follows:

§ 165.T05–0431 Safety Zone; Atlantic Intracoastal Waterway, Oak Island, NC.

(a) *Regulated Area.* The following area is a safety zone: This zone includes the waters directly under and 100 yards either side of the NC 133 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 311.8, at Oak Island, North Carolina (33°55′18″ N/078°04′22″ W).

(b) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05–0431. In addition the following regulations apply:

(1) All vessels requiring greater than 50 feet horizontal clearance are prohibited from entering this zone, except as authorized by the Coast Guard Captain of the Port North Carolina. All other vessels are required to transit the zone at no wake speeds.

(2) All vessels requiring greater than 50 feet horizontal clearance to safely

transit through the NC 133 Fixed Bridge crossing the Atlantic Intracoastal Waterway, mile 311.8, at Oak Island, North Carolina must contact the work supervisor on VHF–FM marine band radio channels 13 and 16 one hour in advance of intended transit.

(3) All Coast Guard assets enforcing this safety zone can be contacted on VHF–FM marine band radio channels 13 and 16.

(4) The operator of any vessel within or in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign, and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(c) *Definitions.* (1) *Captain of the Port North Carolina* means the Commander, Coast Guard Sector North Carolina or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port North Carolina to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This section will be enforced from 8 a.m. September 12, 2012 through 8 p.m. December 12, 2012 unless cancelled earlier by the Captain of the Port.

Dated: July 19, 2012.

A. Popiel,

Captain, U.S. Coast Guard, Captain of the Port Sector North Carolina.

[FR Doc. 2012–18563 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0624]

RIN 1625–AA00

Safety Zone; Fireworks for NC NENA/APCO Conference, Cape Fear River; Wilmington, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the navigable waters of Cape Fear River; Wilmington, NC in support of the Fireworks display for the NC NENA/APCO Conference. This action is necessary to protect the life and property of the maritime public and spectators from the hazards posed by aerial fireworks displays. Entry into or movement within this safety zone during the enforcement period is prohibited without approval of the Captain of the Port.

DATES: This rule is effective on August 28, 2012 and enforced from 8 p.m. to 11 p.m. on August 28, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0624]. 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 BOSN4 Joseph M. Edge, Coast Guard Sector North Carolina, Coast Guard; telephone 252–247–4525, email *Joseph.M.Edge@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

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 the final details for this event were not provided to the Coast Guard until June 25, 2012. As such, it is impracticable to provide a full comment period due to lack of time. Delaying the effective date for comment would be contrary to the public interest, since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The Coast Guard will provide advance notifications to users of the effected waterways of the safety zone via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds, for the reasons noted above, 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 rule is 33 U.S.C.1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1. which collectively authorize the Coast Guard to define regulatory safety zones.

On August 28, 2012, NC NENA/APCO Conference will sponsor a land-based fireworks display on the western shore of the Cape Fear River at Battleship Park. The fireworks debris fallout area will extend over the navigable waters of Cape Fear River. Due to the need to protect mariners and spectators from the hazards associated with the fireworks display, including accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris, vessel traffic will be temporarily restricted from transiting within fireworks launch and fallout area.

C. Discussion of the Final Rule

The Coast Guard is establishing a safety zone on the navigable waters of Cape Fear River within an area bound by a line drawn from the following points: Latitude 34°13′54″ N, longitude 077°57′06″ W; thence northeast to latitude 34°13′57″ N, longitude 077°57′05″ W; thence north to latitude 34°14′11″ N, longitude 077°57′07″ W; thence northwest to latitude 34°14′22″ N, longitude 077°57′19″ W; thence west to latitude 34°14′22″ N, longitude 077°57′06″ W; thence southeast to latitude 34°14′07″ N, longitude 077°57′00″ W; thence south to latitude 34°13′54″ N, longitude 077°56′58″ W; thence to the point of origin, located

approximately 500 yards north of Cape Fear Memorial Bridge. This safety zone will be established and enforced in the vicinity of Wilmington, NC from 8 p.m. to 11 p.m. on August 28, 2012. In the interest of public safety, general navigation within the safety zone will be restricted during the specified date and times. Except for participants and vessels authorized by the Coast Guard Captain of the Port or his representative, no person or vessel may enter or remain in the regulated area.

D. Regulatory Analyses

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

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. Although this regulation restricts access to a small segment of the Cape Fear River, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

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 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 specified portion of Cape Fear River from 8 p.m. to 11 p.m. on August 28, 2012. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) This rule will be enforced for only three hours on August 28, 2012; (2) Vessel traffic will be able to navigate safely around the safety zone without significant impact to their transit plans; and (3) Before the effective period begins, we will issue maritime advisories.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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 INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in

complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a safety zone for a fireworks display launch site and fallout area and is expected to have no impact on the water or environment. This zone is designed to protect mariners and spectators from the hazards associated with aerial fireworks displays. 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, and Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add temporary § 165.T05–0624 to read as follows:

§ 165.T05–0624 Safety Zone: Fireworks For NC NENA/APCO Conference, Cape Fear River, Wilmington, NC.

(a) *Definitions.* For the purposes of this section, Captain of the Port means the Commander, Sector North Carolina. *Representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: specified waters of the Captain of the Port, Sector North Carolina, as defined in 33 CFR 3.25–20, on the navigable waters of Cape Fear River within an area bound by a line drawn from the following points: Latitude 34°13′54″ N, longitude 077°57′06″ W; thence northeast to latitude 34°13′57″ N, longitude 077°57′05″ W; thence north to latitude 34°14′11″ N, longitude 077°57′07″ W; thence northwest to latitude 34°14′22″ N, longitude 077°57′19″ W; thence west to latitude 34°14′22″ N, longitude 077°57′06″ W; thence southeast to latitude 34°14′07″ N, longitude 077°57′00″ W; thence south to latitude 34°13′54″ N, longitude 077°56′58″ W; thence to the point of origin, located approximately 500 yards north of Cape Fear Memorial Bridge.

(c) *Regulations.* (1) The general regulations contained in § 165.23 of this part apply to the area described in paragraph (b) of this section.

(2) Persons or vessels requiring entry into or passage through any portion of the safety zone must first request authorization from the Captain of the Port, or a designated representative, unless the Captain of the Port previously announced via Marine Safety Radio Broadcast on VHF Marine Band Radio channel 22 (157.1 MHz) that this regulation will not be enforced in that portion of the safety zone. The Captain of the Port can be contacted at telephone number (910) 343–3882 or by radio on VHF Marine Band Radio, channels 13 and 16.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(e) Enforcement period. This section will be enforced on August 28, 2012 from 8 p.m. to 11 p.m. unless cancelled earlier by the Captain of the Port.

Dated: July 19, 2012.

A. Popiel,

Captain, U.S. Coast Guard, Captain of the Port, Sector North Carolina.

[FR Doc. 2012–18572 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0699]

RIN 1625–AA00

Safety Zone; Seafair Blue Angels Air Show Performance, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the waters of Lake Washington, Seattle, WA. This action is necessary to safeguard participants and spectators from the safety hazards associated with the Seafair Blue Angels Air Show Performance which include low flying high speed aircraft and will do so by prohibiting entry into the safety zone is unless authorized by the Captain of the Port, Puget Sound or his Designated Representative.

DATES: This rule is effective from 9:00 a.m. on August 2, 2012 through 4:00 p.m. on August 5, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2012–0699. 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 Ensign Nathaniel P. Clinger, Coast Guard Sector Puget Sound Waterways Management Division, telephone 206–217–6045, email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

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 establishing this rule because the current regulation associated with the Seafair Blue Angels Air Show performance (33 CFR 165.1319) is not large enough to safeguard participants and spectators from the safety hazards of this air performance.

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 since the event would be over before notice could be given and comments taken. Notice and comment would also be contrary to the public interest because the public expects to be provided a safe area to observe the Seafair Blue Angels air show. Absent this temporary final rule, the zone provided in 33 CFR 165.1319 will be too small to encompass the anticipated safe flight pattern of the demonstrating aircraft, and would expose spectators to hazards associated with low-flying aircraft over water.

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**, because to do so would be contrary to the public interest since the event would be over before notice could be given and comments taken, and it is immediately necessary to protect the event's spectators from the hazards associated with the Seafair Blue Angels Air Show Performance.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C.1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1. which collectively authorize the Coast Guard to define regulatory safety zones.

The Coast Guard is establishing this safety zone to ensure the safety of the maritime public during the Seattle Blue Angels Air Show. The safety zone in 33 CFR 165.1319 has been determined to be too small to accommodate the anticipated flight pattern of the Blue Angels. This temporary final rule extends the northern boundary line of the existing regulation northward by 500 yards. The remainder of the safety zone contained at 33 CFR 165.1319 remains unchanged.

C. Discussion of the Final Rule

As described in 69 FR 35249, the Coast Guard established a final rule for the Blue Angels Air Show Performance. This rule was meant to protect the public from dangers including excessive noise and falling objects from any potential accidents caused by these low-flying military aircraft. The regulation contained in 33 CFR 165.1319 encompasses ''[a]ll waters of Lake Washington, Washington State, enclosed by the following points: Near the termination of Roanoke Way 47°35′44″ N, 122°14′47″ W; thence to 47°35′48″ N, 122°15′45″ W; thence to 47°36′02.1″ N, 122°15′50.2″ W; thence to 47°35′56.6″ N, 122°16′29.2″ W; thence to 47°35′42″ N, 122°16′24″ W; thence to the east side of the entrance to the west highrise of the Interstate 90 bridge; thence westerly along the south side of the bridge to the shoreline on the western terminus of the bridge; thence southerly along the shoreline to Andrews Bay at 47°33′06″ N, 122°15′32″ W; thence northeast along the shoreline of Bailey Peninsula to its northeast point at 47°33′44″ N, 122°15′04″ W; thence easterly along the east-west line drawn tangent to Bailey Peninsula; thence northerly along the shore of Mercer Island to the point of origin. [Datum: NAD 1983]''

However, the aircraft in question have a flight pattern that will extend past the northern boundary of the regulation in 33 CFR 165.1319. As such, an extension is necessary in order to protect the spectating public.

This rule encompasses the northern portion of the Seafair Blue Angels Air Show Performance Safety Zone, starting at point 47°36′17.28″ N, 122°16′58.56″ W, thence east to point 47°36′17.28″ N, 122°14′49.44″ W, thence south to point 47°35′45.3″ N, 122°14′49.44″ W, thence south west along the shore line to the I–90 bridge at point, 47°35′23.16″ N, 122°15′17.1″ W, thence west along the I–90 bridge to point, 47°35′25.44″ N, 122°17′9.48″ W, and north along the shoreline back to the point of origin. This rule is effective from 9:00 a.m. on August 2, 2012 through 4:00 p.m. on August 5, 2012.

During the periods the safety zone is in effect no person or vessel may enter into, transit, or remain in the safety zone without the permission of the Captain of the Port or his Designated Representative.

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 expectation is based on the fact that the regulated area established by the regulation is not frequented by commercial navigation, and it is small in size, and short in duration.

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 this portion of Lake Washington during the time this regulation is in effect. The zone will not have a significant economic impact because it is limited in size and short in duration. The only vessels likely to be impacted will be recreational boaters and small passenger vessel operators.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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 INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone. 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; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–226 to read as follows:

§ 165.T13–226 Safety Zone; Seafair Blue Angels Air Show Performance, Seattle, WA.

(a) *Location.* The following area is designated as a safety zone: Lake Washington, Seattle, WA. All waters of Lake Washington encompassed by the following points: 47°36′17.28″ N, 122°16′58.56″ W, thence east to point 47°36′17.28″ N, 122°14′49.44″ W, thence south to point 47°35′45.3″ N, 122°14′49.44″ W, thence south west along the shore line to the I–90 bridge at point, 47°35′23.16″ N, 122°15′17.1″ W, thence west along the I–90 bridge to point, 47°35′25.44″ N, 122°17′9.48″ W, and north along the shoreline back to the point of origin.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, no person or vessel may enter or remain in the safety zone created by this section without the permission of the Captain of the Port (COTP) or his Designated Representative. Designated Representatives are Coast Guard Personnel authorized by the Captain of the Port to grant persons or vessels permission to enter or remain in the safety zone created by this section. See 33 CFR part 165, subpart C, for additional information and requirements. The COTP may be assisted by other federal, state or local agencies with the enforcement of this safety zone.

(c) *Effective Period.* This rule is effective from 9:00 a.m. on August 2, 2012 through 4:00 p.m. on August 5, 2012.

Dated: July 19, 2012.

S.J. Ferguson,

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

[FR Doc. 2012–18450 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0641]

RIN 1625–AA00

Safety Zone; Port Valdez, Alaska Maritime Highway System Ferry Terminal

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone encompassing the navigable waters within a 200-yard radius of the Alaska Marine Highway System (AMHS) Terminal in Port Valdez when an AMHS Ferry is arriving or departing when there is an ongoing fishing opener that includes the navigable waters within a 200-yard radius of the AMHS Ferry Terminal. This safety zone is necessary to provide for the safety of passenger vessels and fishing vessels in the area during periods of increased vessel traffic. The purpose of the safety zone is to restrict non-ferry vessel traffic from entering a 200-yard radius of the AMHS Ferry Terminal while the ferry is within 200-yards of the pier. Persons desiring to transit within these safety zones must contact the Captain of the Port, Prince William Sound, Alaska or the designated on scene representative on VHF channel 13 (156.650 MHz) to receive permission.

DATES: This temporary final rule will remain in effect from July 8, 2012, until August 1, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket (COTP Prince William Sound USCG–2012–0641) and are available for inspection or copying at USCG Marine Safety Unit Valdez Office, Valdez, AK between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Danielle Wiley, Chief, Waterways Management, USCG Marine Safety Unit Valdez, at (907) 835–7223, email *danielle.f.wiley@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory 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 fishing openers in Prince William Sound, which includes the Port of Valdez, are announced the evening before the opener by the Alaska Department of Fish and Game, which does not afford time for public feedback on a safety zone that will be in effect only when that opener includes the area of Port Valdez that includes the AMHS Terminal.

In the past, during the month of July, the Alaska Department of Fish and Game has announced fishing openers in the Port of Valdez with less than less than 24 hours advance notice. Furthermore, there have been instances when ferries arriving/departing the AMHS Ferry Terminal have encountered fishing vessels holding station and setting nets in positions that created safety hazards for the passenger vessels that were trying to safely maneuver to and from the pier. Any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest, since immediate action is needed to provide for the safety of life and property on navigable waters during these fishing openers.

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

Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1. which collectively authorize the Coast Guard to define regulatory safety zones.

The safety zone is necessary to protect all vessels operating in the vicinity of the AMHS Ferry Terminal. The safety zone will terminate whenever a departing ferry vessel is more than 200 yards from the AMHS Ferry Terminal. The safety zone will also terminate whenever an arriving ferry vessel moors to the pier. The impact of this rule on commercial and recreational traffic is expected to be minimal because of the limited area and duration of the safety zone.

Discussion of Rule

The Coast Guard is establishing a temporary 200-yard safety zone around the AMHS Ferry Terminal at position 61°07′26″ N and 146°21′50″ W in the navigable waters of Port Valdez. The zone will only be in effect when a ferry vessel is within 200 yards of the AMHS Ferry Terminal, between July 3, 2012, and August 1, 2012, and when there is an Alaska Department of Fish and Game fish opener that includes the 200-yard radius surrounding the AMHS pier. The limited size and duration of the zone is designed to minimize the impact on other vessels transiting the waters of Port Valdez.

Regulatory Analyses

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

Regulatory Planning and Review

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12886, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). This finding is based on the limited size and duration of the safety zone which will have minimal, if any, impact on vessels transiting the waters of Prince William Sound and Port Valdez.

Small Entities

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

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

The ruling will affect the following entities, some of which may be small entities: Recreational, ferry, and fishing vessels for very short periods of time and improve the safe operations for all parties involved by reducing risk to life and property. This rule will only be enforced during an AMHS ferry's arrival or departure from the AMHS Ferry Terminal from July 3, 2012, until August 1, 2012, and from the time a fish opener begins until it expires. Vessel traffic can pass safely around the zone. Before the effective period, we will issue maritime advisories widely available to users of Port Valdez via VHF CH 13. Broadcast Notice to

Mariners will also be made on CH 16. All indications are that there will be minimal impact to small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

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.

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.

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.

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.

Energy Effects

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

Technical Standards

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

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

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 concluded 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 is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction. Under figure 2–1, paragraph (34)(g), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' have been completed and 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; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T17–0641 to read as follows:

§ 165.T17–0641 Safety Zone; Port Valdez, Alaska Marine Highway System Ferry Terminal.

(a) *Location.* The following area is a safety zone: The navigable waters within a 200-yard radius of the Alaska Marine Highway System Ferry Terminal in the Port of Valdez.

(b) *Effective period.* The safety zone in this section will be enforced from July 8, 2012, through August 1, 2012, when there is an Alaska Marine Highway System Ferry within the safety zone and there is a fishing opener that includes the navigable waters within the safety zone during these dates.

(c) *Regulations.* For the purpose of this section, the general regulations contained in 33 CFR 165.23 apply to all but the following vessels in the areas described in paragraph (a), (b), or (c):

(1) Alaska Marine Highway System Ferries.

(2) Vessels that obtain permission through the Duty Officer at Marine Safety Unit Valdez, who can be contacted at (907) 831–0236.

(3) Vessels that obtain permission from the Captain of the Port, who may authorize and designate any Coast Guard commissioned, warrant, or petty officer to act on his behalf in enforcing the safety zone.

Dated: July 8, 2012.

B.J. Hawkins,

Commander, U.S. Coast Guard, Captain of the Port, Prince William Sound.

[FR Doc. 2012–18453 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–1126]

RIN 1625–AA87

Security Zones; Seattle's Seafair Fleet Week Moving Vessels, Puget Sound, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce Seattle's Seafair Fleet Week Moving Vessels Security Zones from 12:00 p.m. on July 31, 2012 through 5:00 p.m. on August 6, 2012. These security zones are necessary to help ensure the security of the vessels from sabotage or other subversive acts during Seafair Fleet Week Parade of Ships. The Designated participating vessels are: the HMCS NANAIMO (NCSM 702), the HMCS EDMONTON (NCSM 703), the HMCS ORIOLE, and the USCGC STRATTON (WMSL 752). During the enforcement period, no person or vessel may enter or remain in the security zones without the permission of the COTP or a Designated Representative. The COTP has granted general permission for vessels to enter the outer 400 yards of the security zones as long as those vessels within the outer 400 yards of the security zones operate at the minimum speed necessary to maintain course unless required to maintain speed by the navigation rules.

DATES: This rule will be enforced from 12:00 p.m. on July 31, 2012 thru 5:00 p.m. on August 6, 2012 unless canceled sooner by the Captain of the Port.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–1126 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1126 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Lieutenant Junior Grade Anthony P. LaBoy, Sector Puget Sound, Waterways Management Division, U.S. Coast Guard; telephone 206–217–6323, email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the security zones for Seattle's Seafair Fleet Week Moving Vessels within the Captain of the Port, Puget Sound Area of Responsibility in 33 CFR 165.1333 from 12:00 p.m. on July 31, 2012 through 5:00 p.m. on August 6, 2012.

Under the provisions of 33 CFR 165.1333, the following areas are security zones: All navigable waters within 500 yards of the HMCS NANAIMO (NCSM 702), HMCS EDMONTON (NCSM 703), HMCS ORIOLE, and the USCGC STRATTON (WMSL 752) while each vessel is in the Sector Puget Sound COTP Zone. No person or vessel may enter or remain in the security zones described in paragraph (a) of this section without the permission of the COTP or his Designated Representative.

The COTP has granted general permission for vessels to enter the outer 400 yards of the security zones as long as those vessels within the outer 400 yards of the security zones operate at the minimum speed necessary to maintain course unless required to maintain speed by the navigation rules. The COTP may be assisted by other federal, state or local agencies with the enforcement of the security zones.

All vessel operators who desire to enter the inner 100 yards of the security zones or transit the outer 400 yards at greater than minimum speed necessary to maintain course must obtain permission from the COTP or his Designated Representative by contacting the on-scene Coast Guard patrol craft on VHF 13 or Channel 16. Requests must include the reason why movement within this area is necessary. Vessel operators granted permission to enter the security zones will be escorted by the on-scene Coast Guard patrol craft until they are outside of the security zones.

This notice is issued under authority of 33 CFR 165.1333 and 5 U.S.C. 552(a). In addition to this notice, the Coast Guard will provide the maritime community with extensive advanced notification of the security zones via the Local Notice to Mariners and marine information broadcasts on the day of the event.

Dated: July 17, 2012.

S.J. Ferguson,

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

[FR Doc. 2012–18570 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[CFDA Number: 84.282P]

Final Definitions, Requirements, and Selection Criteria; Charter Schools Program (CSP)—Charter School Exemplary Collaboration Awards

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Final definitions, requirements, and selection criteria.

SUMMARY: The Assistant Deputy Secretary for Innovation and Improvement announces final definitions, requirements, and selection criteria under the Charter Schools Program—Charter School Exemplary Collaboration Awards (Collaboration Awards). The Assistant Deputy Secretary may use one or more of these definitions, requirements, and selection criteria for competitions in fiscal year (FY) 2012 and later years. We take this action to create incentives for high-quality charter schools to collaborate with non-chartered public schools and non-chartered local educational agencies (LEAs) to share and transfer best educational and operational practices at the elementary and secondary school levels; and disseminate information about these collaborations nationwide.

DATES: *Effective Date:* These final definitions, requirements, and selection criteria are effective August 29, 2012.

FOR FURTHER INFORMATION CONTACT: Nancy Paulu, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W246, Washington, DC 20202–5970; or Erin Pfeltz, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W255, Washington, DC 20202–5970. Emails and telephone numbers: *nancy.paulu@ed.gov* or (202) 205–5392; *erin.pfeltz@ed.gov* or (202) 205–3525.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program

The purpose of the Charter Schools Program (CSP) is to increase national understanding of the charter schools model by—

(1) Providing financial assistance for the planning, program design, and initial implementation of charter schools;

(2) Evaluating the effects of charter schools, including the effects on students, student academic achievement, staff, and parents;

(3) Expanding the number of high-quality charter schools available to students across the Nation; and

(4) Encouraging the States to provide support to charter schools for facilities financing in an amount that is more commensurate with the amount the States have typically provided for traditional public schools.

The purpose of the Collaboration Awards competition (CFDA 84.282P) is to encourage high-quality charter schools (as defined in this notice) to partner with non-chartered public schools (as defined in this notice) and non-chartered LEAs (as defined in this notice) to share and transfer best educational and operational practices, and to disseminate information about such practices. By promoting strong partnerships and supporting the dissemination of information about the activities carried out through the partnerships, these Collaboration Awards should facilitate the exchange of best practices between public charter schools, non-chartered public schools, and non-chartered LEAs; and help the United States Department of Education (Department) identify and publicize successful collaborations. The Collaboration Awards competition is designed to encourage public charter schools, non-chartered public schools, and non-chartered LEAs to share resources and responsibilities; build trust and teamwork; boost academic excellence; and provide students and their parents with a range of effective educational options. The Department, through the Collaboration Awards competition, aims to increase national understanding of the charter schools model.

Program Authority

The CSP is authorized under 20 U.S.C. 7221–7221i; CSP national activities are authorized under 20 U.S.C. 7221d.

The Department published a notice of proposed definitions, requirements, and selection criteria (NPP) for the Collaboration Awards in the **Federal Register** on April 25, 2012 (77 FR 24690). The NPP contained background information and our reasons for proposing the particular definitions, requirements, and selection criteria.

There are differences between the definitions, requirements, and selection criteria proposed in the NPP and these final definitions, requirements, and selection criteria, as discussed in the *Analysis of Comments and Changes* section elsewhere in this notice. The most significant changes are as follows: (1) Clarifying that only high-quality charter schools are eligible to apply for Collaboration Awards; (2) adding a definition for ''high-quality charter school''; (3) creating an additional selection criterion, ''Quality of the lead applicant,'' which allows consideration of the extent to which an applicant is a high-quality charter school; (4) changing the title of the first selection criterion from ''Record of and potential for success'' to ''Record of and potential for success of collaboration''; (5) altering the title of the Collaboration Awards competition from ''Exemplary Charter School Collaboration Awards'' to ''Charter School Exemplary Collaboration Awards'' in order to emphasize that the collaboration itself must be exemplary; and (6) adding ''school climate'' and access to charter schools for students with disabilities to the list of potential areas suitable for a collaboration.

Public Comment: In response to our invitation in the NPP, eight parties submitted comments on the proposed definitions, requirements, and selection criteria.

Generally, we do not address technical and other minor changes. In addition, we do not address general comments that raise concerns not directly related to the definitions, requirements, or selection criteria.

Analysis of Comments and Changes: An analysis of the comments and any changes in the definitions, requirements, and selection criteria since publication of the NPP follows.

Priorities

Comment: One commenter suggested that we create a new priority, not included in the NPP, to encourage collaboration between public charter schools and non-chartered public schools that aims to improve access to charter schools for students with disabilities. The commenter stated that disseminating information about successful collaborations related to improving access to charter schools for students with disabilities would also make a positive contribution to the field of special education.

Discussion: We agree that improving access to charter schools for students with disabilities is important, and an area in which charter schools frequently look for best practices and models. Because this is the first year of the competition, however, we believe that it is best to encourage applications from a broad range of charter schools and to avoid requirements or priorities that might discourage potential applicants from applying. This does not preclude the possibility of a priority related to improving access to charter schools for students with disabilities being included in future years.

Change: We decline to create a priority to encourage collaboration between public charter schools and non-chartered public schools that aims to improve access to charter schools for students with disabilities. The Final Application Requirements section of this notice, however, lists examples of areas that might be appropriate for collaboration. This list includes access to charter schools by students with disabilities as an area suitable for collaboration. We have removed ''students with other special needs'' from the list in the Final Application Requirements section of areas that might be appropriate for collaboration because it duplicates other areas listed: ''Special education services and access to charter schools by students with disabilities'' and ''English learners.''

Definitions

Comment: One commenter suggested that the proposed definition of ''collaboration'' align more closely with the intent of the Collaboration Awards as described in the NPP's Summary and Purpose of Program sections. The commenter recommended an expanded and more detailed definition of ''collaboration'' that incorporates much of the language used in the Summary and Purpose of Program sections.

Discussion: We decline to revise the definition of ''collaboration'' because a more detailed definition could be unnecessarily restrictive and could limit how applicants think about collaboration. The final definition reads, ''Collaboration refers to the activities of a partnership in which two or more organizations or entities work together to accomplish a common goal, which may involve sharing or transferring of best practices or strategies.'' We consider this definition appropriate because it provides applicants the flexibility to be creative in continuing, modifying, or expanding their collaborations.

Change: None.

Comment: Two commenters recommended that we define ''exemplary'' in order to clarify the expectations and standards for applicants and to help them determine whether their schools are qualified to apply for an award.

Discussion: The Collaboration Awards competition is designed to identify exemplary partnerships between high-quality public charter schools and non-chartered public schools and non-chartered LEAs, as well as to support the dissemination of information about the activities carried out through the partnerships. To clarify the requirements for both the applicant and the collaboration, we are making several revisions to the final requirements, definitions, and selection criteria.

Changes: (1) We have changed the competition's title from ''Exemplary Charter School Collaboration Awards'' to ''Charter School Exemplary Collaboration Awards'' to emphasize that the collaboration itself must be exemplary. (2) We have revised paragraph (a)(1) of the Final Program Requirements section of this notice to clarify that eligible applicants must be high-quality charter schools. (3) We have included a definition of ''high-quality charter school'' in this notice. Our definition is similar to the definition of ''high-quality charter school'' provided in the notice of final priorities for the replication and expansion of high-quality charter schools (CFDA No.84.282M), published in the **Federal Register** on July 12, 2011 (76 FR 40901). (4) We have changed the title of the first selection criterion from ''Record of and potential for success'' to ''Record of and potential for success of collaboration.'' (5) We have added a selection criterion, ''Quality of the lead applicant.'' This criterion will allow reviewers to provide points to applicants based on the extent to which the lead applicant is a high-quality charter school.

Eligibility Requirements

Comment: Three commenters recommended that high-performing magnet schools be allowed to apply for Collaboration Awards. They cited what they believe is a wealth of outstanding and innovative programs in magnet schools that are worth sharing with others. All three commenters noted that some of the Nation's highest-quality schools today are magnet schools that began as low-performing schools with students from low-income families admitted by lottery.

Discussion: We agree that there are numerous high-performing magnet schools that are worthy of participating in a collaborative initiative. Because the Collaboration Awards are authorized under the CSP, however, only charter schools are the lead applicants. In order to qualify for a Collaboration Award, a charter school must enter into a partnership with a non-chartered public school (as defined in this notice) or a non-chartered LEA (as defined in this notice). Magnet schools are non-chartered public schools and, as such, would be eligible to participate in this competition as partners with high-quality charter schools.

Change: None.

Comment: None.

Discussion: The NPP stated in the Proposed Eligibility Requirements section that ''an applicant may submit more than one application if each application proposes to carry out substantially different authorized activities.'' We are removing this language from the Final Eligibility Requirements because applicants do not need specific authorization to submit more than one application for a Collaboration Award. Applicants should be aware, however, that it is highly unlikely that more than one application from the same applicant will be approved for funding because the Department anticipates making only a limited amount of funding available for Collaboration Awards and it is within the Secretary's discretion to fund applications out of rank order in order to achieve geographic diversity.

Change: We have removed the statement in the Eligibility section that ''An applicant may submit more than one application if each application proposes to carry out substantially different authorized activities.''

Application Requirements

Comment: One commenter suggested that we revise the Application Requirements section to include ''school climate'' on the list of areas that may be suitable for a collaboration. The commenter cited the recent movie ''Bully,'' which documented the effects of bullying, and stated that communities and schools want to learn from others about providing all students with a safe learning environment. The commenter also cited parts of the ESEA that support the importance of a safe and positive school climate for all students. Finally, the commenter cited research that links a positive school climate to many indicators of a school's success.

Discussion: We agree that a healthy school climate is an important factor in achieving positive educational outcomes. Bullying is one of many issues (drugs and gangs are examples of others) that can have a negative effect on the school environment.

Change: We have revised paragraph (a)(3) of the Final Application Requirements section of this notice to include school climate on the list of potential areas suitable for a collaboration.

Selection Criteria

Comment: One commenter recommended that we incorporate the following three indicators of operational quality into the first proposed selection criterion, ''Record of and potential for success of the collaboration'': (1) Financial performance and sustainability; (2) performance and stewardship; and (3) parent and community engagement. The commenter noted that these three indicators were developed and published by a well-respected consortium of charter school organizations as a tool to help the charter school community determine operational quality.

Discussion: We agree that indicators similar to those recommended by the commenter will help applicants demonstrate operational quality and improve the overall quality of applications received. Applicants can use these indicators to show more clearly the extent to which their proposed collaboration and dissemination plans will improve operational practices and productivity among all partners in the collaboration.

Change: We have incorporated three indicators similar to those suggested by the commenter in the first selection criterion, ''Record of and potential for success of the collaboration.'' The element in the NPP stated: ''Improved operational practices and productivity among all partners.'' The revised element (B)(i) of the first selection criterion now reads: ''Improved operational practices and productivity among all partners in such areas as financial performance and

sustainability, governing board performance and stewardship, and parent and community engagement.''

Comment: One commenter suggested that we expand the first proposed selection criterion, ''Record of and potential for success of the collaboration,'' to include four indicators of academic quality: (1) Student achievement level; (2) student progress over time; (3) postsecondary readiness and success; and (4) student engagement.

Discussion: Three of the four indicators that the commenter lists were included in the first selection criterion proposed in the NPP and are also included in the Final Selection Criteria. The first selection criterion contains an element, ''Improved student achievement,'' which peer reviewers will use to judge how the collaboration has improved student achievement in the past, as well as how it will improve student achievement in the future. The first selection criterion also addresses postsecondary readiness and success with elements such as improved high school graduation rates, improved rates of college matriculation and college graduation, and improved rates of attendance and graduation from other postsecondary (i.e., non-college) institutions or programs. However, the first selection criterion, as proposed, did not address student engagement. We agree with the commenter that it should do so and have expanded it accordingly.

Change: We have revised element (B)(iii) in the first selection criterion, ''Record of and potential for success of the collaboration,'' by adding two factors related to student engagement—attendance and retention. The revised element now reads, ''Improved student attendance and retention, and improved high school graduation rates.''

Comment: One commenter noted that the NPP states that the proposed selection criteria for this competition were designed to expand the number of high-quality charter schools, among other things. The commenter stated, however, that the competition's proposed selection criteria would not encourage applicants to address issues or undertake activities designed primarily to increase the number of high-quality charter schools. The commenter recommended adding a selection criterion aimed at encouraging applicants to develop a collaboration project that might increase the number of high-quality charter schools nationwide and improve services to students attending these schools. Specifically, the commenter recommended a new selection criterion that would reward collaborators for jointly: (1) Developing a process to ensure equitable funding for public charter schools and non-chartered public schools; (2) sharing data and information among schools; and (3) developing and implementing activities in schools, such as teacher professional development, building maintenance, and nutrition programs.

Discussion: The commenter is correct in that one purpose of these Collaboration Awards is to increase national understanding of the charter school model by expanding the number of high-quality charter schools available to students nationwide. We also agree that the commenter's proposed selection criterion (and its three elements) would promote this purpose. We believe, however, that the definitions, requirements, and selection criteria set forth in this notice will be more effective not only in increasing the number of high-quality charter schools available to students across the Nation, but also, in promoting the other purposes of the Collaboration Awards.

Change: Although we decline to add the new selection criterion proposed by the commenter, we have revised section (a)(1) of the Eligibility Requirements of this notice to allow public charter schools that do not qualify as high-quality charter schools (as defined in this notice) to be included as partners in the collaboration so long as (1) the lead applicant is a high-quality charter school; (2) the lead applicant is separate and distinct from other charter schools included as partners in the collaboration; and (3) at least one non-chartered public school (as defined in this notice) or non-chartered LEA (as defined in this notice) also is a part of the collaboration. We also have added a sentence to section (a)(2) of the Eligibility Requirements section of this notice to clarify that public charter schools that are not high-quality charter schools are ineligible to serve as the lead applicant or fiscal agent; and revised section (b)(4) of this notice (Funding Restrictions) to allow collaborations to expand by adding public charter schools that are not high-quality charter schools, as described in the grant application. We think these changes further support the goal of increasing the number of high-quality charter schools.

Final Program Requirements

The Assistant Deputy Secretary for Innovation and Improvement establishes the following program requirements for the Collaboration Awards. We may apply one or more of these requirements in any year in which this program is in effect.

(a) *Eligibility:*

(1) Eligible applicants must be high-quality charter schools (as defined in this notice) that apply in partnership with at least one non-chartered public school (as defined in this notice) or non-chartered LEA (as defined in this notice) and have the support of the partner(s) to participate in the Collaboration Awards competition in accordance with requirements in the Final Application Requirements section of this notice. Other public charter schools that do not qualify as high-quality charter schools may be included in the collaboration so long as (1) the lead applicant is a high-quality charter school; (2) the lead applicant is separate and distinct from any other charter schools included as partners in the collaboration; and (3) at least one non-chartered public school (as defined in this notice) or non-chartered LEA (as defined in this notice) also is a part of the collaboration.

(2) The partnership must comply with the requirements for group applications set forth in 34 CFR 75.127–75.129.

Note: Only an eligible entity (a high-quality charter school) may apply for a grant or be the fiscal agent for a grant. Thus, neither a non-chartered public school (as defined in this notice) nor a non-chartered LEA (as defined in this notice) is eligible to serve as the lead applicant or fiscal agent for a Collaboration Award. Nor is a public charter school that is not a high-quality charter school eligible to serve as the lead applicant or fiscal agent.

(3) Eligible applicants may not have any significant compliance issues (as defined in this notice), including in the areas of student safety, financial management, and statutory or regulatory compliance.

(b) *Funding Restrictions:* A Collaboration Award recipient must use the grant funds for one or more of the following: (1) Continuing the collaboration for which it received the award, as described in its grant application; (2) modifying the collaboration for which it received the award, as described in the grant application; (3) expanding the collaboration for which it received the award by adding additional areas of collaboration, as described in the grant application; (4) expanding the collaboration for which it received the award by adding additional partners (non-chartered public schools (as defined in this notice), non-chartered LEAs (as defined in this notice), or public charter schools that are not high-quality charter schools), as described in the grant application. Collaboration Award recipients also must use a portion of the grant funds to disseminate information about the

collaboration activities to other public schools, including public charter schools, non-chartered public schools (as defined in this notice), and non-chartered LEAs (as defined in this notice). All activities carried out under the Collaboration Awards must fall within the scope of authorized activities set forth in section 5205(a) of the ESEA.

Final Application Requirements

The Assistant Deputy Secretary for Innovation and Improvement establishes the following application requirements for the CSP Collaboration Awards competition. We may apply one or more of these requirements in any year in which this program is in effect.

An applicant for a Collaboration Award must—

(a) Provide a detailed narrative describing (1) the applicant's past or existing collaboration (which may involve more than one partner); (2) the applicant's proposal to continue, modify, or expand (by adding new areas of collaboration or new partners) the collaboration; and (3) the applicant's plan to disseminate information about the collaboration (which may include information about best practices) to other public schools, including public charter schools, non-chartered public schools, and non-chartered LEAs.

The proposed collaboration may focus on a wide range of areas within the scope of activities authorized under section 5205(a) of the ESEA. The list of potential areas includes, but is not limited to, curriculum and instruction, data management and sharing, organization and management, personnel, facilities, finances, Federal programs, standards, assessments, special education services and access to charter schools by students with disabilities, English learners, student transportation, professional development and training, and school climate.

(b) Provide written assurances from authorized officials of the entities involved in the partnership that all participants—

- Agree to submit an application for an award under the competition and have read, understand, and agree with the application for the competition; and
- Authorize the executive summary or narrative of the application, with proprietary information redacted, to be published on the U.S. Department of Education's Web site (ed.gov), *data.ed.gov,* the National Charter School Resource Center Web site (*charterschoolcenter.org*), or any other Web site or publication deemed appropriate by the Secretary;

(c) Submit a partnership agreement that meets the requirements of 34 CFR 75.128(b);

(d) Provide a clear description of the goals and desired outcomes of the proposed collaboration and current or proposed measures that would be used to gauge success in meeting those goals and desired outcomes;

(e) Describe any past, existing, or anticipated obstacles to implementing the collaboration or to disseminating information about the collaboration, and the strategies that were or will be used to overcome those obstacles;

(f) Specify how the award money will be used to implement the collaboration and to disseminate information about the collaboration in accordance with section 5205(a) of the ESEA; and

(g) Specify how the award money will be allocated between the lead applicant and the partner(s) named in the application, including the specific activities that will be carried out by the lead applicant and its partner(s).

Definitions

In addition to the definitions in section 5210 of the ESEA, which include the definition of ''charter school,'' we are establishing the following definitions for the Collaboration Awards competition. We may apply one or more of these definitions in any year in which we make awards under a Collaboration Awards competition.

Collaboration means the activities of a partnership in which two or more organizations or entities work together to accomplish a common goal, which may involve sharing or transferring best practices or strategies.

High-quality charter school means a charter school (as defined in section 5210(1) of the ESEA) that has no significant compliance issue (as defined in this notice) and shows evidence of strong academic results for the past three years (or over the life of the school if the school has been open for fewer than three years), based on the following factors:

(1) Increased student achievement (as defined in this notice) and attainment for all students, including, as applicable, educationally disadvantaged students served by the charter school.

(2) Either—

(i) Demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school; or

(ii) No significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school and significant gains in student achievement (as defined in this notice) with all populations of students served by the charter school.

(3) Results (including, where applicable and available, performance on statewide tests, attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates) for low-income and other educationally disadvantaged students served by the charter school that are above the average achievement results for such students in the State.

Non-chartered local educational agency (LEA) means an LEA that does not qualify as a charter school as defined in section 5210(1) of the ESEA or under State law.

Non-chartered public school means a public school that does not qualify as a charter school under section 5210(1) of the ESEA or under State law.

Significant compliance issue means a violation that did, will, or could lead to the revocation of a school's charter.

Student achievement means—

(a) For tested grades and subjects: (1) A student's score on the State's assessments under the ESEA; and (2) as appropriate, other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across schools.

(b) For non-tested grades and subjects: alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools.

Final Selection Criteria

The Secretary establishes the following selection criteria for Collaboration Awards competitions and may apply one or more of these criteria alone or in combination with one or more selection criteria (1) based on the CSP authorizing statute or (2) in 34 CFR 75.210, in any year in which this program is in effect. In the notice inviting applications or the application package, or both, we will announce the maximum possible points assigned to each criterion.

The Secretary may make awards to the top-rated applications proposing to carry out activities in specific areas of focus (e.g., curriculum and instruction, data management and sharing, organization and management) within the scope of authorized activities under section 5205(a) of the ESEA. In a particular year, the Secretary may

restrict applications to one or more areas of focus. Additionally, in making awards, the Secretary may fund applications out of rank order in order to ensure that the Collaboration Awards are distributed throughout each area of the Nation or a State.

(1) *Record of and potential for success of collaboration.* (A) The extent to which the applicant's past or existing collaboration has improved educational outcomes and operational practices; and (B) The extent to which the applicant's proposed collaboration and dissemination plan will achieve one or more of the following demonstrable results:

(i) Improved operational practices and productivity among all partners in such areas as financial performance and sustainability, governing board performance and stewardship, and parent and community engagement.

(ii) Improved student achievement (as defined in this notice).

(iii) Improved student attendance and retention, and improved high school graduation rates.

(iv) Improved rates of college matriculation and college graduation.

(v) Improved rates of attendance and graduation from other postsecondary (i.e., non-college) institutions or programs.

(2) *Quality of the lead applicant.* (A) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in significantly increasing student achievement (as defined in this notice) and attainment for all students, including, as applicable, educationally disadvantaged students served by the charter school.

(B) Either—

(i) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school; or

(ii) The degree, including the consistency over the past three years, to which there have not been significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school and to which significant gains in student achievement (as defined in this notice) have been made with all populations of students served by the charter school.

(C) The degree, including the consistency over the past three years, to which the applicant has achieved results (including, where applicable and available, performance on statewide tests, student attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates) for students from low-income families and other educationally disadvantaged students served by the charter school that are above the average academic achievement results for such students attending other public schools in the State.

(3) *Quality of the project design.* The extent to which the applicant proposes a high-quality plan to use its Collaboration Award funds to improve educational outcomes and operational practices in public schools, including public charter schools.

(4) *Potential for scalability.* The extent to which the applicant's proposed collaboration can be replicated or adapted beyond the participating partners by other public schools or LEAs, including public charter schools and charter school LEAs, and sustained over the long-term.

(5) *Innovation.* The extent to which the applicant demonstrates that its proposed collaboration, as well as its dissemination plan, are either (a) substantially different from other efforts in its area of focus; or (b) substantially more effective than similar efforts in its area of focus.

Final Definitions, Requirements, and Selection Criteria

Note: This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use one or more of these definitions, requirements, and selection criteria we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these final definitions, requirements, and selection criteria only on a reasoned determination that their benefits justify their costs. In choosing

among alternative regulatory approaches, we selected those approaches that maximize net benefits. The Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 does not require you to respond to a collection of information unless it displays a valid OMB control number. The collection of information is approved under OMB control number 1855–0026.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to either of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 25, 2012.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2012–18573 Filed 7–27–12; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2012–0080; FRL–9704–7]

Approval and Promulgation of Implementation Plans; Tennessee: Prevention of Significant Deterioration and Nonattainment New Source Review; Fine Particulate Matter ($PM_{2.5}$)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve changes to the Tennessee State Implementation Plan (SIP), submitted by the Tennessee Department of Environment and Conservation (TDEC) through the Division of Air Pollution Control to EPA on July 29, 2011. The July 29, 2011, SIP revision modifies Tennessee's New Source Review (NSR) Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) programs. Tennessee's July 29, 2011, SIP revision proposes to incorporate, into the Tennessee SIP, NSR provisions for $PM_{2.5}$ as amended in EPA's 2008 NSR $PM_{2.5}$ Implementation Rule. Also, Tennessee's July 29, 2011, SIP revision makes a corrective and clarifying administrative change to rule 1200–03–09–.01. EPA is approving Tennessee's July 29, 2011, SIP revision because it is consistent with the Clean Air Act (CAA or Act) and EPA regulations regarding NSR permitting.

DATES: *Effective Date:* This rule will be effective August 29, 2012.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2012–0080. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: For information regarding the Tennessee SIP, contact Ms. Twunjala Bradley, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Bradley's telephone number is (404) 562–9352; email address: *bradley.twunjala@epa.gov.* For information regarding NSR, contact Ms. Yolanda Adams, Air Permits Section, at the same address above. Ms. Adams' telephone number is (404) 562–9214; email address: *adams.yolanda@epa.gov.* For information regarding the $PM_{2.5}$ NAAQS, contact Mr. Joel Huey, Regulatory Development Section, at the same address above. Mr. Huey's telephone number is (404) 562–9104; email address: *huey.joel@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background
II. This Action
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I. Background

EPA is taking final action on Tennessee's July 29, 2011, SIP revision to adopt rules equivalent to federal requirements for NSR permitting.[1] Tennessee's July 29, 2011, SIP revision includes changes to Tennessee's Air Quality Regulations, Chapter 1200–03–09—Construction and Operating Permits, Rule Number .01—Construction Permits, to adopt federal PSD and NNSR promulgated in the rule entitled ''Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$), '' Final Rule, 73 FR

[1] Tennessee's July 29, 2011, SIP revision also contains changes to Tennessee Chapter 1200–03–26—Administrative Fees Schedule provisions. EPA is not proposing action on this part of the submittal as these provisions are not part of the federally-approved Tennessee SIP.

28321 (May 16, 2008), hereafter referred to as the ''NSR $PM_{2.5}$ Rule.'' Also, Tennessee's July 29, 2011, SIP revision includes clarifying changes to rule 1200–03–09–.01.

On June 11, 2012, EPA published a proposed rulemaking to approve the aforementioned changes to Tennessee's NSR PSD program. *See* 77 FR 34302. Comments on the proposed rulemaking were due on or before July 11, 2012. No comments, adverse or otherwise, were received on EPA's June 11, 2012 proposed rulemaking. Pursuant to section 110 of the CAA, EPA is now taking final action to approve the changes to Tennessee's NSR PSD program as provided in EPA's June 11, 2012, proposed rulemaking. A summary of the background for today's final action is provided below. For more detail, please refer to EPA's proposed rulemaking at 77 FR 34302.

A. NSR $PM_{2.5}$ Rule

EPA finalized a rule on May 16, 2008, that revised the NSR program requirements to establish the framework for implementing preconstruction permit review for the $PM_{2.5}$ NAAQS in both attainment and nonattainment areas. Specifically, the NSR $PM_{2.5}$ Rule established the following NSR requirements to implement the $PM_{2.5}$ NAAQS: (1) Require NSR permits to address directly emitted $PM_{2.5}$ and precursor pollutants; (2) establish significant emission rates for direct $PM_{2.5}$ and precursor pollutants (including sulfur dioxide (SO_2) and nitrogen oxides (NO_X)); (3) establish $PM_{2.5}$ emission offsets; (4) provide exceptions to inhalable particles smaller than or equal to 10 micrometers in diameter) (PM_{10}) grandfather policy; and (5) require states to account for gases that condense to form particles (condensables) in $PM_{2.5}$ and PM_{10} emission limits in PSD or nonattainment NSR permits. Additionally, the NSR $PM_{2.5}$ Rule authorized states to adopt provisions in their nonattainment NSR rules that would allow interpollutant offset trading. *See* 73 FR 28321. States were required to provide SIP submissions to address the requirements for the NSR $PM_{2.5}$ Rule by May 16, 2011. Tennessee's July 29, 2011, SIP revision addresses the PSD and NNSR requirements related to EPA's May 16, 2008, NSR $PM_{2.5}$ Rule.

1. PM_{10} Surrogate and Grandfathering Policy

In the NSR $PM_{2.5}$ Rule, EPA required that major stationary sources seeking permits must begin directly satisfying the $PM_{2.5}$ requirements, as of the effective date of the rule, rather than relying on PM_{10} as a surrogate, with two exceptions.[2] The first exception is a ''grandfathering'' provision in the federal PSD program at 40 CFR 52.21(i)(1)(xi). This grandfathering provision applied to sources that had applied for, but had not yet received, a final and effective PSD permit before the July 15, 2008, effective date of the May 2008 final rule. The second exception was that states with SIP-approved PSD programs could continue to implement the Seitz Memo's PM_{10} Surrogate Policy for up to three years (until May 2011) or until the individual revised state PSD programs for $PM_{2.5}$ are approved by EPA, whichever comes first. On May 18, 2011 (76 FR 28646), EPA took final action to repeal the $PM_{2.5}$ grandfathering provision at 40 CFR 52.21(i)(1)(xi). This final action ended the use of the 1997 PM_{10} Surrogate Policy for PSD permits under the federal PSD program at 40 CFR 52.21. In effect, any PSD permit applicant previously covered by the grandfathering provision (for sources that completed and submitted a permit application before July 15, 2008)[3] that did not have a final and effective PSD permit before the effective date of the repeal will not be able to rely on the 1997 PM_{10} Surrogate Policy to satisfy the PSD requirements for $PM_{2.5}$ unless the application includes a valid surrogacy demonstration. *See* 76 FR 28646. In its July 29, 2011, SIP revision, Tennessee elected not to adopt the grandfathering provision at 40 CFR 52.21(i)(1)(xi), into its PSD regulations. Therefore, Tennessee's July 29, 2011, SIP revision is consistent with federal regulations since it does not contain the repealed grandfathering provision.

2. ''Condensable'' Provision

In the NSR $PM_{2.5}$ Rule, EPA revised the definition of ''regulated NSR pollutant'' for PSD to add a paragraph providing that ''particulate matter (PM) emissions, $PM_{2.5}$ emissions and PM_{10} emissions'' shall include gaseous emissions from a source or activity which condense to form particulate matter at ambient temperatures and that on or after January 1, 2011, such condensable particulate matter shall be accounted for in applicability determinations and in establishing emissions limitations for PM, $PM_{2.5}$ and PM_{10} in permits issued. *See* 40 CFR 51.166(b)(49)(vi), 52.21(b)(50)(vi) and ''Emissions Offset Interpretative Ruling'' (40 CFR Part 51, Appendix S). On March 16, 2012,[4] EPA proposed a rulemaking to amend the definition of ''regulated NSR pollutant'' promulgated in the NSR $PM_{2.5}$ Rule regarding the PM condensable provision at 40 CFR 51.166(b)(49)(vi), 52.21(b)(50)(i) and EPA's Emissions Offset Interpretative Ruling. *See* 77 FR 15656. The rulemaking proposes to remove the inadvertent requirement in the NSR $PM_{2.5}$ Rule that the measurement of condensable ''particulate matter emissions'' be included as part of the measurement and regulation of ''particulate matter emissions.''[5] Tennessee's July 29, 2011, SIP revision adopts EPA's definition for regulated NSR pollutant for condensables (at 40 CFR 51.166(b)(49)(vi)), including the term ''particulate matter emissions,'' as promulgated in the NSR $PM_{2.5}$ Rule.

On May 1, 2012, the State of Tennessee provided a letter to EPA with clarification of the State's intent in light of EPA's March 12, 2012, proposed rulemaking. Specifically, in that letter, the State of Tennessee requested that EPA not approve the term ''particulate matter emissions'' (at rule 1200–03–09–.01(4)(b)47(vi)) as part of the definition for ''regulated NSR pollutant'' regarding the inclusion of condensable emissions in applicability determinations and in establishing emissions limitations for PM.

3. Interpollutant Trading

The NSR $PM_{2.5}$ final Rule authorized states to adopt provisions in their NNSR rules that would allow major stationary sources and major modifications located in areas designated nonattainment for $PM_{2.5}$ to offset emissions increases of direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors with reductions of either direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors in accordance with offset

[2] After EPA promulgated the NAAQS for $PM_{2.5}$ in 1997, the Agency issued guidance documents related to using PM_{10} as a surrogate for $PM_{2.5}$ entitled ''Interim Implementation of New Source Review Requirements for $PM_{2.5}$.'' John S. Seitz, EPA, October 23, 1997 (the ''Seitz memo'') and ''Implementation of New Source Review Requirements in PM–2.5 Nonattainment Areas'' (the ''2005 $PM_{2.5}$ Nonattainment NSR Guidance'').

[3] Sources that applied for a PSD permit under the federal PSD program on or after July 15, 2008, are already excluded from using the 1997 PM_{10} Surrogate Policy as a means of satisfying the PSD requirements for $PM_{2.5}$. *See* 76 FR 28321.

[4] In EPA's June 11, 2012, proposed rulemaking, EPA cited March 12, 2012, as the publication date for the particulate matter emissions correction notice. The correct publication date is March 16, 2012.

[5] The term ''particulate matter emissions'' includes particles that are larger than $PM_{2.5}$ and PM_{10} and is an indicator measured under various New Source Performance Standards (NSPS) (40 CFR part 60). In addition to the NSPS for PM, it is noted that states have regulated ''particulate matter emissions'' for many years in their SIPs for PM, and the same indicator has been used as a surrogate for determining compliance with certain standards contained in 40 CFR part 63, regarding National Emission Standards for Hazardous Air Pollutants.

ratios contained in the approved SIP for the applicable nonattainment area. The inclusion, in whole or in part, of the interpollutant trading offset provisions for $PM_{2.5}$ is discretionary on the part of the states. In the preamble to the NSR $PM_{2.5}$ Rule, EPA included preferred or presumptive offset ratios, applicable to specific $PM_{2.5}$ precursors, that states may adopt in conjunction with the new interpollutant trading offset provisions for $PM_{2.5}$, and for which the state could rely on the EPA's technical work to demonstrate the adequacy of the ratios for use in any $PM_{2.5}$ nonattainment area.[6]

The preferred ratios were subsequently the subject of a petition for reconsideration which the EPA Administrator granted in 2009. As a result of the reconsideration, on July 21, 2011, EPA issued a memorandum entitled ''Revised Policy to Address Reconsideration of Interpollutant Trading Provisions for Fine Particles ($PM_{2.5}$)'' (hereafter referred to as the ''Interpollutant Trading Memorandum''). The Interpollutant Trading Memorandum indicated that the existing preferred offset ratios are no longer considered presumptively approvable and that any precursor offset ratio submitted as part of the NSR SIP for a $PM_{2.5}$ nonattainment area must be accompanied by a technical demonstration showing the net air quality benefits of such ratio for the $PM_{2.5}$ nonattainment area in which it will be applied. Tennessee's July 29, 2011, SIP revision adopts the interpollutant policy but not the preferred trading ratios established in the NSR $PM_{2.5}$ Rule.

II. This Action

Tennessee's July 29, 2011, SIP revision adopts NSR $PM_{2.5}$ Rule provisions into the Tennessee SIP at Chapter 12000–03–09 including: (1) Requirement for NSR permits to address directly emitted $PM_{2.5}$ and precursor pollutants; (2) significant emission rates for direct $PM_{2.5}$ and precursor pollutants (SO_2 and NO_X); (3) PSD and NNSR requirements of states to address condensable PM in establishing enforceable emission limits for PM_{10} or $PM_{2.5}$; (4) $PM_{2.5}$ emission offsets; and (5) optional interpollutant trading provision set forth at 40 CFR 51.165(a)(11). These amendments to the Tennessee rules became state-effective June 27, 2011. Specifically, the SIP revision establishes that the State's existing NSR permitting program requirements for PSD and NNSR apply to the $PM_{2.5}$ NAAQS and its precursors; revise the definitions of ''*significant''* at 1200–03–09–.01(4)(b)24(i) and (5)(b)1(x)(I) to establish significant emission rates for direct $PM_{2.5}$ and $PM_{2.5}$ precursors for major modifications at existing sources (as amended at 40 CFR 51.165(a)(1)(x)(A) and 51.166(b)(23)(i)); revise the term ''*regulated NSR pollutant''* at 1200–03–09–.01(4)(b)47 and (5)(b)1(xlix) to include $PM_{2.5}$, recognize $PM_{2.5}$ precursors and include the requirement that condensable emissions be accounted for in applicability determinations and in establishing emissions limitations for PM (as amended at 40 CFR 51.165(a)(1)(xxxvii)(C) and 51.166(b)(49)); and adopt NNSR emission offsets (a ratio of 1:1) for direct $PM_{2.5}$ at 1200–03–09–.01(5)2(v) (as amended at 40 CFR 51.165(a)(9)).

Additionally, Tennessee's July 29, 2011, SIP revision does not include the grandfathering provision at 40 CFR 52.21(i)(1)(ix) promulgated in the NSR $PM_{2.5}$ Rule. Therefore, Tennessee's July 29, 2011, SIP revision is consistent with federal regulations. The July 29, 2011, SIP revision adopts the elective interpollutant trading provision policy at 1200–03–09(5)(b)2.(v)(XV) set forth at 40 CFR 51.165(a)(11) for the purpose of offsets under the $PM_{2.5}$ NNSR program. Pursuant to EPA's July 21, 2011, Interpollutant Trading Memorandum, the preferred precursor offset ratios included in the preamble to the NSR $PM_{2.5}$ Rule are no longer considered presumptively approvable. Therefore, any precursor offset ratio submitted to EPA for approval as part of the NSR SIP for a $PM_{2.5}$ nonattainment area must be accompanied by a technical demonstration showing the suitability of the ratios for that particular nonattainment area. Tennessee's adoption of the interpollutant trading policy and not the trading ratios does not in any way allow a major stationary source or major modification in the State to obtain offsets through interpollutant trading, nor does it affect the approvability of Tennessee's July 29, 2011, SIP revision.[7]

Regarding the condensable provision, in light of Tennessee request in its May 1, 2012, letter and EPA's intention to amend the definition of ''regulated NSR pollutant'' as discussed in the correction rulemaking,[8] EPA is not taking action to approve the terminology ''particulate matter emissions'' into the Tennessee SIP (at 1200–03–09–.01(4)(b)47(vi)) for the condensable provision in the definition of ''regulated NSR pollutant.'' EPA is, however, taking final action to approve into the Tennessee SIP at 1200–03–09–.01(4)(b)47(vi) the remaining condensable requirement at 40 CFR 51.166(b)(49)(vi), which requires that condensable emissions be accounted for in applicability determinations and in establishing emissions limitations for $PM_{2.5}$ and PM_{10}.

TDEC's July 29, 2011, SIP revision also makes an administrative change to Chapter 1200–03–09 for PSD and NNSR including removing the sentence ''For example, if a project involves both an existing emissions unit and a Clean Unit, the projected increase is determined by summing the values determined using the method specified in paragraph (a)(7)(iv)(c) of this section for the existing unit and determined using the method specified in paragraph (a)(7)(iv)(e) of this section for the Clean Unit.'' from the State's hybrid test applicability provision at 1200–03–09–.01(4)(c)4(vi) and 1200–03–09–.01(5)(b)2(xvii). Tennessee proposed this change to be consistent with federal language amended in the June 13, 2007, final rulemaking regarding the vacated portions of the 2002 NSR Reform Rule.[9] *See* 72 FR 32526. This final action approves the aforementioned SIP amendments into Tennessee's SIP to provide for the implementation of $PM_{2.5}$ NAAQS in the State's NSR permitting program.

[6] Alternatively, the preamble indicated that states may adopt their own ratios, subject to EPA's approval, that would have to be substantiated by modeling or other technical demonstrations of the net air quality benefit for ambient $PM_{2.5}$ concentrations.

[7] If a major stationary source or source with a major modification in Tennessee requests to obtain offsets through interpollutant trading, the State of Tennessee would first be required, consistent with the requirements of section 51.165(a)(11), to revise its SIP to adopt appropriate trading ratios. Tennessee would need to submit to EPA a technical demonstration showing how either the preferred ratios established in the NSR $PM_{2.5}$ Rule or the State's own ratios are appropriate for the State's particular $PM_{2.5}$ nonattainment as well as a revision to the NSR program adopting the ratios into the SIP. EPA would then have to approve the demonstration and ratios into the Tennessee SIP prior to any major stationary source or major modification obtaining offsets through the interpollutant trading policy.

[8] On March 16, 2012, EPA proposed to correct the inadvertent inclusion of ''particulate matter emissions'' in the definition of ''regulated NSR pollutant'' as an indicator for which condensable emissions must be addressed. *See* 77 FR 75656. The comment period for this proposed rulemaking ended May 15, 2012.

[9] On June 13, 2007, EPA took final action to revise the 2002 NSR Reform Rules to remove from federal law all provisions pertaining to clean units and the pollution control projects exemption that were vacated by the United States Court of Appeals for the District of Columbia Rule. *New York* v. *United States, 413 F.3d 3 (D.C. Cir. 2005*). *See* 72 FR 32526. EPA's efforts to remove the vacated provisions included removing the language from the hybrid test applicability provision at 40 CFR 51.166(a)(7)(iv)(f), 51.165(f)(6) and 52.21(a)(2)(iv)(f).

III. Final Action

Pursuant to section 110 of the CAA, EPA is taking final action to approve Tennessee's July 29, 2011, SIP revisions adopting federal regulations amended in the NSR $PM_{2.5}$ Rule to implement the $PM_{2.5}$ NAAQS for the NSR program. EPA is also taking final action to approve corrective and clarifying administrative changes to Tennessee's regulations because they are consistent with section 110 of the CAA and its implementing regulations.

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 28, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: July 16, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Therefore, 40 CFR part 52 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.*

■ 2. Section 52.2220(c) is amended under Chapter 1200–3–9 by revising the entry for ''Section 1200–3–9–.01'' to read as follows:

§ 52.2220 Identification of plan

* * * * *

(c) * * *

TABLE 1—EPA-APPROVED TENNESSEE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	* * *
Chapter 1200–3–9 Construction and Operating Permits				
Section 1200–3–9–.01.	Construction Permits.	6/27/11	7/30/12 [Insert citation of publication].	EPA is approving Tennessee's July 29, 2011, SIP revisions to Chapter 1200–3–9–.01 with the exception of the term ''particulate matter emissions'' at 1200–03–09–.01(4)(b)47(vi) as part of the definition for ''regulated NSR pollutant'' regarding the inclusion of condensable emissions in applicability determinations and in establishing emissions limitations. EPA is approving Tennessee's May 28, 2009, SIP revisions to Chapter 1200–3–9–.01 with the exception of the ''baseline actual emissions'' calculation revision found at 1200–3–9–.01(4)(b)45(i)(III), (4)(b)45(ii)(IV), (5)(b)1(xlvii)(I)(III) and (5)(b)1(xlvii)(II)(IV) of the submittal.

TABLE 1—EPA-APPROVED TENNESSEE REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	* * *

* * * * *

[FR Doc. 2012–18393 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2011–0809; FRL–9705–2]

Approval and Promulgation of Implementation Plans; Florida; Sections 128 and 110(a)(1) and (2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve in part, and disapprove in part, the State Implementation Plan (SIP) submissions, submitted by the State of Florida, through the Florida Department of Environmental Protection (FDEP) on December 13, 2007, and supplemented on April 18, 2008 and May 24, 2012, to demonstrate that the State meets the requirements of sections 110(a)(1) and (2) of the Clean Air Act (CAA or Act) for the 1997 8-hour ozone national ambient air quality standards (NAAQS). Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure'' SIP. FDEP certified that the Florida SIP contains provisions that ensure the 1997 8-hour ozone NAAQS are implemented, enforced, and maintained in Florida (hereafter referred to as ''infrastructure submission''). EPA is now taking three related actions on FDEP's infrastructure submissions for Florida. First, EPA is taking final action to disapprove in part portions of sections 110(a)(2)(C) and 110(a)(2)(J) of the December 13, 2007, submittal as it relates to the regulation of greenhouse gas (GHG) emissions. Second, EPA is taking final action to approve FDEP's May 24, 2012, submission, which addresses the substantive requirements of section 128 relating to State board requirements as applicable to the infrastructure SIP pursuant to section 110(a)(2)(E)(ii), and the substantive requirements of section 110(a)(2)(G), which relates to the authority to implement emergency powers under section 303 of the CAA. Third, and with the exception of the aforementioned portions of sections 110(a)(2)(C) and (J), EPA is finalizing its determination that Florida's infrastructure submission, provided to EPA on December 13, 2007, supplemented on April 18, 2008, addresses all other required infrastructure elements for the 1997 8-hour ozone NAAQS.

DATES: *Effective Date:* This rule will be effective August 29, 2012.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2011–0809. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can be reached via electronic mail at *ward.nacosta@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

Upon promulgation of a new or revised NAAQS, sections 110(a)(1) and (2) of the CAA require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance for that new NAAQS.

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 1997 8-hour ozone NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with previous ozone NAAQS.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for ''infrastructure'' SIP requirements related to a newly established or revised NAAQS. As already mentioned, these requirements include SIP infrastructure elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAQS. The requirements that are the subject of this final rulemaking are listed below [1] and in EPA's October 2,

[1] Two elements identified in section 110(a)(2) are not governed by the three year submission deadline

Continued

2007, memorandum entitled ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards.''

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.[2]
- 110(a)(2)(D): Interstate transport.[3]
- 110(a)(2)(E): Adequate resources.
- 110(a)(2)(F): Stationary source monitoring system.
- 110(a)(2)(G): Emergency power.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(I): Areas designated nonattainment and meet the applicable requirements of part D.[4]
- 110(a)(2)(J): Consultation with government officials; public notification; and Prevention of Significant Deterioration (PSD) and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

On July 18, 1997, EPA promulgated a new NAAQS for ozone based on 8-hour average concentrations, thus states were required to provide submissions to address sections 110(a)(1) and (2) of the CAA for this new NAAQS. Florida provided its infrastructure submission for the 1997 8-hour ozone NAAQS on December 13, 2007. On March 27, 2008, Florida was among other states that received a finding of failure to submit because its infrastructure submission was deemed incomplete for element 110(a)(2)(G) for the 1997 8-hour ozone NAAQS by March 1, 2008. *See* 73 FR 16205. Section 110(a)(2)(G) relates to the requirement for states to provide ''emergency power'' authority comparable to that in section 303 of the CAA and adequate contingency plans to implement such authority.

In FDEP's December 13, 2007, submission, and in a letter dated April 18, 2008, FDEP cited State statutes as evidence that Florida has the authority to implement emergency powers for the 1997 8-hour ozone NAAQS as required by section 110(a)(2)(G). EPA, however, proposed a Federal Implementation Plan (FIP) with respect to this element of the infrastructure SIP because the statutes cited by FDEP had not been approved into the Florida SIP. *See* 77 FR 23181 (April 18, 2012).[5] On April 19, 2012, FDEP submitted, for parallel processing, draft changes to address the deficiencies of the Florida SIP regarding the substantive requirements of section 110(a)(2)(G). EPA published a supplemental proposed rulemaking action on this draft revision on May 18, 2012, to (1) incorporate provisions to address Florida's authority for emergency powers and adequate contingency plans to implement such authority; and (2) propose approval for element 110(a)(2)(G) of Florida's infrastructure SIP. *See* 77 FR 29581. On May 24, 2012, FDEP submitted a final submission to EPA to satisfy to CAA section 110(a)(2)(G). Therefore, in today's rulemaking, EPA will not finalize the FIP for section 110(a)(2)(G) as it is no longer necessary and is instead finalizing full approval of this substantive SIP revision to address the section 110(a)(2)(G) requirements. As a result of this substantive revision to the SIP, EPA is also finalizing its approval of section 110(a)(2)(G) of Florida's infrastructure SIP among the other infrastructure elements approved today.

With respect to section 110(a)(2)(E)(ii), EPA's April 18, 2012, proposed rulemaking described EPA's intention to conditionally approve FDEP's December 13, 2007, infrastructure submission regarding this sub-element. EPA proposed conditional approval of this sub-element because the State's implementation plan did not contain provisions to address the requirements of CAA section 128. However, on March 13, 2012, FDEP submitted a letter to EPA that included a commitment to submit a SIP revision to address the CAA section 128 requirements. *See* 77 FR 23181. The letter Florida submitted to EPA can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2011–0809. On April 19, 2012, FDEP submitted, for parallel processing, a draft SIP revision to fully address the deficiencies within the Florida SIP to address CAA section 128 requirements. EPA proposed action on this draft revision on May 18, 2012, which included both a proposed substantive revision to the Florida SIP to incorporate rules satisfying section 128 of the CAA, and a proposed approval for sub-element 110(a)(2)(E)(ii) of Florida's infrastructure SIP. *See* 77 FR 29581. On May 24, 2012, FDEP submitted a final submission to EPA to satisfy the requirements of CAA section 128.

With respect to sections 110(a)(2)(C) and (J), EPA has issued two regulatory revisions—the 1997 8-Hour Ozone NAAQS Implementation Rule New Source Review (NSR) Update—Phase 2 final rule (hereafter referred to as the ''Ozone Implementation NSR Update'' or ''Phase 2 Rule'') (70 FR 71612 (November 29, 2005)); and the Greenhouse Gas Tailoring Rule (hereafter referred to as the ''GHG Tailoring Rule'') (75 FR 31514 (EPA's June 3, 2010))—that necessitated updates to Florida's SIP in order for EPA to approve these infrastructure elements for purposes of the 1997 8-hour Ozone NAAQS.[6]

Regarding the Phase 2 Rule, on October 19, 2007, and July 1, 2011, FDEP submitted revisions to EPA, for approval into the Florida SIP, to adopt federal requirements for NSR permitting

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of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA, and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. Today's final rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or (C). In a March 14, 2012, final rulemaking, EPA addressed the section 110(a)(2)(C) requirements for Tennessee. *See* 77 FR 14976.

[2] This rulemaking only addresses requirements for this element as they relate to attainment areas.

[3] Today's final rule does not address element 110(a)(2)(D)(i) (Interstate Transport) for the 1997 8-hour ozone NAAQS. Interstate transport requirements were formerly addressed by Florida consistent with the Clean Air Interstate Rule (CAIR). On December 23, 2008, CAIR was remanded by the D.C. Circuit Court of Appeals, without vacatur, back to EPA. *See North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008). Prior to this remand, EPA took final action to approve Florida's SIP revision, which was submitted to comply with CAIR. *See* 72 FR 58016 (October 12, 2007). In so doing, Florida's CAIR SIP revision addressed the interstate transport provisions in section 110(a)(2)(D)(i) for the 1997 8-hour ozone NAAQS. In response to the remand of CAIR, EPA has recently finalized a new rule to address the interstate transport of nitrogen oxides (NOx) and sulfur oxides (SOx) in the eastern United States. *See* 76 FR 48208 (August 8, 2011) Transport Rule). EPA's action on element 110(a)(2)(D)(i) will be addressed in a separate action.

[4] This requirement was inadvertently omitted from EPA's October 2, 2007, memorandum entitled ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' but as mentioned above is not relevant to today's rulemaking.

[5] On March 23, 2012, FDEP sent a letter to EPA requesting conditional approval of section 110(a)(2)(G). In this letter, Florida committed to submit a SIP revision to address the substantive requirements of section 110(a)(2)(G) by June 2012. The letter Florida submitted to EPA can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2011–0809. EPA notes that a conditional approval cannot satisfy an obligation for the Agency to implement a FIP.

[6] Florida's authority to regulate new and modified sources of the ozone precursors, volatile organic compounds (VOCs) and nitrogen oxides (NO_X), to assist in the protection of air quality in nonattainment, attainment or unclassifiable areas is established in Chapters 62–210, *Stationary Sources—General Requirements, Section 200—Definitions,* and 62–212, *Stationary Sources—Preconstruction Review, Section 400—Prevention of Significant Deterioration* of the Florida SIP.

promulgated in the Phase 2 Rule. These revisions also modified provisions of Florida's SIP at Chapter 62–210 and 62–212 to recognize NO_X as an ozone precursor. EPA finalized approval of these revisions into the SIP on June 15, 2012. *See* 77 FR 35862.

Regarding the GHG Tailoring Rule, EPA has identified errors in Florida's federally-approved SIP that result in the State's failure to address, or provide adequate legal authority for, the implementation of a GHG PSD program in Florida. Approval of a revision to address GHGs is required to meet sections 110(a)(2)(C) and 110(a)(2)(J). On December 30, 2010, EPA promulgated a FIP [7] because Florida failed to submit, by its December 22, 2010, deadline, the corrective SIP revision to apply its PSD program to sources of GHGs consistent with the thresholds described in the GHG Tailoring rule. Since Florida currently does not have adequate legal authority to address the new GHG PSD permitting requirements at or above the levels of emissions set in the GHG Tailoring Rule, or at other appropriate levels, its SIP does not satisfy portions of section 110(a)(2)(C) and section 110(a)(2)(J) of the infrastructure SIP requirements. As a result, on April 18, 2012, EPA proposed to disapprove FDEP's submission for sections 110(a)(2)(C) and 110(a)(2)(J) as they relate to GHG PSD permitting requirements. *See* 77 FR 23181.

II. This Action

EPA is taking final action to approve in part, and disapprove in part, Florida's infrastructure submissions as demonstrating that the State meets the applicable requirements of sections 110(a)(1) and (2) of the CAA for the 1997 8-hour ozone NAAQS. Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA, which is commonly referred to as an ''infrastructure'' SIP. Florida, through FDEP, certified that the Florida SIP contains provisions that ensure the 1997 8-hour ozone NAAQS is implemented, enforced, and maintained in Florida. EPA received no adverse comments on its April 18, 2012, and May 18, 2012, proposed rulemakings of Florida's December 13, 2007, infrastructure submission and April 19, 2012, draft SIP revision regarding the substantive requirements of CAA sections 128 and 110(a)(2)(G).

Today's disapprovals of Florida's infrastructure submissions are limited to the portions of section 110(a)(2)(C) and section110(a)(2)(J) related to GHG PSD permitting as proposed on April 18, 2012. *See* 77 FR 23181. EPA's disapproval of this portion of these elements does not result in any further obligation on the part of Florida because EPA has already promulgated a FIP for the Florida PSD program to address permitting GHGs at or above the GHG Tailoring Rule thresholds (76 FR 25178). Thus, today's final action to disapprove FDEP's submission for elements related to the GHG PSD permitting portion of sections 110(a)(2)(C) and 110(a)(2)(J) will not require any further action by either FDEP or EPA. The FIP that is currently in place to address GHG requirements in Florida will remain unless and until Florida submits a final submission to EPA for federal approval and EPA takes final action on that submission.

In addition to the above-described infrastructure submission final actions, EPA is also today finalizing two substantive SIP actions related to infrastructure elements 110(a)(2)(E)(ii) and (G) proposed in EPA's May 18, 2012, supplemental proposed rule. *See* 77 FR 29581. EPA is also announcing that it does not intend to finalize the proposed FIP for section 110(a)(2)(G) as it is no longer necessary due to the substantive SIP revisions for this element finalized today. The substantive revisions were submitted by Florida to EPA on May 24, 2012. *See* 77 FR 29581.

Based upon the aforementioned, EPA has determined that Florida's infrastructure submission, provided to EPA on December 13, 2007, and supplemented on April 18, 2008, addresses all the required infrastructure elements for the 1997 8-hour ozone NAAQS, with the exception of CAA section 110(a)(2)(E)(ii), pertaining to CAA section 128 requirements and section 110(a)(2)(G). Florida's May 24, 2012, submission addresses the substantive requirements of CAA sections 128, 110(a)(2)(E)(ii), and 110(a)(2)(G). EPA has determined that the remaining infrastructure elements addressed in Florida's December 13, 2007, submission, supplemented on April 18, 2008, and May 24, 2012, with the exception of the portions of sections 110(a)(2)(C) and (J) related to GHG PSD permitting, are consistent with section 110 of the CAA.

III. Final Action

EPA is taking final action to approve in part, and disapprove in part, the December 13, 2007, submission, supplemented on April 18, 2008, and the May 24, 2012, submission, for the 1997 8-hour ozone NAAQS because these submissions are consistent with section 110 of the CAA. FDEP has addressed the elements of the CAA 110(a)(1) and (2) SIP requirements pursuant to EPA's October 2, 2007, guidance to ensure that the 1997 8-hour ozone NAAQS are implemented, enforced, and maintained in Florida. EPA is also taking final action to approve a substantive SIP revision submitted by Florida on May 24, 2012, to address requirements related to sections 128, 110(a)(2)(E)(ii) and (G) of the CAA because these revisions are consistent with the Act.

IV. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement

[7] Action to Ensure Authority to Issue Permits under the Prevention of Significant Deterioration Program to Sources of Greenhouse Gas Emissions: Federal Implementation Plan—Final Rule, 75 FR 82246 (December 30, 2010).

Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 28, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects 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.

Dated: July 16, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Therefore, 40 CFR part 52 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.*

■ 2. Section 52.520 in paragraph (e) is amended by adding three new entries for ''110(a)(1) and (2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards,'' ''Section 128 Requirements,'' and ''Sections 110(a)(2)(E)(ii) and (G) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards'' at the end of the table to read as follows:

§ 52.520 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register** notice	Explanation
* * *	*	* *		*
110(a)(1) and (2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards.	12/13/2007	7/30/2012	[Insert citation of publication].	
Section 128 Requirements	5/24/2012	7/30/2012	[Insert citation of publication].	
Sections 110(a)(2)(E)(ii) and (G) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards.	5/24/2012	7/30/2012	[Insert citation of publication].	

■ 3. Section 52.523 is added to read as follows:

§ 52.523 Control strategy: Ozone

(a) Disapproval. EPA is disapproving portions of Florida's infrastructure SIP for the 1997 8-hour ozone NAAQS regarding the State's ability to provide adequate legal authority for the implementation of a Greenhouse Gas Prevention of Significant Deterioration program, specifically with respect to sections 110(a)(2)(C) and 110(a)(2)(J). A FIP is currently in place and approved for Florida at 40 CFR 52.37 for these requirements.

(b) [Reserved]

[FR Doc. 2012–18316 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2010–0115; FRL–9701–9]

RIN 2060–AQ23

Method 16C for the Determination of Total Reduced Sulfur Emissions From Stationary Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates Method 16C for measuring total reduced sulfur (TRS) emissions from stationary sources. Method 16C offers the advantages of real-time data collection and uses procedures that are already in use for measuring other pollutants. Method 16C will be a testing option that is used at the discretion of the tester.

DATES: This final rule is effective on July 30, 2012.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2010–0115. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available either electronically at *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Docket Facility and the Public Reading Room are open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Foston Curtis, Office of Air Quality Planning and Standards, Air Quality Assessment Division, Measurement Technology Group (E143–02), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1063; fax number: (919) 541–0516; email address: *curtis.foston@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. General Information

A. Does this action apply to me?

Method 16C applies to TRS measurement from kraft pulp mills subject to Subpart BB of the New Source Performance Standards (NSPS). The methods required under Subpart BB for TRS are sometimes used under the petroleum refineries NSPS (Subpart J). Method 16C may also be applicable to sources regulated by state and local regulations that adopt the Subpart BB testing requirements.

Regulated Entities. Categories and entities potentially affected include the following:

Category	NAICS [a]	Examples of regulated entities
Industry	322110	Kraft Pulp Mills.
Industry	324110	Petroleum Refineries.

[a] North American Industry Classification System.

This table is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. This table lists examples of the types of entities the EPA is now aware could potentially be affected by this final action. Other types of entities not listed could also be affected. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Where can I obtain a copy of this action?

In addition to being available in the docket, an electronic copy of this rule will also be available on the Worldwide Web (www) through the Technology Transfer Network (TTN). Following the Administrator's signature, a copy of the final rule will be placed on the TTN's policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control.

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by September 28, 2012. Under section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by this action may not be challenged separately in any civil or criminal proceedings brought by EPA to enforce these requirements.

II. Background

Method 16C was proposed in the **Federal Register** on September 2, 2010, with a public comment period that ended November 1, 2010. Two comment letters were received from the public.

III. Summary of Method 16C

Method 16C uses the sampling procedures of Method 16A and the analytical procedures of Method 6C to measure TRS. Total reduced sulfur is defined as hydrogen sulfide, methyl mercaptan, dimethyl sulfide, and dimethyl disulfide. As in Method 16A, the sample is collected from the source through a heated probe and immediately conditioned in a citrate buffer scrubber. The conditioned sample is oxidized in a tube furnace to convert TRS to sulfur dioxide (SO_2). The oxidized sample is then analyzed for SO_2 using a real-time SO_2 analyzer as in Method 6C.

This method may be used as an alternative to Methods 16, 16A, and 16B for determining TRS. Its use has been allowed on a case-by-case basis and, based on our experience, it is a good alternative. Method 16C offers advantages over currently required methods by supplying real-time data in the field using analyzers and procedures that are currently used for other pollutants. Performance checks contained in the method ensure that bias and calibration precision are periodically checked and maintained.

This rule will not require the use of Method 16C but will allow it as an alternative method at the discretion of the user. This method does not impact testing stringency; data are collected under the same conditions and time intervals as the current methods.

IV. Public Comments on Proposed Method 16C

Two public comment letters were received on the proposed rule. The comments pointed out contradictions in different sections of the method for the analyzer calibration error test and the system bias check. In one instance, the analyzer calibration acceptance criterion was listed as 5 percent and in another place it was listed as 2 percent. The rule was corrected to state that 5 percent is the correct criterion for this test. For the system bias check, unclear language was amended to specifically state that the pre-test bias check is mandatory, not optional. An additional comment led to the dropping of the sample correction for moisture since it is not needed for most analyzers. The public comments are addressed in the Summary of Comments and Responses Document that has been added to the docket.

V. Statutory and Executive Order Reviews

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

This action is not a ''significant regulatory action'' under the terms of Executive Order 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).

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). This final rule does not add information collection requirements beyond those currently required under the applicable regulations. This final rule adds an alternative test method that may be used at the discretion of the source.

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities because Method 16C is not a required test method but may be used at the discretion of the source. Any small entity choosing to use Method 16C would likely do so because it is less burdensome or more advantageous than the other methods allowed.

D. Unfunded Mandates Reform Act

This action contains no federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. This action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Any small entity choosing to use Method 16C would likely do so because it is less burdensome or more advantageous than the other methods allowed.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This final rule adds Method 16C for use as a new alternative method. Thus, Executive Order 13132 does not apply to this action.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This final rule provides an additional testing option for measuring pollutants to what is currently mandated. It does not add any new requirements and does not affect pollutant emissions or air quality. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets EO 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 EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

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

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

I. National Technology Transfer and Advancement Act

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

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

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

Executive Order (EO) 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 has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This final rule does not relax the control measures on sources regulated by the rule and, therefore, will not cause emissions increases from these sources.

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 July 30, 2012.

List of Subjects in 40 CFR Part 60

Administrative practice and procedures, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 23, 2012.

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, Title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401–7601.

■ 2. Amend Appendix A–6 to Part 60 by adding ''Method 16C'' in alphanumeric order to read as follows:

Appendix A–6 to Part 60—Test Methods 16 Through 18

* * * * *

Method 16C—Determination of Total Reduced Sulfur Emissions From Stationary Sources

1.0 Scope and Application

What is Method 16C?

Method 16C is a procedure for measuring total reduced sulfur (TRS) in stationary source emissions using a continuous instrumental analyzer. Quality assurance and quality control requirements are included to assure that you, the tester, collect data of known quality. You must document your adherence to these specific requirements for equipment, supplies, sample collection and analysis, calculations, and data analysis. This method does not completely describe all equipment, supplies, and sampling and analytical procedures you will need but refers to other methods for some of the details. Therefore, to obtain reliable results, you should also have a thorough knowledge of these additional test methods which are found in appendix A to this part:

(a) Method 6C—Determination of Sulfur Dioxide Emissions from Stationary Sources (Instrumental Analyzer Procedure)

(b) Method 7E—Determination of Nitrogen Oxides Emissions from Stationary Sources (Instrumental Analyzer Procedure)

(c) Method 16A—Determination of Total Reduced Sulfur Emissions from Stationary Sources (Impinger Technique)

1.1 Analytes. What does Method 16C determine?

Analyte	CAS No.
Total reduced sulfur including:	N/A
Dimethyl disulfide (DMDS), [$(CH_3)_2S_2$]	62–49–20
Dimethyl sulfide (DMS), [$(CH_3)_2S$]	75–18–3
Hydrogen sulfide (H_2S)	7783–06–4
Methyl mercaptan (MeSH), (CH_4S)	74–93–1
Reported as: Sulfur dioxide (SO_2)	7449–09–5

1.2 Applicability. This method is applicable for determining TRS emissions from recovery furnaces (boilers), lime kilns, and smelt dissolving tanks at kraft pulp mills, and from other sources when specified in an applicable subpart of the regulations.

1.3 Data Quality Objectives. Adherence to the requirements described in Method 16C will enhance the quality of the data obtained.

2.0 Summary of Method

2.1 An integrated gas sample is extracted from the stack. The SO_2 is removed selectively from the sample using a citrate buffer solution. The TRS compounds are then thermally oxidized to SO_2 and determined as SO_2 by an instrumental analyzer. This method is a combination of the sampling procedures of Method 16A and the analytical procedures of Method 6C (referenced in Method 7E), with minor modifications to facilitate their use together.

3.0 Definitions

Analyzer calibration error, Calibration curve, Calibration gas, Low-level gas, Mid-level gas, High-level gas, Calibration drift, Calibration span, Data recorder, Direct calibration mode, Gas analyzer, Interference check, Measurement system, Response time, Run, System calibration mode, System performance check, and *Test* are the same as used in Methods 16A and 6C.

4.0 Interferences

4.1 Reduced sulfur compounds other than those defined as TRS, if present, may be measured by this method. Compounds like carbonyl sulfide, which is partially oxidized to SO_2 and may be present in a lime kiln exit stack, would be a positive interferent. Interferences may vary among instruments, and instrument-specific interferences must be evaluated through the interference check.

4.2 Particulate matter from the lime kiln stack gas (primarily calcium carbonate) can cause a negative bias if it is allowed to enter the citrate scrubber; the particulate matter will cause the pH to rise and H_2S to be absorbed before oxidation. Proper use of the particulate filter, described in Section 6.1.3 of Method 16A, will eliminate this interference.

5.0 Safety

5.1 Disclaimer. This method may involve hazardous materials, operations, and equipment. This test method may not address all of the safety problems associated with its use. It is the responsibility of the user to establish appropriate safety and health practices before performing this test method.

5.2 Hydrogen Sulfide. Hydrogen sulfide is a flammable, poisonous gas with the odor of rotten eggs. Hydrogen sulfide is extremely hazardous and can cause collapse, coma, and death within a few seconds of one or two inhalations at sufficient concentrations. Low concentrations irritate the mucous membranes and may cause nausea, dizziness, and headache after exposure. It is the responsibility of the user of this test method to establish appropriate safety and health practices.

6.0 Equipment and Supplies

What do I need for the measurement system?

The measurement system is similar to those applicable components in Methods 16A and 6C. Modifications to the apparatus are accepted provided the performance criteria in Section 13.0 are met.

6.1 Probe. Teflon tubing, 6.4-mm (¼ in.) diameter, sequentially wrapped with heat-resistant fiber strips, a rubberized heat tape (plug at one end), and heat-resistant adhesive tape. A flexible thermocouple or other suitable temperature measuring device must be placed between the Teflon tubing and the fiber strips so that the temperature can be monitored to prevent softening of the probe. The probe must be sheathed in stainless steel to provide in-stack rigidity. A series of bored-out stainless steel fittings placed at the front of the sheath will prevent moisture and particulate from entering between the probe and sheath. A 6.4-mm (¼ in.) Teflon elbow (bored out) must be attached to the inlet of the probe, and a 2.54 cm (1 in.) piece of Teflon tubing must be attached at the open end of the elbow to permit the opening of the probe to be turned away from the particulate stream; this will reduce the amount of particulate drawn into the sampling train. The probe is depicted in Figure 16A–2 of Method 16A.

6.2 Probe Brush. Nylon bristle brush with handle inserted into a 3.2-mm (⅛ in.) Teflon tubing. The Teflon tubing should be long enough to pass the brush through the length of the probe.

6.3 Particulate Filter. 50-mm Teflon filter holder and a 1- to 2-μm porosity, Teflon filter (may be available through Savillex Corporation, 5325 Highway 101, Minnetonka, Minnesota 55343, or other suppliers of filters). The filter holder must be maintained in a hot box at a temperature sufficient to prevent moisture condensation. A temperature of 121 °C (250 °F) was found to

be sufficient when testing a lime kiln under sub-freezing ambient conditions.

6.4 SO_2 Scrubber. Three 300-ml Teflon segmented impingers connected in series with flexible, thick-walled, Teflon tubing. (Impinger parts and tubing may be available through Savillex or other suppliers.) The first two impingers contain 100 ml of citrate buffer, and the third impinger is initially dry. The tip of the tube inserted into the solution should be constricted to less than 3 mm (⅛ in.) ID and should be immersed to a depth of at least 5 cm (2 in.).

6.5 Combustion Tube. Quartz glass tubing with an expanded combustion chamber 2.54 cm (1 in.) in diameter and at least 30.5 cm (12 in.) long. The tube ends should have an outside diameter of 0.6 cm (¼ in.) and be at least 15.3 cm (6 in.) long. This length is necessary to maintain the quartz-glass connector near ambient temperature and thereby avoid leaks. Alternative combustion tubes are acceptable provided they are shown to combust TRS at concentrations encountered during tests.

6.6 Furnace. A furnace of sufficient size to enclose the combustion chamber of the combustion tube with a temperature regulator capable of maintaining the temperature at 800 ± 100 °C (1472 ± 180 °F). The furnace operating temperature should be checked with a thermocouple to ensure accuracy.

6.7 Sampling Pump. A leak-free pump is required to pull the sample gas through the system at a flow rate sufficient to minimize the response time of the measurement system and must be constructed of material that is non-reactive to the gas it contacts. For dilution-type measurement systems, an eductor pump may be used to create a vacuum that draws the sample through a critical orifice at a constant rate.

6.8 Calibration Gas Manifold. The calibration gas manifold must allow the introduction of calibration gases either directly to the gas analyzer in direct calibration mode or into the measurement system, at the probe, in system calibration mode, or both, depending upon the type of system used. In system calibration mode, the system must be able to flood the sampling probe and vent excess gas. Alternatively, calibration gases may be introduced at the calibration valve following the probe. Maintain a constant pressure in the gas manifold. For in-stack dilution-type systems, a gas dilution subsystem is required to transport large volumes of purified air to the sample probe, and a probe controller is needed to maintain the proper dilution ratio.

6.9 Sample Gas Manifold. The sample gas manifold diverts a portion of the sample to the analyzer, delivering the remainder to the by-pass discharge vent. The manifold should also be able to introduce calibration gases directly to the analyzer. The manifold must be made of material that is non-reactive to SO_2 and be configured to safely discharge the bypass gas.

6.10 SO_2 Analyzer. You must use an instrument that uses an ultraviolet, non-dispersive infrared, fluorescence, or other detection principle to continuously measure SO_2 in the gas stream provided it meets the performance specifications in Section 13.0.

6.11 Data Recording. A strip chart recorder, computerized data acquisition system, digital recorder, or data logger for recording measurement data must be used.

7.0 Reagents and Standards

Note: Unless otherwise indicated, all reagents must conform to the specifications established by the Committee on Analytical Reagents of the American Chemical Society. When such specifications are not available, the best available grade must be used.

7.1 Water. Deionized distilled water must conform to ASTM Specification D 1193–77 or 91 Type 3 (incorporated by reference—see § 60.17). The $KMnO_4$ test for oxidizable organic matter may be omitted when high concentrations of organic matter are not expected to be present.

7.2 Citrate Buffer. Dissolve 300 g of potassium citrate (or 284 g of sodium citrate) and 41 g of anhydrous citric acid in 1 liter of water (200 ml is needed per test). Adjust the pH to between 5.4 and 5.6 with potassium citrate or citric acid, as required.

7.3 Calibration Gas. Refer to Section 7.1 of Method 7E (as applicable) for the calibration gas requirements. Example calibration gas mixtures are listed below.

(a) SO_2 in nitrogen (N_2).
(b) SO_2 in air.
(c) SO_2 and carbon dioxide (CO_2) in N_2.
(d) SO_2 and oxygen (O_2) in N_2.
(e) $SO_2/CO_2/O_2$ gas mixture in N_2.
(f) CO_2/NO_X gas mixture in N_2.
(g) $CO_2/SO_2/NO_X$ gas mixture in N_2.

For fluorescence-based analyzers, the O_2 and CO_2 concentrations of the calibration gases as introduced to the analyzer must be within 1.0 percent (absolute) O_2 and 1.0 percent (absolute) CO_2 of the O_2 and CO_2 concentrations of the effluent samples as introduced to the analyzer. Alternatively, for fluorescence-based analyzers, use calibration blends of SO_2 in air and the nomographs provided by the vendor to determine the quenching correction factor (the effluent O_2 and CO_2 concentrations must be known). This requirement does not apply to ambient-level fluorescence analyzers that are used in conjunction with sample dilution systems. Alternatively, H_2S in O_2 or air may be used to calibrate the analyzer through the tube furnace.

7.4 System Performance Check Gas. You must use H_2S (100 ppmv or less) stored in aluminum cylinders with the concentration certified by the manufacturer. Hydrogen sulfide in nitrogen is more stable than H_2S in air, but air may be used as the balance gas. **Note:** Alternatively, H_2S recovery gas generated from a permeation device gravimetrically calibrated and certified at some convenient operating temperature may be used. The permeation rate of the device must be such that at the appropriate dilution gas flow rate, an H_2S concentration can be generated in the range of the stack gas or within 20 percent of the emission standard.

7.5 Interference Check. Examples of test gases for the interference check are listed in Table 7E–3 of Method 7E.

8.0 Sample Collection, Preservation, Storage, and Transport

8.1 Pre-sampling Tests. Before measuring emissions, perform the following procedures:

(a) Calibration gas verification,
(b) Calibration error test,
(c) System performance check,
(d) Verification that the interference check has been satisfied.

8.1.1 Calibration Gas Verification. Obtain a certificate from the gas manufacturer documenting the quality of the gas. Confirm that the manufacturer certification is complete and current. Ensure that your calibration gas certifications have not expired. This documentation should be available on-site for inspection. To the extent practicable, select a high-level gas concentration that will result in the measured emissions being between 20 and 100 percent of the calibration span.

8.1.2 Analyzer Calibration Error Test. After you have assembled, prepared, and calibrated your sampling system and analyzer, you must conduct a 3-point analyzer calibration error test before the first run and again after any failed system performance check or failed drift test to ensure the calibration is acceptable. Introduce the low-, mid-, and high-level calibration gases sequentially to the analyzer in direct calibration mode. For each calibration gas, calculate the analyzer calibration error using Equation 16C–1 in Section 12.2. The calibration error for the low-, mid-, and high-level gases must not exceed 5.0 percent or 0.5 ppmv. If the calibration error specification is not met, take corrective action and repeat the test until an acceptable 3-point calibration is achieved.

8.1.3 System Performance Check. A system performance check is done (1) to validate the sampling train components and procedure (prior to testing), and (2) to validate a test run (after a run). You must conduct a performance check in the field prior to testing, and after each 3-hour run or after three 1-hour runs. A performance check consists of sampling and analyzing a known concentration of H_2S (system performance check gas) and comparing the analyzed concentration to the known concentration. To conduct the system performance check, mix the system performance check gas (Section 7.4) and ambient air, that has been conditioned to remove moisture and sulfur-containing gases, in a dilution system such as that shown in Figure 16A–3 of Method 16A. Alternatively, ultra-high purity (UHP) grade air may be used. Adjust the gas flow rates to generate an H_2S concentration in the range of the stack gas or within 20 percent of the applicable standard and an oxygen concentration greater than 1 percent at a total flow rate of at least 2.5 liters/min (5.3 ft3/hr). Use Equation 16A–3 from Method 16A to calculate the concentration of system performance check gas generated. Calibrate the flow rate from both gas sources with a soap bubble flow meter so that the diluted concentration of H_2S can be accurately calculated. Alternatively, mass flow controllers with documented calibrations may be used if UHP grade air is being used. Sample duration should be sufficiently long to ensure a stable response from the analyzer.

Analyze in the same manner as the emission samples. Collect the sample through the probe of the sampling train using a manifold or other suitable device that will ensure extraction of a representative sample. The TRS sample concentration measured between system performance checks is corrected by the average of the pre- and post-system performance checks.

8.1.4 Interference Check. Same as in Method 7E, Section 8.2.7.

8.2 Measurement System Preparation.

8.2.1 For the SO_2 scrubber, measure 100 ml of citrate buffer into the first and second impingers; leave the third impinger empty. Immerse the impingers in an ice bath, and locate them as close as possible to the filter heat box. The connecting tubing should be free of loops. Maintain the probe and filter temperatures sufficiently high to prevent moisture condensation, and monitor with a suitable temperature sensor. Prepare the oxidation furnace and maintain at 800 ± 100°C (1472 ± 180°F).

8.2.2 Citrate Scrubber Conditioning Procedure. Condition the citrate buffer scrubbing solution by pulling stack gas through the Teflon impingers as described in Section 8.4.1.

8.3 Pretest Procedures. After the complete measurement system has been set up at the site and deemed to be operational, the following procedures must be completed before sampling is initiated.

8.3.1 Leak-Check. Appropriate leak-check procedures must be employed to verify the integrity of all components, sample lines, and connections. For components upstream of the sample pump, attach the probe end of the sample line to a manometer or vacuum gauge, start the pump and pull a vacuum greater than 50 mm (2 in.) Hg, close off the pump outlet, and then stop the pump and ascertain that there is no leak for 1 minute. For components after the pump, apply a slight positive pressure and check for leaks by applying a liquid (detergent in water, for example) at each joint. Bubbling indicates the presence of a leak.

8.3.2 Initial System Performance Check. A system performance check using the test gas (Section 7.4) is performed prior to testing to validate the sampling train components and procedure.

8.4 Sample Collection and Analysis.

8.4.1 After performing the required pretest procedures described in Section 8.1, insert the sampling probe into the test port ensuring that no dilution air enters the stack through the port. Condition the sampling system and citrate buffer solution for a minimum of 15 minutes before beginning analysis. Begin sampling and analysis. A source test consists of three test runs. A test run shall consist of a single sample collected over a 3-hour period or three separate 1-hour samples collected over a period not to exceed six hours.

8.5 Post-Run Evaluations.

8.5.1 System Performance Check. Perform a post-run system performance check before replacing the citrate buffer solution and particulate filter and before the probe is cleaned. The check results must not exceed the 100 ± 20 percent limit set forth in Section 13.2. If this limit is exceeded, the intervening run is considered invalid. However, if the recovery efficiency is not in the 100 ± 20 percent range, but the results do not affect the compliance or noncompliance status of the affected facility, the Administrator may decide to accept the results of the compliance test.

8.5.2 Calibration Drift. After a run or series of runs, not to exceed a 24-hour period after initial calibration, perform a calibration drift test using a calibration gas (preferably the level that best approximates the sample concentration) in direct calibration mode. This drift must not differ from the initial calibration error percent by more than 3.0 percent or 0.5 ppm. If the drift exceeds this limit, the intervening run or runs are considered valid, but a new analyzer calibration error test must be performed and passed before continuing sampling.

9.0 Quality Control

Section	Quality control measure	Effect
8.1.2	Analyzer calibration error test	Establishes initial calibration accuracy within 5.0%.
8.1.3, 8.5.1	System performance check	Ensures accuracy of sampling/analytical procedure to 100 ± 20%.
8.5.2	Calibration drift test	Ensures calibration drift is within 3.0%.
8.1.4	Interference check	Checks for analytical interferences.
8.3	Sampling equipment leak-check	Ensures accurate measurement of sample gas flow rate, sample volume.

10.0 Calibration

10.1 Calibrate the system using the gases described in Section 7.3. Perform the initial 3-point calibration error test as described in Section 8.1.2 before you start the test. The specification in Section 13 must be met. Conduct an initial system performance test described in Section 8.1.3 as well before the test to validate the sampling components and procedures before sampling. After the test commences, a system performance check is required after each run. You must include a copy of the manufacturer's certification of the calibration gases used in the testing as part of the test report. This certification must include the 13 documentation requirements in the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, September 1997, as amended August 25, 1999.

11.0 Analytical Procedure

Because sample collection and analysis are performed together (see Section 8.0), additional discussion of the analytical procedure is not necessary.

12.0 Calculations and Data Analysis

12.1 Nomenclature.

ACE = Analyzer calibration error, percent of calibration span.
CD = Calibration drift, percent.
C_{Dir} = Measured concentration of a calibration gas (low, mid, or high) when introduced in direct calibration mode, ppmv.
C_{H2S} = Concentration of the system performance check gas, ppmv H_2S.
C_M = Average of initial and final system calibration bias check responses for the upscale calibration gas, ppmv.
C_{MA} = Actual concentration of the upscale calibration gas, ppmv.
C_O = Average of the initial and final system calibration bias check responses from the low-level (or zero) calibration gas, ppmv.
C_{OA} = Actual concentration of the low-level calibration gas, ppmv.
C_S = Measured concentration of the system performance gas when introduced in system calibration mode, ppmv H_2S.
C_V = Manufacturer certified concentration of a calibration gas (low, mid, or high), ppmv SO_2.
C_{SO2} = Unadjusted sample SO_2 concentration, ppmv.
C_{TRS} = Total reduced sulfur concentration corrected for system performance, ppmv.
DF = Dilution system (if used) dilution factor, dimensionless.
SP = System performance, percent.

12.2 Analyzer Calibration Error. Use Equation 16C–1 to calculate the analyzer calibration error for the low-, mid-, and high-level calibration gases.

$$ACE = \frac{C_{Dir} - C_v}{C_v} x\,100 \qquad \text{Eq. 16C-1}$$

12.3 System Performance Check. Use Equation 16C–2 to calculate the system performance.

$$SP = \frac{C_S - C_{H2S}}{C_{H2S}} x\,100 \qquad \text{Eq. 16C-2}$$

12.4 Calibration Drift. Use Equation 16C–3 to calculate the calibration drift at a single concentration level after a run or series of runs (not to exceed a 24-hr period) from initial calibration. Compare the single-level calibration gas error (ACE_n) to the original error obtained for that gas in the initial analyzer calibration error test (ACE_i).

$$CD = \left|ACE_i - ACE_n\right| \qquad \text{Eq. 16C-3}$$

12.5 TRS Concentration as SO_2. For each sample or test run, calculate the arithmetic average of SO_2 concentration values (e.g., 1-minute averages). Then calculate the sample TRS concentration by adjusting the average value of C_{SO2} for system performance using Equation 16C–4a if you use a non-zero gas as your low-level calibration gas, or Equation 16C–4b if you use a zero gas as your low-level calibration gas.

$$C_{TRS} = (C_{SO2\ Avg} - C_M)\frac{C_{MA} - C_{OA}}{C_M - C_O} + C_{MA} \qquad \text{Eq. 16C-4a}$$

$$C_{TRS} = \frac{(C_{SO2\ Avg} - C_O)C_{MA}}{C_M - C_O} \qquad \text{Eq. 16C-4b}$$

13.0 Method Performance

13.1 Analyzer Calibration Error. At each calibration gas level (low, mid, and high), the calibration error must either not exceed 5.0 percent of the calibration gas concentration or $|C_{Dir} - C_v|$ must be ≤0.5 ppmv.

13.2 System Performance. Each system performance check must not deviate from the system performance gas concentration by more than 20 percent. Alternatively, the results are acceptable if $|C_s - C_{H2S}|$ is ≤0.5 ppmv.

13.3 Calibration Drift. The calibration drift at the end of any run or series of runs within a 24-hour period must not differ by more than 3.0 percent from the original ACE at the test concentration level or $|ACEi - ACE_n|$ must not exceed 0.5 ppmv.

13.4 Interference Check. For the analyzer, the total interference response (i.e., the sum of the interference responses of all tested gaseous components) must not be greater than 2.5 percent of the calibration span. Any interference is also acceptable if the sum of the responses does not exceed 0.5 ppmv for a calibration span of 5 to 10 ppmv, or 0.2 ppmv for a calibration span <5 ppmv.

14.0 Pollution Prevention [Reserved]

15.0 Waste Management [Reserved]

16.0 References

1. The references are the same as in Section 16.0 of Method 16, Section 17.0 of Method 16A, and Section 17.0 of Method 6C.
2. National Council of the Paper Industry for Air and Stream Improvement, Inc,. A Study of TRS Measurement Methods. Technical Bulletin No. 434. New York, NY. May 1984. 12p.
3. Margeson, J.H., J.E. Knoll, and M.R. Midgett. A Manual Method for TRS Determination. Draft available from the authors. Source Branch, Quality Assurance Division, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

17.0 Tables, Diagrams, Flowcharts, and Validation Data [Reserved]

* * * * *

[FR Doc. 2012–18513 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 122

[EPA–HQ–OW–2012–0142; FRL–9705–6]

RIN 2040–AF40

National Pollutant Discharge Elimination System Permit Regulation for Concentrated Animal Feeding Operations: Removal of Vacated Elements in Response to 2011 Court Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is amending its regulations to eliminate the requirement that an owner or operator of a Concentrated Animal Feeding Operation (CAFO) that ''proposes to discharge'' must apply for a National Pollutant Discharge Elimination System (NPDES) Permit. This rulemaking also removes the voluntary certification option for unpermitted CAFOs because removal of the ''propose to discharge'' requirement renders the certification option unnecessary. Its purpose had been to allow CAFO owners and operators to certify that they were not violating the requirement that owners or operators of CAFOs that propose to discharge must seek permit coverage. Both of these

provisions were included in the EPA's rulemaking entitled ''Revised National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitations Guidelines for Concentrated Animal Feeding Operations in Response to the Waterkeeper Decision,'' (the 2008 CAFO Rule).

DATES: This final rule is effective on July 30, 2012.

ADDRESSES: The record for this rulemaking is available for inspection and copying at the Water Docket, located at the EPA Docket Center (EPA/DC), EPA West 1301 Constitution Ave. NW., Washington, DC 20004. The record is also available via the EPA Dockets at *http://www.regulations.gov* under docket number EPA–HQ–OW–2012–0142. The rule and key supporting documents are also available electronically on the Internet at *http://www.epa.gov/npdes/caforule.*

FOR FURTHER INFORMATION CONTACT: For further information contact Louis Eby, Water Permits Division, Office of Wastewater Management (4203M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, telephone number: (202) 564–6599, email address: *eby.louis@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information
II. Background and Rationale for Action
III. Implementation
IV. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act
V. Statutory Authority

I. General Information

A. Does this action apply to me?

This action applies to CAFOs as specified in section 502(14) of the Clean Water Act (CWA), 33 U.S.C. 1362(14) and defined in the NPDES regulations at 40 CFR 122.23. Table 1.1 provides a list of standard industrial codes for operations potentially regulated under this revised rule. The rule also applies to States and Tribes with authorized NPDES Programs.

TABLE 1.1—OPERATIONS POTENTIALLY REGULATED BY THIS RULE

Category	Examples of regulated entities	North American Industry Classification System (NAICS)	Standard Industrial Classification (SIC)
Industry	Operators of animal production operations that meet the definition of a CAFO:		
	Beef cattle feedlots (including veal calves)	112112	0211
	Beef cattle ranching and farming	112111	0212
	Hogs	11221	0213
	Sheep and Goats	11241, 11242	0214
	General livestock except dairy and poultry	11299	0219
	Dairy farms	11212	0241
	Broilers, fryers, and roaster chickens	11232	0251
	Chicken eggs	11231	0252
	Turkey and turkey eggs	11233	0253
	Poultry hatcheries	11234	0254
	Poultry and eggs	11239	0259
	Ducks	11239	0259
	Horses and other equines	11292	0272

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the definitions and other provisions of 40 CFR 122.23.

II. Background and Rationale for Action

On November 20, 2008, the EPA published a final rule (73 FR 70418) that revised the NPDES permitting requirements and Effluent Limitations Guidelines and Standards for CAFOs in response to the order issued by the U.S. Court of Appeals for the Second Circuit in *Waterkeeper Alliance et al.* v. *EPA,* 399 F.3d 486 (2d Cir. 2005). The 2008 CAFO Rule included a number of changes, including a requirement that CAFO owners or operators that discharge or propose to discharge must apply for an NPDES permit. The 2008 CAFO Rule also created a voluntary option for unpermitted CAFO owners and operators to certify to the permitting authority that the CAFO does not discharge or propose to discharge.

On March 15, 2011, the United States Court of Appeals for the Fifth Circuit (the Court) issued an opinion that, among other things, vacated those portions of the 2008 CAFO Rule requiring CAFOs that propose to discharge to apply for an NPDES permit. *National Pork Producers Council* v. *EPA,* 635 F.3d 738, 756 (5th Cir. 2011). This action removes from the Code of Federal Regulations (CFR) the specific ''propose to discharge'' requirement in 40 CFR 122.23(d).

Today's action also deletes the timing requirements in 40 CFR 122.23(f) related to when CAFO owners and operators must seek coverage under an NPDES permit. These provisions extended the time by which facilities newly required to obtain NPDES permits must apply for a permit. The date-specific deadlines in those sections have passed. The revision clarifies that all CAFOs must have a permit at the time that they discharge.

The rule also removes 40 CFR 122.23(g) to make conforming changes to EPA's requirements for renewing permit coverage.

Also, this action removes from the CFR the option in 40 CFR 122.23(i) and (j) for owners and operators to

voluntarily certify that a CAFO does not discharge or propose to discharge. The option provides that properly certified CAFOs would ''not be in violation of the requirement that CAFOs that propose to discharge seek permit coverage. * * *'' Removing the requirement that CAFOs apply for permits if they ''propose to discharge'' renders the option to certify unnecessary and therefore the EPA is eliminating it.

The EPA is not providing an opportunity for comment on this final rule. The Administrative Procedure Act of 1946 (APA) makes provision for the procedural path we are following in this action. In general, the APA requires that general notice of proposed rulemaking shall be published in the **Federal Register**. Such notice must provide an opportunity for public participation in the rulemaking process. The APA does provide an avenue for an agency to directly issue a final rulemaking in certain specific instances. This may occur, in particular, when an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. See 5 U.S.C. 553(b)(3)(B).

The EPA finds that a notice-and-comment rulemaking is unnecessary and not in the public interest because this action is ministerial in nature. The EPA has no discretion given the specific circumstances presented in the Court's opinion. The EPA is bound by the decisions of the court and must act in accordance with that decision. The EPA accepts the decision of the Court that vacated the requirement that CAFOs that propose to discharge apply for NPDES permits and the EPA lacks discretion to reach a different conclusion. Providing an opportunity for notice and comment is therefore unnecessary and would not serve any public interest.

III. Implementation

For the reasons cited above, the EPA is making this action effective upon publication. See 5 U.S.C. 553(d)(3). This action removes content from the CFR that has been found to be contrary to the CWA by a United States Court of Appeals. This is a ministerial but necessary action on the part of the EPA. Given the EPA's lack of discretion in this matter, the EPA has good cause to act in the public interest to implement the court's remedy by amending the CFR without delay.

The deadline has passed by which states were required to make any changes to their approved state NPDES program legal authorities necessary to conform to the 2008 CAFO Rule. States that have not yet done so must make the necessary changes to conform to the 2008 CAFO Rule, less the vacated provisions.

IV. Statutory and Executive Order Reviews

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

This rule withdraws Federal requirements applicable to CAFOs that propose to discharge as well as the option to certify that a CAFO does not discharge or propose to discharge. It imposes no regulatory requirements on any person or entity, does not interfere with the action or planned action of another agency, and does not have any budgetary impacts or raise novel legal or policy issues. The rule imposes no additional cost on the regulated community. The rule imposes no additional effort on the State regulators. Thus, this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011) and is therefore not subject to review under the Executive Orders.

B. Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), because it is administratively withdrawing Federal requirements.

C. Regulatory Flexibility Act

Today's final rule is not subject to the Regulatory Flexibility Act (RFA), which generally requires an agency to prepare a regulatory flexibility analysis for any rule that will have a significant economic impact on a substantial number of small entities. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute. Although the rule is subject to the APA, the Agency has invoked the ''good cause'' exemption under 5 USC 553(b), therefore it is not subject to the notice and comment requirement.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. Similarly, the EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments and is therefore not subject to UMRA section 203.

E. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), 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.''

This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule imposes no regulatory requirements on any State, Tribal, or local government. Thus, Executive Order 13132 does not apply to this rule.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (59 FR 22951, 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 rule does not have tribal implications, as specified in Executive Order 13175. It imposes no regulatory requirements or costs on any Tribal government. It does 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 and Safety Risks)

This rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and the EPA has no reason to believe the environmental health or safety risks addressed by this rule present a disproportionate risk to children.

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

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

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

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

The EPA has determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it merely removes regulations that were vacated by the U.S. Court of Appeals and, therefore, does not affect the level of protection provided to human health or the environment.

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. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of July 30, 2012. 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).

V. Statutory Authority

This rule is issued under the authority of sections 101, 301, 304, 306, 308, 402, and 501 of the CWA. 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342, and 1361.

List of Subjects in 40 CFR Part 122

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

Dated: July 19, 2012.

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, 40 CFR part 122 is amended as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 et seq.

■ 2. Section 122.23 is amended as follows:
■ a. By revising the heading of paragraph (d).
■ b. By revising paragraph (d)(1).
■ c. By revising paragraph (f).
■ d. By removing and reserving paragraph (g).
■ e. By removing paragraphs (i) and (j).

§ 122.23 Concentrated animal feeding operations (applicable to State NPDES programs, see § 123.25).

* * * * *

(d) *NPDES permit authorization.*—(1) *Permit Requirement.* A CAFO must not discharge unless the discharge is authorized by an NPDES permit. In order to obtain authorization under an NPDES permit, the CAFO owner or operator must either apply for an individual NPDES permit or submit a notice of intent for coverage under an NPDES general permit.

* * * * *

(f) *By when must the owner or operator of a CAFO have an NPDES permit if it discharges?* A CAFO must be covered by a permit at the time that it discharges.

* * * * *

[FR Doc. 2012–18378 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–B–1260]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps (FIRMs) in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The modified BFEs may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This interim rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This interim rule involves no policies that have federalism implications under Executive Order 13132, Federalism.

Executive Order 12988, Civil Justice Reform. This interim rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location and case No.	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Florida: Sumter	Unincorporated areas of Sumter County (11–04–4816P).	Sept. 22, 2011, Sept. 29, 2011, *The Sumter County Times.*	The Honorable Don Burgess, Chairman, Sumter County Board of Commissioners, 7375 Powell Road, Wildwood, FL 34785.	Jan. 27, 2012	120296
North Carolina: Orange.	Town of Chapel Hill (10–04–6903P).	Nov. 23, 2011, Nov. 30, 2011, *The Chapel Hill Herald.*	The Honorable Mark Kleinschmidt, Mayor, Town of Chapel Hill, 405 Martin Luther King, Jr. Boulevard, Chapel Hill, NC 27514.	Mar. 29, 2012	370180
Texas: Bexar	City of San Antonio (11–06–2247P).	Nov. 28, 2011, Dec. 5, 2011, *The San Antonio Express-News.*	The Honorable Julian Castro, Mayor, City of San Antonio, 100 Military Plaza, San Antonio, TX 78205.	Dec. 21, 2011	480045

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: July 12, 2012.

Sandra K. Knight,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–18493 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket ID FEMA–2012–0003]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified BFEs will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Maps (FIRMs) in effect

for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below of the modified BFEs for each community listed. These modified BFEs have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this final rule includes the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection.

The modified BFEs are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These modified BFEs are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings. The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132, Federalism.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p.376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location and case No.	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Alabama:					
Mobile (FEMA Docket No.: B–1240).	City of Mobile (11–04–2597P).	Nov. 10, 2011, Nov. 17, 2011, *The Press-Register.*	The Honorable Samuel L. Jones, Mayor, City of Mobile, 205 Government Street, South Tower, 10th Floor, Mobile, AL 36602.	Mar. 16, 2012	015007
Mobile (FEMA Docket No.: B–1235).	Unincorporated areas of Mobile County (11–04–1739P).	Oct. 27, 2011, Nov. 3, 2011, *The Press-Register.*	The Honorable Merceria Ludgood, Chair, Mobile County Commission, 205 Government Street, Mobile, AL 36644.	Mar. 2, 2012	015008
Arizona:					
Coconino (FEMA Docket No.: B–1244).	City of Flagstaff (11–09–0801P).	Oct. 27, 2011, Nov. 3, 2011, *The Arizona Daily Sun.*	The Honorable Sara Presler, Mayor, City of Flagstaff, 211 West Aspen Avenue, Flagstaff, AZ 86001.	Mar. 2, 2012	040020
Maricopa (FEMA Docket No.: B–1244).	City of Peoria (11–09–3985P).	Dec. 8, 2011, Dec. 15, 2011, *The Arizona Business Gazette.*	The Honorable Bob Barrett, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	Nov. 29, 2011	040050
California:					
Orange (FEMA Docket No.: B–1240).	City of Laguna Beach (11–09–3647P).	Nov. 4, 2011, Nov. 11, 2011, *The Laguna Beach Coastline Pilot.*	The Honorable Toni Iseman, Mayor, City of Laguna Beach, 505 Forest Avenue, Laguna Beach, CA 92651.	Mar. 12, 2012	060223
Santa Clara (FEMA Docket No.: B–1240).	City of San Jose (12–09–0140P).	Dec. 2, 2011, Dec. 9, 2011, *The San Jose Mercury News.*	The Honorable Chuck Reed, Mayor, City of San Jose, 200 East Santa Clara Street, San Jose, CA 95113.	Dec. 22, 2011	060349
Colorado:					
Adams (FEMA Docket No.: B–1235).	City of Commerce City (10–08–1048P).	Oct. 25, 2011, Nov. 1, 2011, *The Commerce City Sentinel Express.*	The Honorable Paul Natale, Mayor, City of Commerce City, 7887 East 60th Avenue, Commerce City, CO 80022.	Mar. 2, 2012	080006

State and county	Location and case No.	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
El Paso (FEMA Docket No.: B–1240).	City of Colorado Springs (11–08–0869P).	Nov. 2, 2011, Nov. 9, 2011, *The El Paso County Advertiser and News*.	The Honorable Steve Bach, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Colorado Springs, CO 80903.	Mar. 8, 2012	080060
El Paso (FEMA Docket No.: B–1240).	Unincorporated areas of El Paso County (11–08–0869P).	Nov. 2, 2011, Nov. 9, 2011, *The El Paso County Advertiser and News*.	The Honorable Dennis Hisey, Chairman, El Paso County Board of Commissioners, 27 East Vermijo Avenue, Colorado Springs, CO 80903.	Mar. 8, 2012	080059
Routt (FEMA Docket No.: B–1244).	Town of Hayden (11–08–0603P).	Nov. 6, 2011, Nov. 13, 2011, *The Steamboat Pilot & Today*.	The Honorable Jim Haskins, Mayor, Town of Hayden, 178 West Jefferson Avenue, Hayden, CO 81639.	Mar. 12, 2012	080157
Weld (FEMA Docket No.: B–1244).	City of Fort Lupton (11–08–0714P).	Nov. 9, 2011, Nov. 16, 2011, *The Greeley Tribune*.	The Honorable Tommy Holton, Mayor, City of Fort Lupton, 130 South McKinley Avenue, Fort Lupton, CO 80621.	Mar. 15, 2012	080183
Weld (FEMA Docket No.: B–1244).	Unincorporated areas of Weld County (11–08–0714P).	Nov. 9, 2011, Nov. 16, 2011, *The Greeley Tribune*.	The Honorable Douglas Rademacher, Chairman, Weld County Board of Commissioners, 1150 O Street, Greeley, CO 80631.	Mar. 15, 2012	080266
Florida:					
Escambia (FEMA Docket No.: B–1240).	Unincorporated areas of Escambia County (11–04–7674P).	Nov. 25, 2011, Dec. 2, 2011, *The Pensacola News Journal*.	The Honorable Wilson Robertson, Chairman, Escambia County Board of Commissioners, 221 Palafox Place, Suite 400, Pensacola, FL 32502.	Nov. 17, 2011	120080
Indian River (FEMA Docket No.: B–1240).	Town of Indian River Shores (11–04–7942P).	Nov. 25, 2011, Dec. 2, 2011, *The Indian River Press Journal*.	The Honorable Thomas W. Cadden, Mayor, Town of Indian River Shores, 6001 North Highway A1A, Indian River Shores, FL 32963.	Nov. 17, 2011	120121
Lee (FEMA Docket No.: B–1240).	Unincorporated areas of Lee County (12–04–0044P).	Nov. 25, 2011, Dec. 2, 2011, *The News-Press*.	The Honorable John Manning, Chairman, Lee County Board of Commissioners, 2120 Main Street, Fort Myers, FL 33901.	Nov. 17, 2011	125124
Lee (FEMA Docket No.: B–1244).	Unincorporated areas of Lee County (12–04–0347P).	Dec. 7, 2011, Dec. 14, 2011, *The News-Press*.	The Honorable John Manning, Chairman, Lee County Board of Commissioners, 2120 Main Street, Fort Myers, FL 33901.	Nov. 29, 2011	125124
Orange (FEMA Docket No.: B–1240).	City of Orlando (11–04–7338P).	Nov. 22, 2011, Nov. 29, 2011, *The Orlando Sentinel*.	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32802.	Mar. 28, 2012	120186
Orange (FEMA Docket No.: B–1244).	City of Orlando (11–04–8600P).	Dec. 5, 2011, Dec. 12, 2011, *The Orlando Sentinel*.	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32802.	Nov. 22, 2011	120186
Hawaii:					
Hawaii (FEMA Docket No.: B–1240).	City and County of Honolulu (11–09–3899P).	Nov. 10, 2011, Nov. 17, 2011, *The Honolulu Star-Advertiser*.	The Honorable Peter B. Carlisle, Mayor, City and County of Honolulu, 530 South King Street, Room 300, Honolulu, HI 96813.	Mar. 16, 2012	150001
Mississippi:					
DeSoto (FEMA Docket No.: B–1235).	City of Olive Branch (11–04–4496P).	Oct. 27, 2011, Nov. 3, 2011, *The DeSoto Times-Tribune*.	The Honorable Sam Rikard, Mayor, City of Olive Branch, 9200 Pigeon Roost Road, Olive Branch, MS 38654.	Mar. 2, 2012	280286
Lee (FEMA Docket No.: B–1240).	City of Saltillo (10–04–8523P).	Nov. 4, 2011, Nov. 11, 2011, *The Northeast Mississippi Daily Journal*.	The Honorable Bill Williams, Mayor, City of Saltillo, 395 Mobile Street, Saltillo, MS 38866.	Mar. 12, 2012	280261
Lee (FEMA Docket No.: B–1240).	Unincorporated areas of Lee County (10–04–8523P).	Nov. 4, 2011, Nov. 11, 2011, *The Northeast Mississippi Daily Journal*.	The Honorable Joe McKinney, Chairman, Lee County Board of Supervisors, 200 West Jefferson Street, Suite 100, Tupelo, MS 38801.	Mar. 12, 2012	280227
New Mexico:					
Chaves (FEMA Docket No.: B–1244).	City of Roswell (11–06–0142P).	Nov. 17, 2011, Nov. 24, 2011, *The Roswell Daily Record*.	The Honorable Del Jurney, Mayor, City of Roswell, 425 North Richardson Avenue, Roswell, NM 88202.	Mar. 23, 2012	350006
Chaves (FEMA Docket No.: B–1244).	Unincorporated areas of Chaves County (11–06–0142P).	Nov. 17, 2011, Nov. 24, 2011, *The Roswell Daily Record*.	The Honorable Stanton L. Riggs, Chaves County Manager, 1 Saint Mary's Place, Roswell, NM 88203.	Mar. 23, 2012	350125
Santa Fe (FEMA Docket No.: B–1244).	Unincorporated areas of Santa Fe County (11–06–0697P).	Nov. 29, 2011, Dec. 6, 2011, *The Santa Fe New Mexican*.	The Honorable Virginia Vigil, Chairman, Santa Fe County Commissioners, 102 Grant Avenue, Santa Fe, NM 87501.	Nov. 23, 2011	350069
New York:					
Dutchess (FEMA Docket No.: B–1244).	Town of Dover (12–02–0166P).	Nov. 23, 2011, Nov. 30, 2011, *The Poughkeepsie Journal*.	The Honorable Ryan Courtien, Supervisor, Town of Dover, 126 East Duncan Hill Road, Dover Plains, NY 12522.	May 3, 2012	361335
North Carolina:					
Stanly (FEMA Docket No.: B–1244).	City of Albemarle (11–04–3287P).	Nov. 3, 2011, Nov. 10, 2011, *The Stanly News & Press*.	The Honorable Elbert L. Whitley, Jr., Mayor, City of Albemarle, 144 North 2nd Street, Albemarle, NC 28001.	Mar. 9, 2012	370223
Stanly (FEMA Docket No.: B–1244).	Unincorporated areas of Stanly County (11–04–3287P).	Nov. 3, 2011, Nov. 10, 2011, *The Stanly News & Press*.	Mr. Andy Lucas, Stanly County Manager, 1000 North 1st Street, Suite 10, Albemarle, NC 28001.	Mar. 9, 2012	370361
Texas:					

State and county	Location and case No.	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Denton (FEMA Docket No.: B–1244).	City of Denton (11–06–3838P).	Nov. 17, 2011, Nov. 24, 2011, *The Denton Record-Chronicle*.	The Honorable Mark A. Burroughs, Mayor, City of Denton, 215 East McKinney Street, Denton, TX 76201.	Nov. 10, 2011	480194
Tarrant (FEMA Docket No.: B–1244).	City of Southlake (11–06–2709P).	Nov. 10, 2011, Nov. 17, 2011, *The Fort Worth Star-Telegram*.	The Honorable John Terrell, Mayor, City of Southlake, 1400 Main Street, Suite 270, Southlake, TX 76092.	Mar. 16, 2012	480612
Virginia:					
Loudoun (FEMA Docket No.: B–1244).	Unincorporated areas of Loudoun County (11–03–0738P).	Nov. 30, 2011, Dec. 7, 2011, *The Loudoun Times Mirror*.	The Honorable Scott K. York, Chairman, Loudoun County Board of Supervisors, 1 Harrison Street, Leesburg, VA 20175.	Apr. 5, 2012	510090

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: July 12, 2012.

Sandra K. Knight,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–18494 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 111213751–2102–02]

RIN 0648–XC129

Fisheries of the Exclusive Economic Zone Off Alaska; Arrowtooth Flounder in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the non-specified reserve to the initial total allowable catch of arrowtooth flounder in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to allow the fisheries to continue operating. It is intended to promote the goals and objectives of the fishery management plan for the Bering Sea and Aleutian Islands management area.

DATES: Effective July 25, 2012 through 2400 hrs, Alaska local time, December 31, 2012. Comments must be received at the following address no later than 4:30 p.m., Alaska local time, August 9, 2012.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS 2012–0150, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*. To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS 2012–0150 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on that line.
- *Mail:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.
- *Fax:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Fax comments to 907–586–7557.
- *Hand delivery to the Federal Building:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Deliver comments to 709 West 9th Street, Room 420A, Juneau, AK.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address) submitted voluntarily by the sender will be publicly accessible.

Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7269.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the (BSAI) exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2012 initial total allowable catch (ITAC) of arrowtooth flounder in the BSAI was established as 21,250 metric tons (mt) by the final 2012 and 2013 harvest specifications for groundfish of the BSAI (77 FR 10669, February 23, 2012). In accordance with § 679.20(a)(3) the Regional Administrator, Alaska Region, NMFS, has reviewed the most current available data and finds that the ITAC for arrowtooth flounder in the BSAI needs to be supplemented from the non-specified reserve in order to promote efficiency in the utilization of fishery resources in the BSAI and allow fishing operations to continue.

Therefore, in accordance with § 679.20(b)(3), NMFS apportions from the non-specified reserve of groundfish 1,075 mt to the arrowtooth flounder ITAC in the BSAI. This apportionment is consistent with § 679.20(b)(1)(i) and does not result in overfishing of a target species because the revised ITAC is equal to or less than the specifications of the acceptable biological catch in the final 2012 and 2013 harvest specifications for groundfish in the BSAI (77 FR 10669, February 23, 2012).

The harvest specification for the 2012 arrowtooth flounder ITAC included in the harvest specifications for groundfish in the BSAI is revised as follows: 22,325 mt for arrowtooth flounder in the BSAI.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) and § 679.20(b)(3)(iii)(A) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the apportionment of the non-specified reserves of groundfish to the arrowtooth flounder fishery in the BSAI. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet and processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 24, 2012.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Under § 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES**) until August 9, 2012.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: July 25, 2012.

James P. Burgess,

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

[FR Doc. 2012–18512 Filed 7–25–12; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 146
Monday, July 30, 2012

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.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 741

RIN 3133–AD96

Maintaining Access to Emergency Liquidity

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice of proposed rulemaking with request for comment (NPRM).

SUMMARY: The NCUA Board (Board) is requesting public comment on a proposed regulation requiring federally insured credit unions (FICUs) with assets of $10 million or more to have a contingency funding plan that clearly sets out strategies for addressing liquidity shortfalls in emergency situations. The NPRM also requires FICUs with assets of $100 million or more to have access to a backup federal liquidity source for emergency situations. Finally, the NPRM requires FICUs with less than $10 million in assets to maintain a basic written policy that provides a board-approved framework for managing liquidity and a list of contingent liquidity sources that can be employed under adverse circumstances. The NPRM follows an earlier Advance Notice of Proposed Rulemaking (ANPR) requesting public comment on the scope and requirements of a regulation regarding backup liquidity requirements.

DATES: We must receive your comments on or before September 28, 2012.

ADDRESSES: You may submit comments by any one of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name]—Comments on Notice of Proposed Rulemaking for Part 741, Maintaining Access to Emergency Liquidity'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You can view all public comments on NCUA's Web site at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Lisa Henderson, Staff Attorney, Office of General Counsel, at the address above or telephone (703) 518–6540; or J. Owen Cole, Jr., Director, Division of Credit and Capital Markets, Office of Examination and Insurance, at the address above or telephone (703) 518–6620.

SUPPLEMENTARY INFORMATION:

I. Background
II. Proposed Rule
III. Regulatory Procedures

I. Background

A. Why did NCUA initiate this rulemaking?

The recent financial crisis demonstrated the importance of access to reliable emergency liquidity. Currently, 6,019 [1] FICUs have access to the Central Liquidity Facility (CLF or facility) by belonging to a corporate credit union that is in turn part of the agent group headed by U.S. Central Bridge Corporate Federal Credit Union (U.S. Central Bridge).[2] U.S. Central Bridge temporarily holds CLF stock on behalf of the whole agent group, but it is expected to close in October 2012. When U.S. Central Bridge redeems the CLF stock upon its closure,[3] these FICUs will no longer have the CLF as a source of backup liquidity, unless they choose to join the CLF directly. In light of these changes, the Board issued an ANPR on the issue of maintaining credit union system liquidity. 76 FR 79553 (Dec. 22, 2011).

B. What is the CLF and how does it operate?

Before discussing the specifics of the ANPR's request, the Board believes it may be helpful to repeat some of the background material the ANPR provided regarding the recent financial crisis and the structure and operations of the CLF.

Depository institutions need to have access to sources of emergency liquidity from both their own balance sheets and through credit facilities. When a depository institution exhibits liquidity problems and its credit providers have uncertainty about its true financial condition, that institution's ability to obtain credit can rapidly diminish or cease altogether. The inability of a depository institution to fund its business-as-usual operations by borrowing can, in turn, cause its ultimate insolvency and failure if, for example, it were forced to sell assets at distressed prices to raise necessary funds. In the financial crisis, even institutions that were healthy used emergency liquidity facilities when risk aversion reduced the availability of even short-term liquidity and funding costs became prohibitively high. Without access to governmental liquidity facilities, the scope of the crisis and damage to the economy would have been much more severe.

Governmental liquidity facilities were created by Congress to provide a stability mechanism to preempt illiquidity situations before they lead to unnecessary insolvencies or cause systemic disruptions to the depository industry. This is because depository institutions are a key element of financial services and the overall economy. Federal entities that exist to provide liquidity assistance are unique in their capacity to obtain funding in times of crisis, and this is based on their backing by the full faith and credit of the U.S. government. These liquidity

[1] This number is based on the 2012 agent member annual stock adjustment. It excludes credit unions that are not regular members of the CLF and not members of a corporate credit union.

[2] NCUA established U.S. Central Bridge to provide an orderly transition in resolving the failure of U.S. Central Corporate Federal Credit Union, which historically held the CLF capital stock on behalf of the majority of credit unions.

[3] *See* 12 U.S.C. 1795d(c); 12 CFR 725.6(d)(1).

facilities are viewed as the ultimate backstop for institutions seeking emergency liquidity in time of need and have proven to be a critical component of the U.S. government's contingency management during times of widespread instability.

By way of example, CLF figured prominently in NCUA's contingency plans during the financial crisis. Through various contingency programs, such as the Credit Union System Investment Program, the Credit Union Homeowners Affordability Relief Program, and loans to the National Credit Union Share Insurance Fund (NCUSIF), CLF facilitated access to billions of dollars of external liquidity. These programs totaled approximately $18.4 billion and were orchestrated during the period between December 2008 and March 2009. Total CLF activity during the height of the crisis reached as much as $20.5 billion, including approximately $2.1 billion in liquidity-need loans outstanding. By having ready access to contingent liquidity through CLF, NCUA was in a position to inject a critical amount of emergency liquidity into the credit union system. These liquidity injections helped stabilize confidence and gave NCUA time to work through the financial difficulties arising from the failure of the system's largest corporate credit unions. They, combined with other actions taken by the Board, were instrumental in maintaining the continuity of vital credit union services and helped avert higher potential losses to the system.

Essentially, CLF provides a form of liquidity insurance to its member credit unions through its ability to make liquidity advances to members funded with matched borrowings from the Federal Financing Bank.[4] A credit union primarily serving natural persons may become a ''regular'' member of the facility by subscribing to the capital stock of the facility. 12 U.S.C. 1795c(a); 12 CFR § 725.3. A credit union or group of credit unions primarily serving other credit unions may become an agent member of the facility by obtaining approval from the Board and subscribing to the capital stock of the facility on behalf of credit unions in its membership that are not regular members. 12 U.S.C. 1795c(b); 12 CFR 725.4. Currently, there is one agent group representative, with 19 agent members within that group.

Historically, most natural person credit unions have not elected to become regular members. Instead, they have qualified for membership in CLF by joining a corporate that was in turn a CLF agent and part of the agent group headed by U.S. Central Bridge. As the agent group representative, U.S. Central Bridge subscribed to, and absorbed the costs of, capital stock on behalf of all underlying natural person credit unions represented by the respective corporate credit unions in U.S. Central Bridge's agent group. U.S. Central Bridge is expected to close in October 2012, and its role as CLF agent group representative will cease at that time. When that occurs, the natural person credit unions that have relied on the existing agent group arrangement for liquidity insurance will no longer have that protection.

C. What did the ANPR do?

The ANPR requested public comment on the scope and requirements of a regulation to require FICUs to have access to backup federal liquidity sources for use in times of financial emergency and distressed economic circumstances. The ANPR stated that the Board was contemplating requiring FICUs to demonstrate this access in one of four ways: (1) Becoming a member in good standing of the CLF directly; (2) becoming a member in good standing of the CLF through a corporate credit union; (3) obtaining and maintaining demonstrated access to the Federal Reserve Discount Window (Discount Window), through which the Federal Reserve System lends reserve funds to depository institutions; or (4) maintaining a certain percentage of assets in highly liquid Treasury securities.

D. What did the commenters say about the ANPR?

NCUA received a total of 60 comments on the ANPR. Approximately two-thirds of the commenters were either in favor of issuing a regulation to require FICUs to have access to emergency liquidity or were silent on the issue but offered suggestions if a regulation was developed. The remaining one-third opposed a liquidity requirement.

The commenters who supported a regulation argued that an emergency liquidity requirement would strengthen the credit union movement, help protect the NCUSIF, and improve the safety and soundness of the industry. The commenters who opposed the regulation primarily argued that a liquidity backstop requirement would be counterproductive and that NCUA should address liquidity concerns about individual credit unions through the exam process. They argued that existing tools, such as the Interagency Policy Statement on Funding and Liquidity Risk Management (Liquidity Policy Statement),[5] were adequate.

The Board has carefully considered all of the comments and continues to believe that it is essential for every FICU, regardless of size and complexity, to have a management process for identifying, measuring, monitoring, and controlling liquidity risk that is commensurate with its respective needs. As the Liquidity Policy Statement advises, all financial institutions should have a formal contingency funding plan (CFP) that clearly sets out the strategies for addressing liquidity shortfalls in emergency situations.

At this time, however, for FICUs under $10 million in assets, the Board proposes to require only the maintenance of a basic written policy that provides a board-approved framework for managing liquidity and a list of contingent liquidity sources that can be employed under adverse circumstances. The Board determined that the very smallest credit unions present relatively limited safety and soundness liquidity concerns. This determination was made in light of the fact that these institutions tend to have lower loan-to-share ratios, shorter duration assets, and higher amounts of balance sheet liquidity than larger credit unions.

NCUA's primary concern with liquidity adequacy in credit unions is their ability to handle a rapid loss of liquidity, including a rapid loss of shares or loss of access to sources of borrowing. When a credit union's cash and liquid assets are depleted, it naturally will turn to external funding sources and may even need to tap an emergency liquidity lender like CLF or the Discount Window to maintain stability of operations. The level of a credit union's on-balance sheet liquidity provides a measure of its capacity to respond to such events and, in turn, its vulnerability to a liquidity loss scenario. NCUA views the capacity to handle runoff as a major indicator for liquidity risk and a useful way to evaluate a credit union's liquidity risk management.

NCUA has analyzed credit unions' contingent liquidity needs using a

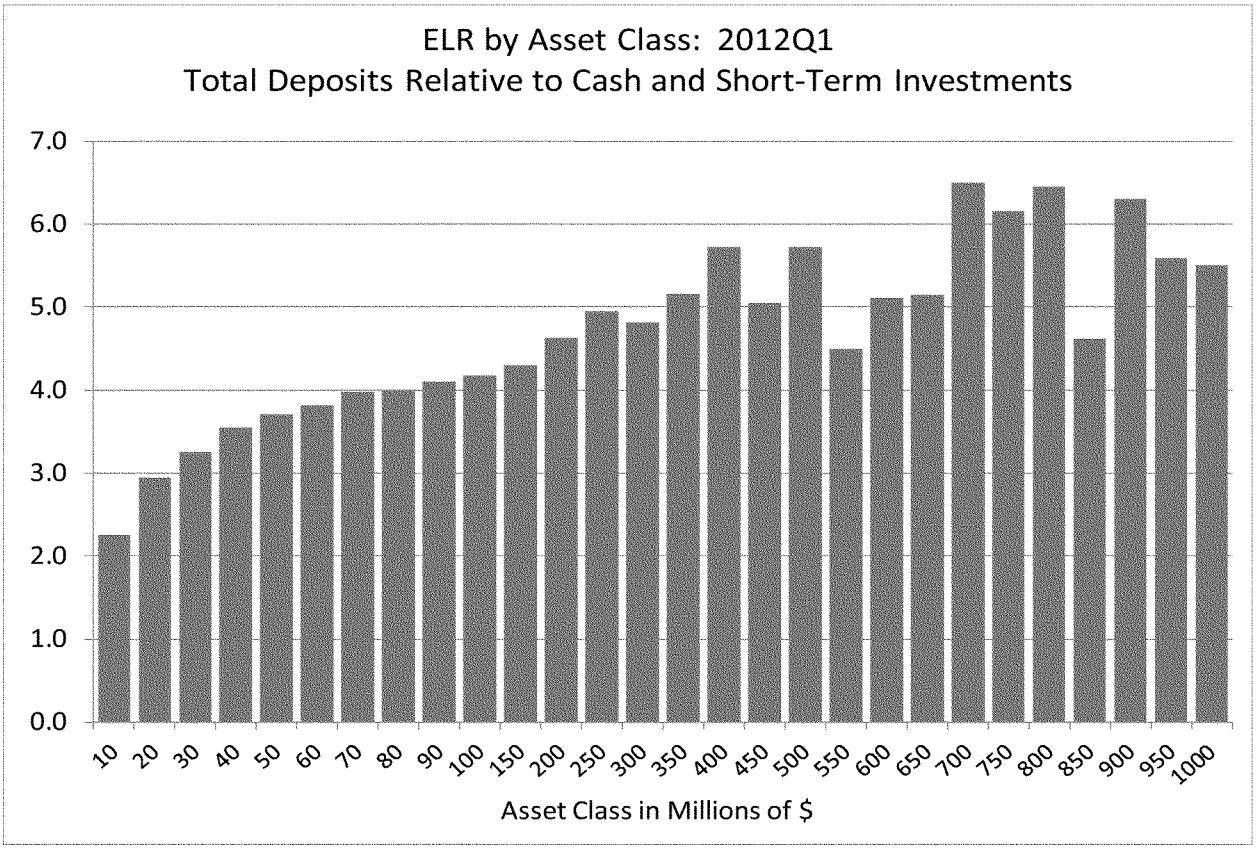
[4] The Federal Financing Bank (FFB) is a government corporation created by Congress in 1973 under the general supervision of the Secretary of the Treasury. The FFB was established to centralize and reduce the cost of federal borrowing, as well as federally-assisted borrowing from the public. 87 STAT. 937, 12 U.S.C. 2281.

[5] *See* 75 FR 13656 (Mar. 22, 2010); *see also* NCUA Letter to Credit Unions No. 10–CU–14, available at *http://www.ncua.gov/Resources/Pages/LCU2010-14.aspx.*

measure of interest rate-sensitive liabilities held by each credit union as a proportion of its cash and short-term investments and a measure of all deposits as a proportion of its cash and short-term investments. These measures are highly correlated. The second, broader, measure is called the ''emergency liquidity ratio'' or ''ELR.'' The ELR can be calculated for every FICU from existing call report information [6] and has been used to inform determination of asset thresholds in the proposed rule. It provides a comparison among FICUs of the relative amount of short-term assets available to fund an unexpected and immediate outflow of deposits.

NCUA computed the ELR for all FICUs using March 2012 call report data. The data reveal that generally the ratio of shares to cash and short-term assets gets larger in larger total asset cohorts. In other words, small credit unions tend to have a lower ELR and larger credit unions tend to have a higher ELR. The ELR is a risk ratio: The higher the measure, the greater the implied susceptibility to a liquidity event. In light of the general rise in ELR with increasing asset size, the proposed rule requires FICUs with assets of at least $10 million to have formal CFPs, as defined in the rule.

The following chart illustrates first quarter 2012 median ELR by asset class for FICUs.



In general, over the $100 million asset threshold, the ELR generally rises to a level that, combined with institution size, suggests the need for demonstrated access to a source of emergency liquidity. Furthermore, larger credit unions have a greater degree of interconnectedness with other market entities and are more likely to adversely affect the credit union system, public perception, and the NCUSIF when experiencing unexpected or severe liquidity circumstances. The recent financial crisis serves as a stark reminder of how large-scale liquidity events imperil even the strongest and most well-capitalized institutions if they do not have ready access to a reliable source of emergency funds. Consistent with the Liquidity Policy Statement, the Board seeks to strengthen the credit union system's ability to withstand the potential impact of stressful liquidity events and circumstances, and believes this comes in part from strengthening capacity at the institutional level. The proposed rule requires these larger FICUs to have a pre-established contingency capability to respond to unexpected and/or severe liquidity events.

The Board is proposing different asset thresholds in this rule to minimize regulatory burden on smaller FICUs, while simultaneously ensuring adequate regulatory coverage of total FICU assets. It specifically requests comment, however, on whether such asset thresholds are appropriate for this rule. It also seeks comment on whether NCUA should use a specific liquidity risk measure—such as the ELR—to further distinguish among FICUs with the most significant liquidity risk and should, in turn, use those levels to determine the scope of the rule's application.

[6] A credit union's ELR is computed by dividing total deposits by the sum of cash plus investments less than one year. Deposits include all deposits and shares. Cash and investments less than one year include cash on hand, total cash on deposit, cash equivalents, and total investments less than one year.

While it is beyond the scope of this proposed rule, the Board is exploring whether certain Basel III [7] liquidity measures and monitoring tools should be incorporated into NCUA's supervisory expectations for the very largest credit unions, those over $500 million.[8] Basel III's proposed standards include, for example, the potential use of such measures as a liquidity coverage ratio and a net stable funding ratio. The standards also include liquidity monitoring tools to track maturity mismatches on the balance sheet, funding concentrations, and the amount of unencumbered assets available for secured borrowing. These measures and monitoring tools are designed to enhance the liquidity risk management framework and improve the banking sector's ability to absorb shocks arising from financial and economic stress. NCUA must similarly consider the impact that its very largest FICUs could have on the liquidity of the credit union system and the NCUSIF by virtue of their size, complexity, and potential interconnectedness. The Board requests comment on the costs and benefits of applying Basel III liquidity measures and monitoring tools to FICUs with assets over $500 million.

E. What did the commenters say in response to specific questions in the ANPR?

The ANPR asked commenters to address a number of specific questions. The questions and comments received are discussed below.

(1) What are the standards and provisions, along with associated considerations, that should accompany a requirement for federally insured credit unions to maintain access to backup federal liquidity sources for use in times of financial emergency and distressed economic circumstances? Should an NCUA requirement to maintain access to backup federal liquidity sources contain an exemption for credit unions under a certain asset threshold, and if so, what should that threshold be?

In response to this question, most commenters suggested that membership in a Federal Home Loan Bank (FHLB) should be an acceptable backup liquidity option. This is discussed further in the responses to Question (2) below.

Nine commenters stated that any liquidity requirement should contain an exemption for small credit unions. The Board agrees that regulatory burden needs to appropriately match the safety and soundness risks. As a result, the proposed rule imposes minimal new requirements on FICUs with less than $10 million in assets. For FICUs with between $10 million and $100 million in assets, the proposed rule only requires the development and maintenance of a CFP to address emergency liquidity shortfalls.

(2) Are there other sources of credit beyond the CLF and Discount Window the Board should consider as acceptable to satisfy the need for a backup federal liquidity source? For example, would a credit union's maintenance of a certain percentage of its assets in highly liquid (maturity of 90 days or less) Treasury securities satisfy the need? If so, what is the appropriate percentage? Also, how should NCUA ensure that these securities are available to be pledged or sold?

Forty-seven commenters stated that any emergency liquidity regulation should include the option of membership in a FHLB. However, two commenters explicitly stated that FHLB membership should *not* be included as an emergency liquidity option, arguing that the FHLBs do not serve as emergency liquidity providers.

The Board believes it is important to draw a distinction between ordinary funding and emergency liquidity. Well-diversified sources of external funding are central to sound liquidity risk management. FHLB membership is certainly one way a credit union can diversify to guarantee a smooth flow of funding for ordinary operations. Another key element of liquidity risk management, however, is reliable emergency funding. Institution-specific issues and market conditions can combine to quickly deplete a credit union's on-balance sheet liquidity reserve. In such situations, the Discount Window and the CLF stand ready to lend on pre-specified terms as long as a credit union meets minimal borrowing standards and possesses eligible collateral. The FHLBs can and do offer short-term loans, in addition to longer-term advances. The Board recognizes, however, that the FHLBs are private institutions which are not obligated, and may not be able, to meet emergency liquidity demands in the same way the Discount Window and CLF are statutorily designed to do. Accordingly, the Board has not included FHLB membership as an emergency liquidity option in the proposed rule. The Board notes, however, that FHLBs can provide valuable services to credit unions of all sizes and encourages credit unions to consider the merits of FHLB membership.

Several commenters stated that, rather than holding Treasury securities, FICUs should be able to demonstrate liquidity by holding cash, short-term marketable securities, certificates of deposit, saleable loans, and other similar assets. However, the commenters did not specify the percentage of a FICU's assets that should be maintained in liquid assets, saying that the amount would be different for each credit union and would depend on the makeup of the credit union's balance sheet. The Board generally disagrees that there are other assets apart from cash and short-term Treasury securities that, during a liquidity crisis, truly can be converted into cash quickly with minimal price impact. During the recent financial crisis, even seemingly highly liquid money market mutual funds temporarily could not easily be exchanged for cash and had to be stabilized with federal government guarantee programs.

The Board still believes that maintaining a portfolio of short-term Treasury securities remains an important source of funds to meet emergency liquidity demands. It encourages all FICUs to ensure that Treasury securities are readily available and not pledged or otherwise encumbered for some other purpose. However, the Board does not wish to impose a one-size-fits-all requirement on a FICU's portfolio of liquid assets. Instead, it encourages each FICU to determine its own appropriate level of liquid assets as part of its normal asset-liability and interest rate risk management programs. NCUA will evaluate all FICUs' liquidity in the normal course of examination and supervision reviews, including their contingency options for meeting unexpected or emergency needs. The Board believes that it is prudent for FICUs to have both a cushion of highly liquid assets on its balance sheet and access to contingent sources of liquidity, but it does not believe it is sound practice for larger credit unions to meet their emergency liquidity needs solely by holding highly liquid assets. A credit union may need to use its portfolio of highly liquid assets as collateral to secure an advance from contingency funding and/or emergency liquidity providers. The Board does not wish to limit the liquidity insurance of credit unions to their existing holdings of highly liquid assets, as these alone may be insufficient in a crisis. Accordingly,

[7] See Basel Committee on Banking Supervision, ''Basel III: International Framework for Liquidity Risk Measurement, Standards and Monitoring,'' Dec. 2010, available at *http://www.bis.org/publ/bcbs188.htm.*

[8] NCUA has previously imposed additional requirements on credit unions with assets of $500 million or greater. *See* 12 CFR 715.5, 715.6, 741.202; *see also* 77 FR 5155 (Feb. 2, 2012) (adding Appendix B to 12 CFR part 741, effective Sept. 30, 2012).

the proposed rule does not include Treasury securities as an option for demonstrating access to a backup liquidity source.

(3) How can CLF best play a role in the immediate term upon U.S. Central Bridge's wind down and over the long term in satisfying a credit union's need for a contingency liquidity source? How should that role be executed? Are changes to the CLF statute to modernize the way the CLF functions over the long term warranted, and if so what changes should be pursued? For example, should the CLF function more like the Discount Window?

Some commenters questioned the value of the CLF, while others argued for its ongoing utility. The Board believes the CLF will continue to serve as an important emergency funding source for FICUs and is including it as an optional liquidity backstop in the proposed rule.

(4) What is the best way for credit unions to access CLF (e.g., either directly or through an agent)? Should corporate credit unions continue to play a role and, if so, to what extent should they be encouraged to purchase CLF stock as agents for natural person credit unions?

Six commenters were in favor of corporates continuing to act as CLF agents for natural person credit unions, and six were opposed. Of those who were opposed, several stated that the corporates cannot afford to recapitalize the CLF.

The Board understands that many corporates cannot afford to purchase stock for all member credit unions, as required by the FCU Act and NCUA regulations. *See* 12 U.S.C. 1757c(b)(2); 12 CFR 725.4(a)(2). However, as discussed more fully below, the Board believes that corporates, independent of agent membership, can still facilitate natural person credit union membership in the CLF by acting as advisors and financial intermediaries for credit unions that wish to join the facility directly.

II. Proposed Rule

A. How would the proposed rule affect FICUs with less than $10 million in assets?

The Board is proposing to add new § 741.12 to part 741, to be titled ''Access to Emergency Liquidity.'' The requirement for FICUs under $10 million, set forth in paragraph (a), is to maintain a basic written policy that provides a credit union board-approved framework for managing liquidity and a list of contingent liquidity sources that can be employed under adverse circumstances. However, the Board encourages such FICUs to follow all of the liquidity risk management guidance in the Liquidity Policy Statement, including having a fully developed CFP to address emergency liquidity shortfalls. A basic liquidity policy involves merely specifying an overall approach to managing an institution's liquidity risk. Such a policy establishes liquidity measures and associated benchmarks, a reporting requirement to keep the board apprised of the institution's liquidity position, and a contingent source, or sources, of funding, such as a corporate credit union or correspondent bank. In contrast, a fully developed CFP also provides for evaluation of liquidity stress scenarios, outlines specific actions to be taken and specific sources of liquidity in emergency liquidity events, and provides for periodic testing of contingent liquidity sources. Specific features of a sound CFP appear in paragraph (d) of new § 741.12. As the Liquidity Policy Statement notes, failure to maintain an adequate liquidity risk management process raises safety and soundness concerns. *See* 75 FR 13656, 13660 (Mar. 22, 2010).

B. How would the proposed rule affect FICUs with $10 million to $100 million in assets?

Paragraph (b) of new § 741.12 requires any FICU with assets of at least $10 million to have a fully developed, written CFP that clearly sets out strategies for addressing liquidity shortfalls in emergency situations. Paragraph (d) of the new section details the requirements of a CFP.

C. How would the proposed rule affect FICUs with $100 million or more in assets?

In addition to the requirement to have a written CFP, paragraph (c) of new § 741.12 would require any FICU with assets of $100 million or more to ensure it has immediate, established access to a federal backup liquidity source. The proposed rule provides that a FICU could demonstrate access by any one of the following three ways:

(1) *Becoming a regular member of the CLF.* The FCU Act and NCUA regulations establish the requirements for regular CLF membership. *See* 12 U.S.C. 1795c(a); 12 CFR 725.3. The primary requirement is subscribing to CLF capital stock in an amount not less than one half of one percent of the credit union's unimpaired capital and surplus. The Board believes that there are instances in which natural person credit unions are willing and financially able to become regular members, but may be discouraged by the administrative requirements of regular membership and the provisions of the CLF Repayment, Security, and Credit Reporting Agreement governing extensions of credit. The Board notes that, pursuant to the authority of corporate credit unions to provide liquidity-related services to their members,[9] and in accordance with procedures established by the Board, corporates may facilitate natural person credit unions becoming regular CLF members. For example, a corporate may perform services such as assisting with applications of credit, serving as a collateral custodian and administrator, and assisting with credit reporting requirements. The Board recognizes that some credit unions that rely on their corporate for correspondent activities would benefit if such activities included an arrangement designed to simplify understanding and compliance with facility requirements and assist with advances of credit before and after a liquidity-need application is approved by CLF.[10]

(2) *Becoming a member of the CLF through an Agent.* As noted above, for a corporate to serve as a CLF agent, it must subscribe to CLF stock for all of its members that are not regular CLF members.

(3) *Establishing borrowing access through the Discount Window.* The Discount Window serves all depository institutions that meet eligibility requirements established by Federal Reserve regulations.[11] To gain access to the Discount Window, the Federal Reserve requires specific agreements to be executed. Information regarding these agreements, as set forth in Operating Circular No. 10, and Discount Window operation can be found at *www.frbdiscountwindow.org.*

D. How would the proposed rule work?

Credit unions' assets can grow and shrink rapidly, and a particular FICU's assets may cross the $10 million or $100 million threshold repeatedly over a short period of time. In light of this fluctuation, paragraph (e) of the

[9] *See* 12 CFR 704.12(a)(5).

[10] A corporate acting as a CLF correspondent would *not* be an agent member of the CLF within the meaning of 12 U.S.C. 1795c(b) or 12 CFR 725.4, as it would not subscribe to CLF stock for its members. For a natural person credit union to be a regular member of the CLF, it must subscribe to CLF stock.

[11] Any depository institution holding liabilities potentially subject to reserve requirements under Federal Reserve regulations can establish access to the Discount Window. Such ''reserveable liabilities'' include transaction accounts and nonpersonal time deposits. For most credit unions, share draft accounts would be the principal reserveable liability.

proposed rule provides that a FICU is subject to the requirements of a higher asset category when two consecutive Call Reports show its assets to be in that higher category. A FICU will then have 120 days from the effective date of that second Call Report to meet the triggered requirements.

III. Regulatory Procedures

a. Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any proposed regulation may have on a substantial number of small entities (those under $10 million in assets). The proposed rule requires small FICUs to establish a basic liquidity policy, a best practice for every depository institution. Since the policy should require only modest effort, it will not have a significant economic impact on a substantial number of small credit unions.

b. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden. 44 U.S.C. 3507(d); 5 CFR part 1320. For purposes of the PRA, a paperwork burden may take the form of a reporting, recordkeeping, or disclosure requirement, each referred to as an information collection.

NCUA has determined the proposed requirement that credit unions under $10 million in assets maintain a basic written liquidity policy will require some institutions to formalize liquidity risk management procedures. NCUA conservatively estimates that all 2,475 credit unions under $10 million in total assets may have to formalize their liquidity risk policies and that this task should take approximately 8 hours per credit union. The expected burden of the requirement is: 2,475 FICUs x 8 hours = 19,800 hours.

NCUA has further determined the proposed requirement to establish and document a CFP constitutes an information collection requirement but that, because of the Liquidity Policy Statement, approximately 610 out of 3,110 (or 20%) of FICUs with assets of at least $10 million will already have established such a plan. NCUA estimates that 2,500 FICUs will have to develop a written CFP and that the task should take a FICU approximately 24 hours. The expected burden of the requirement is: 2,500 FICUs × 24 hours = 60,000 hours.

NCUA has also determined the proposed requirement to either become a member of the CLF or establish borrowing access through the Federal Reserve's Discount Window creates a new information collection requirement. There are 1,434 FICUs with assets of at least $100 million, 1,048 of which are not currently regular members of CLF and/or do not report having established Discount Window access. NCUA estimates that it should take a FICU approximately 4 hours to complete the necessary paperwork to establish either CLF or Discount Window access. The expected burden of the requirement is: 1,048 FICUs × 4 hours = 4,192 hours.

While the proposed regulation provides the option of establishing CLF membership through an agent, NCUA estimates that no corporates will opt to be agent members at this time and, therefore, no FICUs will establish membership in this manner.

Summary of Collection Burden

Written Liquidity Policy: 2,475 FICUs × 8 hours = 19,800 hours.

CFP: 2,500 FICUs × 24 hours = 60,000 hours.

Regular CLF membership or Discount Window borrowing access: 1,048 FICUs × 4 hours = 4,192 hours.

Total Burden Hours: 83,992 hours.

As required by the PRA, NCUA is submitting a copy of this proposal to OMB for its review and approval. Persons interested in submitting comments with respect to the information collection aspects of the proposed rule should submit them to OMB at the address noted below.

The NCUA considers comments by the public on this proposed collection of information in:

- Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the NCUA, including whether the information will have a practical use;
- Evaluating the accuracy of the NCUA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

The Paperwork Reduction Act requires OMB to make a decision concerning the collection of information contained in the proposed regulation between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the NCUA on the substantive aspects of the proposed regulation.

Comments on the proposed information collection requirements should be sent to: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, DC 20503; Attention: NCUA Desk Officer, with a copy to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

c. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. The proposed rule would 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. NCUA has determined that this proposal does not constitute a policy that has federalism implications for purposes of the executive order.

d. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule will not affect family well-being within the meaning of § 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

List of Subjects in 12 CFR Part 741

Credit, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on July 24, 2012.

Mary F. Rupp,

Secretary of the Board.

For the reasons stated above, the National Credit Union Administration proposes to amend 12 CFR part 741 as follows:

PART 741—REQUIREMENTS FOR INSURANCE

1. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781–1790, and 1790d; 31 U.S.C. 3717.

2. Amend part 741 by adding a new § 741.12 to read as follows:

* * * * *

§ 741.12 Access to Emergency Liquidity.

(a) Any credit union insured pursuant to Title II of the Act which has assets of less than $10 million must maintain a basic written policy that provides a credit union board-approved framework for managing liquidity and a list of contingent liquidity sources that can be employed under adverse circumstances.

(b) Any credit union which is insured pursuant to Title II of the Act which has assets of $10 million or more must establish and document a contingency funding plan (CFP) that meets the requirements of paragraph (d).

(c) In addition to the requirement specified in paragraph (b) to establish and maintain a CFP, any credit union which is insured pursuant to Title II of the Act and which has assets of $100 million or more must establish and document access to at least one contingent federal liquidity source for use in times of financial emergency and distressed economic circumstances. Credit unions must conduct advance planning and periodic testing to ensure that contingent funding sources are readily available when needed. A credit union may demonstrate access to a contingent federal liquidity source by:

(1) Maintaining Regular membership in the Central Liquidity Facility (Facility), as described in part 725 of this chapter;

(2) Maintaining membership in the Facility through an Agent, as described in part 725 of this chapter; or

(3) Establishing borrowing access at the Federal Reserve Discount Window.

(d) CFP. A credit union must have a written CFP commensurate with its complexity, risk profile, and scope of operations that sets out strategies for addressing liquidity shortfalls in emergency situations. The CFP may be a separate policy or may be incorporated into an existing policy such as an asset/liability policy, a funds management policy, or a business continuity policy. The CFP must address, at a minimum, the following:

(1) The sufficiency of the institution's liquidity sources to meet normal operating requirements as well as contingent events;

(2) The identification of contingent liquidity sources;

(3) Policies to manage a range of stress environments, identification of some possible stress events, and identification of likely liquidity responses to such events;

(4) Lines of responsibility within the institution to respond to liquidity events;

(5) Management processes that include clear implementation and escalation procedures for liquidity events; and

(6) The frequency that the institution will test and update the plan.

(e) A FICU is subject to the requirements of paragraphs (b) or (c) of this section when two consecutive Call Reports show its assets to be at least $10 million or $100 million, respectively. A FICU then has 120 days from the effective date of that second Call Report to meet the new requirements.

[FR Doc. 2012–18565 Filed 7–27–12; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0795; Directorate Identifier 2008–SW–53–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Eurocopter France (Eurocopter) Model AS332C, L, and L1 helicopters to require a one-time inspection of the main rotor head (MRH) swash-plate upper bearing (bearing) for a non-smooth point (friction point). This proposed AD is prompted by a report of the premature deterioration of the MRH bearing of the rotating star installed on a Model AS332L1 helicopter. The proposed actions are intended to detect deterioration of the MRH bearing and to prevent overloading the scissor links which drive the main rotor system, failure of the scissors links, and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by September 28, 2012.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* 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 economic 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 service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005; telephone (800) 232–0323; or at *http://www.eurocopter.com.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *gary.b.roach@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a

report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD No. 2008–0172–E, dated September 9, 2008 (EAD No. 2008–0172–E), for the Eurocopter Model AS 332 C, C1, L, and L1 helicopters, with an MRH, part number (P/N) 332A31–0001–05 or P/N 332A31–0001–06, having a serial number (S/N) of M172, M216, M261, M308, M547, M677, M811, or M936, and having ''logged less than 275 flight hours since the last overhaul or repair.'' EASA states that Eurocopter received a report of deterioration of an MRH bearing on an MRH that was installed on an AS 332 L1 helicopter. The AS 332 L1 helicopter had logged 72 flight hours since the last overhaul. The EASA states that there was an onset of vibrations in flight and these vibrations were due to premature deterioration of the upper bearing of the MRH swash-plate. They state that this condition, if not corrected, ''could lead to failure of the scissors links and consequently to the control loss of the helicopter.''

FAA's Determination

These helicopters have been approved by the aviation authority of the France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are proposing this AD because we evaluated all information provided by EASA and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Related Service Information

Eurocopter has issued one Emergency Alert Service Bulletin (EASB) with two different numbers, both Revision 0, and both dated September 8, 2008: EASB No. 62.00.73 for Model AS332C, L, and L1 helicopters and non-FAA type certificated Model C1 helicopters; and EASB No. 62.00.30 for non-FAA type certificated Model 532 UC, AC, UL, AL, SC, and UE military helicopters. EASB No. 62.00.73 specifies checking for the absence of a friction point in the MRH bearing. If there is no friction point, EASB No. 62.00.73 specifies checking the condition of the grease in the swash-plate assembly by lubricating the swash-plate, rotating it by hand, and determining if the expelled grease contains traces of metal particles. If the expelled grease does not contain traces of metal particles, EASB No. 62.00.73 specifies checking the swash-plate ''rotation torque'' using a spring scale. If the rotation torque is less than 5.5 kg, EASB No. 62.00.73 specifies checking the bearing for vertical play. If there is a friction point, the expelled grease contains traces of metal particles, the rotation torque is equal to or greater than 5.5 kg, or there is vertical play in the bearing, EASB No. 62.00.73 specifies removing the MRH and sending it to an approved repair station. EASA classified this EASB as mandatory and issued EAD No. 2008–0172–E to ensure the continued airworthiness of these helicopters.

Proposed AD Requirements

This proposed AD would require, within 5 hours time-in-service (TIS), for the specified model helicopters having less than 275 hours TIS since the last MRH overhaul, the following:

- Inspect the MRH bearing for a non-smooth point (friction point) by rotating the MRH swash-plate and:
  - If there is a friction point in the bearing, before further flight, replace the MRH with an airworthy MRH.
  - If there is not a friction point in the bearing, lubricate the MRH swash-plate and rotate it until grease is expelled; inspect the expelled grease for metal particles.
- If there is a metal particle in the grease, before further flight, replace the MRH with an airworthy MRH.
- If there is not a metal particle in the grease, measure the force required to rotate the MRH swash-plate using a spring scale attached to the pitch change rod attachment yokes.
  - If the force to rotate the MRH swash-plate is equal to or greater than 5.5 kg, before further flight, replace the MRH with an airworthy MRH.
  - If the force to rotate the MRH swash-plate is less than 5.5 kg, inspect the MRH swash-plate assembly for vertical play in the bearing. If there is vertical play in the bearing, before further flight, replace the MRH with an airworthy MRH.
- Before installing an MRH, P/N 332A31–0001–05 or P/N 332A31–001–06, with S/N M172, M216, M261, M308, M547, M561, M677, M811, M859, M935, M936, M938, or M942 on any helicopter, inspect the MRH in accordance with the requirements of this AD.

Differences Between This Proposed AD and the EASA AD

The EASA Emergency AD includes Model AS332C1 helicopters. This proposed AD does not include this model helicopter since it is not type certificated in the U.S. The EASA AD does not include S/Ns M561, M859, M935, M938, and M942, whereas this proposed AD does include those S/Ns. The EASA Emergency AD requires operators to comply with the requirements no later than the ''next last flight of the day.'' Our proposed AD would require the actions to be accomplished within 5 hours TIS. Also, the EASA Emergency AD is applicable to the specified helicopters having logged less than 275 flight hours since the last overhaul or repair, whereas our proposed AD would only be applicable to the specified helicopters having less than 275 hours TIS since the last overhaul of the MRH.

Costs of Compliance

We estimate that this proposed AD would affect 6 helicopters of U.S. registry. We estimate that operators may incur the following costs in order to comply with this AD. It would take approximately 1 work-hour per helicopter to accomplish the inspection of the MRH bearing for a friction point, inspection of the swash-plate grease for any metal particles, measurement of the swash-plate force to rotate, and inspection of the bearing for vertical play. It would take approximately 60 work-hours to replace the MRH. These proposed actions would be accomplished at an average labor rate of $85 per work-hour. We estimate the parts cost of replacing an MRH would be approximately $20,000. Based on these figures, we estimate the total cost of the proposed AD on U.S. operators to be $25,610, assuming that all affected helicopters are inspected and that one MRH in the fleet would need to be replaced.

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, 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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):

Eurocopter France (Eurocopter): Docket No. FAA–2012–0795; Directorate Identifier 2008–SW–53–AD.

(a) Applicability

This AD applies to Eurocopter Model AS332C, L, and L1 helicopters with a main rotor head (MRH), part number (P/N) 332A31–0001–05 or P/N 332A31–0001–06, with a serial number (S/N) M172, M216, M261, M308, M547, M561, M677, M811, M859, M935, M936, M938, or M942 installed; having less than 275 hours time-in-service (TIS) since the last overhaul of the MRH; certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as deterioration of the MRH swash-plate upper bearing (bearing), which could result in overloading the scissor links which drive the main rotor system, failure of the scissors links, and subsequent loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

Within 5 hours TIS:

(1) Inspect the MRH bearing for a non-smooth point (friction point) by rotating the MRH swash-plate and:

(i) If there is a friction point in the bearing, before further flight, replace the MRH with an airworthy MRH.

(ii) If there is not a friction point in the bearing, lubricate the MRH swash-plate and rotate it until grease is expelled; inspect the expelled grease for metal particles.

(A) If there is a metal particle in the grease, before further flight, replace the MRH with an airworthy MRH.

(B) If there is not a metal particle in the grease, measure the force required to rotate the MRH swash-plate using a spring scale attached to the pitch change rod attachment yokes.

(*1*) If the force to rotate the MRH swash-plate is equal to or greater than 5.5 kg, before further flight, replace the MRH with an airworthy MRH.

(*2*) If the force to rotate the MRH swash-plate is less than 5.5 kg, inspect the MRH swash-plate assembly for vertical play in the bearing. If there is vertical play in the bearing, before further flight, replace the MRH with an airworthy MRH.

(2) Before installing an MRH, P/N 332A31–0001–05 or P/N 332A31–001–06, with S/N M172, M216, M261, M308, M547, M561, M677, M811, M859, M935, M936, M938, or M942 on any helicopter, inspect the MRH in accordance with paragraph (d)(1) of this AD.

(e) Alternative Methods of Compliance (AMOC)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *gary.b.roach@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

(1) Eurocopter Emergency Alert Service Bulletin, No. 62.00.73, Revision 0, dated September 8, 2008, which is not incorporated by reference, contains additional information about the subject of this AD. For this service information, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005; telephone (800) 232–0323; or at *http://www.eurocopter.com.* You may review this service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in the European Aviation Safety Agency (France) Emergency AD No. 2008–0172–E, dated September 9, 2008.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6400,Tail Rotor System.

Issued in Fort Worth, Texas, on July 20, 2012.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–18454 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0798; Directorate Identifier 2012–CE–023–AD]

RIN 2120–AA64

Airworthiness Directives; Alpha Aviation Concept Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Alpha Aviation Concept Limited Model R2160 Airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as possible installation of non-conforming air filter elements that are not fitted with metallic mesh and could internally collapse resulting in

disruption of the powerplant operation. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 13, 2012.

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

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

For service information identified in this proposed AD, contact Alpha Aviation, 59 Hautapu Road, RD 1, Cambridge 3493, New Zealand; telephone: +64 7 827 0528; fax: +64 7 929 2878; Internet: *www.alphaaviation.co.nz.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; fax: (816) 329–4090; email: *karl.schletzbaum@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–0798; Directorate Identifier 2012–CE–023–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://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 Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, has issued DCA/R2000/41, dated June 8, 2012 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> This emergency AD with the effective date 11 June 2012 is prompted by a report from EASA of finding a non conforming air filter fitted to an overseas aircraft during maintenance. Investigation revealed that air filters with P/N 57.34.00.010 supplied by CEAPR between June 2009 and April 2012 may not have the metallic mesh inside the filter. This AD mandates an inspection of air filters with P/N 57.34.00.010 to determine if a metallic mesh is fitted.

Relevant Service Information

Alpha Aviation has issued Service Bulletin AA–SB–71–006, dated May 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the 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 this State of Design Authority, they have 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 and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD will affect 10 products of U.S. registry. We also estimate that it would take about .5 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $425, or 42.50 per product.

In addition, we estimate that any necessary follow-on actions would take about .5 work-hour and require parts costing $100 for a cost of $142.50 per product. We have no way of determining the number of products that may need these actions.

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 AD:

Alpha Aviation Concept Limited: Docket No. FAA–2012–0798; Directorate Identifier 2012–CE–023–AD.

(a) Comments Due Date

We must receive comments by September 13, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Alpha Aviation Concept Limited Model R2160 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 71, Power Plant.

(e) Reason

This AD was prompted by reports of possible installation of non-conforming air filter elements that are not fitted with metallic mesh and could internally collapse resulting in disruption of the powerplant operation. We are issuing this proposed AD to inspect the air filter element and replace if applicable.

(f) Actions and Compliance

Unless already done, do the following actions following Alpha Aviation Service Bulletin AA–SB–71–006, dated May 2012:

(1) Within the next 30 days time-in-service (TIS) after the effective date of this AD, inspect the air filter part number (P/N) 57.34.00.010 to determine if it has been fitted with a perforated metal liner.

(2) If, after the inspection required in paragraph (f)(1) of this AD, the air filter part number (P/N) 57.34.00.010 is found to include the perforated metal liner, no further action is required.

(3) If, after the inspection required in paragraph (f)(1) of this AD, the air filter is found to not contain the perforated metal liner, before further flight, replace the air filter with a new air filter P/N 57.34.00.010 that does contain the perforated metal liner.

(4) After the effective date of this AD, do not install any air filter P/N 57.34.00.010 that does not have the perforated metal liner depicted in Alpha Aviation Service Bulletin AA–SB–71–006, dated May 2012.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; fax: (816) 329–4090; email: *karl.schletzbaum@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI DCA/R2000/41 issued by the Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, dated June 8, 2012; and Alpha Aviation Service Bulletin AA–SB–71–006, dated May 2012, for related information. For service information related to this AD, contact Alpha Aviation, 59 Hautapu Road, RD 1, Cambridge 3493, New Zealand; telephone: +64 7 827 0528; fax: +64 7 929 2878; Internet: *www.alphaaviation.co.nz.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on July 24, 2012.

James Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–18461 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0794; Directorate Identifier 2006–SW–04–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Eurocopter France (Eurocopter) Model AS350B3 and EC130B4 helicopters. This proposed AD would require revising the Limitations section of the Rotorcraft flight Manual (RFM) to reduce the starter generator operating current to 180 amperes (amps) and installing a placard in the instrument panel indicating the revised limitation. This proposed AD is prompted by the determination that the manufacturer-installed Aircraft Parts Corporation (APC) starter generator has exceeded the shaft horse power extractions allowed for Turbomeca engines. The proposed actions are intended to prevent the engine surge margin being reduced, which can result in engine failure.

DATES: We must receive comments on this proposed AD by September 28, 2012.

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

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

Examining the AD Docket: You may examine the AD docket on the Internet

at *http://www.regulations.gov* 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 economic 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 service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com.* You may review copies of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Chinh Vuong, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5110, fax (817) 222–5961, email *chinh.vuong@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued AD No. 2006–0337, dated November 7, 2006, to correct an unsafe condition for the Eurocopter Model AS350B3 and EC130B4 helicopters. EASA advises that the power drawn by an APC 200 amps starter generator from the engine is above the consumption capacity for the specified Eurocopter model helicopters. Excessive power consumption of the starter generator reduces the engine surge margin, which can result in engine failure.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of these same type designs.

Related Service Information

Eurocopter has issued Alert Service Bulletins (ASBs) No. 01.00.57 for the Model AS350B3 helicopters and No. 04A002 for the Model EC130B4 helicopters. Both ASBs are Revision 1 and both are dated September 14, 2006. The ASBs specify defining the limitation for the APC 200-amp starter generator. EASA classified these ASBs as mandatory and issued AD No. 2006–0337, dated November 7, 2006, to ensure the continued airworthiness of these helicopters.

Proposed AD Requirements

This proposed AD would require, within the next 100 hours time-in-service (TIS), revising the Limitations section of the RFM to reduce the starter generator rating to 180 amps and installing a placard on the instrument panel below the vehicle engine multifunction display indicating the starter generator reduced limitation: ''MAXIMUM CONTINUOUS GENERATOR LOAD 180A.''

Differences Between This Proposed AD and the EASA AD

We would require that this proposed AD be accomplished within 100 hours TIS, rather than 110 flight hours or 12 months as stated in the EASA AD.

Costs of Compliance

We estimate that this proposed AD would affect 363 helicopters of U.S. registry. We estimate that operators may incur the following costs in order to comply with this AD: It would cost $21.25, assuming it takes 15 minutes to revise the RFM and install a placard on the instrument panel of each helicopter at an average labor rate of $85 per work hour, or $7,714 for the fleet.

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, 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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):

Eurocopter France: Docket No. FAA–2012–0794; Directorate Identifier 2006–SW–04–AD.

(a) Applicability

This AD applies to Model AS350B3 and EC130B4 helicopters with an Aircraft Parts Corporation (APC) 200-ampere (amp) starter generator, part number (P/N) 200SGL130Q, installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as excessive power consumption of the starter generator, which reduces the engine surge margin. This condition could result in engine failure and subsequent loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

Within the next 100 hours time-in-service:

(1) Revise Paragraph 2, Limitations, of the Rotorcraft Flight Manual (RFM) Supplement 29 to reduce the maximum current of the starter generator to 180 amps Max. continuous.

(2) Install a placard, 125 millimeters long by 10 millimeters wide, on the instrument panel below the vehicle engine multifunction display indicating the starter generator reduced limitation: ''MAXIMUM CONTINUOUS GENERATOR LOAD = 180A.''

(e) Alternative Methods of Compliance (AMOC)

(1) The Manager, Safety Management Group, Rotorcraft Directorate, FAA, may approve AMOCs for this AD. Send your proposal to: Chinh Vuong, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5110, fax (817) 222–5961, email *chinh.vuong@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

(1) Eurocopter Alert Service Bulletins No. 01.00.57 and No. 04A002, both Revision 1, and both dated September 14, 2006, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com*. You may review copies of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency AD No. 2006–0337, dated November 7, 2006.

(g) Subject

Joint Aircraft Service Component (JASC) Code: Starter-Generator 2435.

Issued in Fort Worth, Texas, on July 20, 2012.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–18463 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Chapter I

[Docket No. FAA–2012–0754]

Airport Improvement Program (AIP): Policy Regarding Access to Airports From Residential Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed policy; implementation of Section 136; opportunity to comment.

SUMMARY: This action proposes a policy, based on Federal law, concerning through-the-fence access to a federally obligated airport from an adjacent or nearby property, when that property is used as a residence. This proposed policy limits application of the FAA's previously published interim policy (76 FR 15028; March 18, 2011) to commercial service airports that certified existing residential through-the-fence access agreements. In addition, this notice proposes to rescind applicability of the interim policy with regard to certain general aviation airports consistent with section 136 of Public Law 112–95 and describes how the FAA will interpret provisions of this law pertaining to residential through-the-fence access.

When the FAA adopted its interim policy on access to airports from residential property, the FAA announced its intent to initiate another policy review in 2014. This supplemental policy review will no longer be necessary.

DATES: Send your comments on or before August 29, 2012. The FAA will consider comments on the proposed policy and its proposed implementation of Section 136 of Public Law 112–95. Any necessary or appropriate revisions resulting from the comments received will be adopted as of the date of a subsequent publication in the **Federal Register**.

ADDRESSES: You may send comments [identified by Docket Number FAA–2012–XXX] using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* To Docket Operations, Room W12–140 on the ground floor of the 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 more information on the notice and comment process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Randall S. Fiertz, Director, Office of Airport Compliance and Management Analysis, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–3085; facsimile: (202) 267–5257.

SUPPLEMENTARY INFORMATION:

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Availability of Documents

You can get an electronic copy of this proposed policy and all other documents in this docket using the Internet by:

(1) Searching the Federal eRulemaking portal (*http://www.regulations.gov/search*);

(2) Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies*; or

(3) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Airport Compliance and Management Analysis, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–3085. Make sure to identify the docket number, notice number, or amendment number of this proceeding.

Authority for the Policy

This notice is published under the authority described in Subtitle VII, part B, chapter 471, section 47122 of title 49 United States Code.

Background

On September 30, 2009, the FAA issued FAA Order 5190.6B, the Airport Compliance Manual. This order contains policy guidance for agency employees monitoring airport sponsor compliance with the grant assurances. Agency guidance that preceded Order 5190.6B discouraged through-the-fence access at airports with grant obligations, and Order 5190.6B contained specific objections to residential through-the-fence access based on more recent agency experiences. Order 5190.6B did not prescribe any specific actions to be taken by airport sponsors with residential through-the-fence access agreements and created ambiguity with regard to the future of these arrangements. The FAA accepted public comments on FAA Order 5190.6B after it was published. Comments received from interested airport sponsors, homeowners, and other parties urged the agency to reconsider its views on residential through-the-fence agreements.

In 2010, the FAA's Office of Airport Compliance initiated a policy review which included the review of written comments, meetings with state aviation officials, visits to airports with residential through-the-fence access, listening sessions with homeowners and homeowners' associations, and discussions with aviation membership associations. The FAA published a proposed revision in agency policy on residential through-the-fence access for public comment in September 2010 (75 FR 54946; September 9, 2010).

In March 2011, the FAA announced the adoption of an interim policy *Airport Improvement Program (AIP): Interim Policy Regarding Access to Airports From Residential Property* (76 FR 15028; March 18, 2011). The interim policy modified sponsor Grant Assurance 5, *Preserving Rights and Powers,* to prohibit new residential through-the-fence access to a federally-obligated airport. The interim policy also required airport sponsors to certify their status with regard to the policy, depict existing access points on the airport layout plan, and develop access plans outlining how the airport sponsor meets certain standards related to the sponsor assurances. When the interim policy was adopted, the FAA announced its intent to initiate another policy review of residential through-the-fence access to federally-obligated airports in 2014.

Since adopting the interim policy, 125 federally-obligated airport sponsors have certified their status as having existing residential through-the-fence access agreements. The 125 locations include four commercial service airports, seven privately-owned reliever airports, and 114 general aviation airports.

On February 14, 2012, the FAA Modernization and Reform Act of 2012 (FMRA) was signed into law (Pub. L. 112–95). Section 136 of this law permits general aviation airports, as defined by the statute, to enter into residential through-the-fence agreements with property owners or associations representing property owners. This must be a written agreement that requires the property owner to:

- Pay access charges that the sponsor determines to be comparable to those fees charged to tenants and operators on-airport making similar use of the airport;
- Bear the cost of building and maintaining the infrastructure the sponsor determines is necessary to provide access to the airfield from property located adjacent to or near the airport;
- Maintain the property for residential, noncommercial use for the duration of the agreement;
- Prohibit access to the airport from other properties through the property of the property owner; and
- Prohibit any aircraft refueling from occurring on the property.

In order to implement this law, the FAA amended the sponsor assurances (77 FR 22376; April 13, 2012). Among the modifications, sponsor assurance 5(g) was redrafted to clarify that sponsors of commercial service airports are not permitted to enter into residential through-the-fence arrangements. However, sponsors of general aviation airports may enter into such an arrangement if the airport sponsor complies with the requirements of section 136 of Public Law 112–95 and the sponsor assurances. In addition, sponsor assurance 29, *Airport Layout Plan,* was amended to require all proposed and existing access points used to taxi aircraft across the airport property boundary be depicted on the airport layout plan (ALP).

A complete list of the current grant assurances can be viewed at: *http://www.faa.gov/airports/aip/grant_assurances/*

The FAA is proposing its interpretation of the FMRA's section 136 and seeks public comment on this interpretation. In light of the public comment period, the FAA's implementing guidance remains in draft form. The agency will refrain from finalizing its implementing guidance until after a final policy is published in a subsequent public notice. As a result, the FAA will not approve any ALPs depicting new residential through-the-fence access points until final guidance has been issued. The FAA will proceed in a timely manner to address public comments and will not unduly delay final agency action with regard to section 136 of the FMRA.

FAA's Interpretation of the FMRA's Section 136

Enforcement

Section 136 permits sponsors of general aviation airports, as defined by the statute at 49 U.S.C. 47102(8), to enter into agreements granting through-the-fence access to residential users, but includes specific terms and conditions. The FAA interprets the inclusion of specific terms and conditions as Congress' intent for the FAA to enforce the provision accordingly. Therefore,

the FAA will request sponsors with existing residential through-the-fence agreements to demonstrate their compliance with the law. Additionally, the FAA will also request sponsors of general aviation airports proposing to establish new residential through-the-fence agreements to demonstrate that their agreements will comply with the law. Airport sponsors are encouraged to review the FAA's Compliance Guidance Letter on FAA Review of Existing and Proposed Residential Through-Fence-Access Agreements, which will be issued in draft form concurrently with this notice.

Although the law became effective on February 14, 2012, the FAA will afford airport sponsors a grace period for compliance. Airport sponsors with existing residential through-the-fence agreements must provide evidence of compliance not later than September 30, 2013. In most cases, the FAA will define evidence of compliance as the airport sponsor's submission of required documentation. This may include copies of access agreements, deeds, covenants, conditions, and restrictions, etc.

Airport sponsors of general aviation airports proposing to establish new or add new residential through-the-fence agreements must provide evidence of compliance prior to executing an agreement with a residential user and/or association representing residential users. The establishment of a new residential through-the-fence agreement which does not comply with the law or results in a violation of the sponsor's commitments with the Federal Government may result in enforcement proceedings under 14 Code of Federal Regulations (CFR) part 16.

The FAA acknowledges that its approach to sponsors with existing residential through-the-fence access agreements will be different than the posture to be taken with sponsors of general aviation airports proposing to establish new or add new residential through-the-fence agreements. This is because airport sponsors with existing agreements may have ceded important rights and powers through the execution of these existing agreements, and their ability to comply with the terms and conditions of the law may be severely hampered. The FAA intends to address such situations on a case-by-case basis, assist these airport sponsors in the development of appropriate mitigations when possible, and report these issues to interested Congressional Committees. Going forward, the FAA expects sponsors of general aviation airports proposing to establish new or add new residential through-the-fence agreements to comply with the terms and conditions of the law. The FAA will not waive these terms and conditions for new agreements.

Applicability

Section 136 applies to sponsors of general aviation airports. The FMRA adopted a definition of ''general aviation airport'' which is now codified at 49 U.S.C. 47102(8). A general aviation airport is defined as a public airport that is located in a State that, as determined by the Secretary, does not have commercial service or has scheduled service with less than 2,500 passenger boardings each year. This definition excludes privately-owned reliever airports. In implementing section 136, the FAA will grandfather the seven privately-owned reliever airports with existing residential through-the-fence access. The owners of these airports will be asked to comply with the law and be treated in a manner similar to general aviation airports as defined in the statute. However going forward, the FAA will apply the statutory prohibition on privately-owned reliever airports and disallow these airports from entering into such agreements. Publically-owned reliever airports are included in the statutory definition of a general aviation airport; sponsors of publically-owned reliever airports will be permitted to enter into residential through-the-fence agreements that comply with the terms and provisions contained in section 136.

The FAA proposes the policy included in this notice to address commercial service airports with existing residential through-the-fence agreements. Commercial service airports which do not currently have residential through-the-fence agreements continue to be prohibited from entering into such agreements by statute.

Terms and Conditions—Commercial Activities

Section 136 states that residential property owners must maintain their property for residential, noncommercial use for the duration of the agreement. The FAA interprets this as a prohibition on commercial aeronautical services offered by residential through-the-fence users that might compete with on-airport aeronautical service providers, whether existing or not, or chill the airport sponsor's ability to attract new commercial service providers on the airport. Therefore, in its review of agreements proposing to establish new residential through-the-fence access, the FAA will interpret this condition as a prohibition on commercial *aeronautical* activities only. Agreements which limit the scope of this prohibition to only commercial aeronautical activities will be acceptable. However, the FAA will not concern itself with unrelated commercial activities which may be permitted by local regulation.

The FAA recognizes that some existing residential through-the-fence agreements permit the co-location of homes and aeronautical businesses. In these cases, the FAA will require airport sponsors to execute two separate agreements with the homeowner. One agreement must address the duration, rights, and limitations of the homeowner's residential through-the-fence access, and the second agreement must address the conduct of the commercial aeronautical activity. The second agreement must be consistent with the FAA's current policies on commercial through-the-fence activities and ensure the off-airport business does not result in unjust economic discrimination for on-airport aeronautical service providers. The FAA encourages airport sponsors with these types of mixed-use arrangements to adopt long-term plans to relocate the off-airport commercial aeronautical activity onto the airport when feasible and practicable to do so. Going forward, airport sponsors proposing to establish a residential through-the-fence agreement must meet the statutory terms and conditions, including the prohibition on using the residential property for commercial aeronautical use. Therefore, agreements which propose the co-location or mixed-use of residential and commercial aeronautical activities will be not be consistent with the law.

Terms and Conditions—Authorized Access

Section 136 states that residential property owners must prohibit access to the airport from other properties through the property of the property owner with access. The FAA interprets this as a prohibition on unauthorized access to the airport; this condition does not necessarily prescribe a scenario in which all residential through-the-fence users must have their own dedicated access point to enter the airport. The FAA encourages sponsors of general aviation airports proposing to establish new residential through-the-fence agreements to limit the number of access points in a manner that is consistent with airport planning practices. Compliance with this condition will require access agreements stipulate that residential through-the-fence access agreement holders are prohibited from permitting unauthorized users (any individual not

party to an access agreement with the airport sponsor) to pass through or ''piggy back'' on their access in order to enter the airport. The FAA expects airport sponsors to establish their own policies, restrictions, and/or requirements to be imposed on fly-in guests who taxi from the airport property to visit off-airport residents.

Terms and Conditions—Fueling

Section 136 states that residential property owners must prohibit any aircraft refueling from occurring on the property with access. The FAA interprets this as a prohibition on the sale of fuel from residential property. The FAA will not concern itself with self-fueling activities which may be permitted by local regulation.

Proposed Final Policy on Existing Through-the-Fence Access to Commercial Service Airports From a Residential Property

Discussion of Revisions to the Interim Policy

In light of section 136 of Public Law 112–95, the FAA proposes the following revisions to the interim policy published on March 18, 2011 (76 FR 54946; September 9, 2010).

Proposed Policy

The law permits sponsors of general aviation airports to enter into residential through-the-fence agreements with property owners or associations representing property owners; however, the law is silent with regard to commercial service airports. The FAA interprets the absence of statutory relief as authority to finalize the interim policy for commercial service airports.

Changes: All references to the policy now clarify that it will be a final measure.

Applicability

The law permits publicly-owned general aviation airports, as defined by the statute, to enter into residential through-the-fence agreements that comply with specific terms and conditions. The FAA's proposed policy regarding access to airports from residential property will apply only to those commercial service airports with existing residential through-the-fence access.

Changes: The proposed policy now refers only to commercial service airports with existing residential through-the-fence access.

Incorporation of the Law

The proposed policy has been revised to incorporate the terms and conditions contained in section 136 of Public Law 112–95, as implemented by the FAA. As a result, the FAA will consider the airport sponsor's ability to establish parity in fees between on- and off-airport users as opposed to an airport sponsor's ability to generate revenue to recover airport costs. This reflects Congress' intent that residential through-the-fence users pay airport access charges that are comparable to those tenants and operators on-airport making similar use of the airport.

Changes: Section I, Section II, Section III, and Section IV now state that airport sponsors will be required to satisfy the law. Section II specifies the terms and conditions contained in the law which must also be satisfied by the airport sponsor. References to ''ability to generate revenue to recover airport costs'' have been replaced with ''parity of access fees''.

FAA's Standards for Compliance—Recovery of Costs of Operating the Airport

The law prescribes a single methodology for evaluating fees charged to residential through-the-fence users. Therefore, the FAA will not propose or consider alternative methodologies. The discussion of these methodologies has been replaced with language from the law.

Changes: References to ''recovery of costs of operating the airport'' have been replaced with ''parity of access fees'' in Section II. The interim policy's explanation of FAA's standard for compliance, which was the requirement for through-the-fence users to bear a fair proportion of airport costs, has been deleted.

Standards for Compliance at Commercial Service Airports Proposing To Extend Through-the-Fence Access

Section 136 of Public Law 112–95 prescribes specific terms and conditions to be contained in agreements establishing residential through-the-fence access. The FAA will require commercial service airports proposing to extend or renew their existing agreements to fully comply with these terms and conditions as a supplemental standard applied by the FAA to review these proposals. In addition, because the law requires residential through-the-fence users to pay access charges comparable to on-airport tenants and users making similar use of the airport, the FAA may no longer entertain alternative financial methodologies.

Changes: A bullet stating ''the new access agreement fully complies with the terms and conditions contained in section 136 of Public Law 112–95'' has been added as a supplemental standard discussed in Section III. The bullet discussing access fees which recover airport costs has been deleted.

Revision of Description of FAA Compliance Guidance Letter

The FAA anticipates issuing a draft Compliance Guidance Letter on FAA Review of Existing and Proposed Through-the-Fence Access Agreements. This title is slightly different than the title of the Compliance Guidance Letter previously issued on March 21, 2011.

Changes: The title ''FAA Implementation and Review of Residential Through-the-Fence Access Arrangements'' has been replaced with ''FAA Review of Existing and Proposed Through-the-Fence Access Agreements'' in Section IV. All references to this Compliance Guidance Letter describe this document as a draft.

Additional Time To Establish Evidence of Compliance and Clarification of Due Date

The FAA believes all airport sponsors with existing residential through-the-fence access should be afforded additional time to comply with the law. Therefore, the FAA is extending the timeframe for commercial service airports to establish evidence of compliance. All access plans will now be due beginning in Fiscal Year 2014.

Changes: All references to ''2013'' have been replaced with ''2014'' in Section IV and Section V. The explanation of the rolling due date contained in the interim policy has been deleted.

Incorporation of Amended Sponsor Assurance 29

On April 13, 2012, the FAA amended sponsor assurance 29 to require all proposed and existing access points used to taxi aircraft across the airport property boundary be depicted on the ALP (77 FR 22376; April 13, 2012). The FAA is incorporating the amended assurance by clarifying that failure to depict all residential through-the-fence access points is a violation of the sponsor's grant assurances.

Changes: The phrase ''may be considered an apparent violation of the sponsor's grant assurances'' has been replaced with ''is a violation of the sponsor's grant assurances'' in Section IV.

Actions Requiring Airport Sponsors To Update the Access Plan

The FAA believes its description of actions triggering airport sponsors to update its access plan can be better refined. In addition, the FAA believes that the identification of a safety

concern should be listed as a new triggering event.

Changes: The FAA proposes to define the actions requiring a commercial service airport sponsor to update its access plan to include development of a master plan or an update to an existing master plan, revisions to an ALP, requests for Federal participation in land acquisition, identification of a safety concern, or substantial changes to the access agreement in Section IV.

Airports Currently in Noncompliance

The interim policy included language discussing the treatment of airport sponsors currently in noncompliance due to grant assurance violations associated with their residential through-the-fence access agreements. No sponsors of commercial service airports are currently in noncompliance due to grant assurance violations associated with their residential through-the-fence access agreements. Therefore, the FAA proposes to eliminate this paragraph from Section IV and renumber the subsequent paragraphs.

Changes: The paragraph titled ''Airports in noncompliance'' and designated as paragraph A.5. in Section IV has been deleted. The paragraphs which follow have been renumbered accordingly.

Airports That Do Not Meet the Compliance Standards

In its interim policy, the FAA proposed to analyze the role played by airports unable to meet the standard of compliance prior to determining the course of action to take. This included determining the role played by the airport in the National Plan of Integrated Airport Systems (NPIAS). Given the more limited applicability of the proposed policy to commercial service airports with existing residential through-the fence access, this analysis is no longer required. The role played by commercial service airports is defined in statute. Instead, the FAA proposes to consider a commercial service airport sponsor's inability to comply with the law and/or the standards of compliance as a militating factor in the FAA's review of any requests for discretionary AIP funding.

Changes: Subparagraphs (a) and (b) of renumbered Section IV.A.5. have been deleted. The last sentence of paragraph (5) proposes that the FAA may consider a commercial service airport's inability to comply with the law and/or the minimum compliance standards as a militating factor in its review of requests for discretionary funding.

Proposed Final Policy on Existing Through-the-Fence Access From a Residential Property

In consideration of the foregoing, the Federal Aviation Administration proposes the following Policy on existing through-the-fence access to federally-obligated commercial service airports from residential property:

Proposed Final Policy on Existing Through-the-Fence Access to Commercial Service Airports From a Residential Property

Applicability

This proposed final Policy applies to commercial service airports with existing residential through-the-fence access.

For the purposes of this proposed final Policy:

In this sense ''access'' means:

1. An access point for taxiing aircraft across the airport boundary; *or*

2. The right of the owner of a particular off-airport residential property to use an airport access point to taxi an aircraft between the airport and that property.

''Existing access'' through the fence is defined as any through-the-fence access that meets one or more of the following conditions:

1. There was a legal right of access from the property to the airport (e.g., by easement or contract) in existence as of September 9, 2010; *or*

2. There was development of the property prior to September 9, 2010, in reliance on the airport sponsor's permission for through-the-fence aircraft access to the airport; or

3. The through-the-fence access is shown on an FAA-approved airport layout plan (ALP) or has otherwise been approved by the FAA in writing, and the owner of the property has used that access prior to September 9, 2010.

''Extend an access'' is defined as an airport sponsor's consent to renew or extend an existing right to access the airport from residential property or property zoned for residential use, for a specific duration of time, not to exceed 20 years.

''Development'' is defined as excavation or grading of land needed to construct a residential property; or construction of a residence.

''Residential property'' is defined as a piece of real property used for single- or multi-family dwellings; duplexes; apartments; primary or secondary residences even when co-located with a hangar, aeronautical facility, or business; hangars that incorporate living quarters for permanent or long-term use; and time-share hangars with living quarters for variable occupancy of any term.

''Transfer of access'' through the fence is defined as one of the following transactions:

1. Sale or transfer of a residential property or property zoned for residential use with existing through-the-fence access; or

2. Subdivision, development, or sale as individual lots of a residential property or property zoned for residential use with existing through-the-fence access.

I. Existing Through-the-Fence Access From Residential Property at Federally-Obligated Commercial Service Airports

The agency understands that it may not be practical or even possible to terminate through-the-fence access at many of those commercial service airports where that access already exists. Where access could be terminated, property owners have claimed that termination could have substantial adverse effects on their property value and investment, and sponsors seeking to terminate this access could be exposed to costly lawsuits. Accordingly, the FAA will not consider the existence of existing residential through-the-fence access by itself to place a sponsor in noncompliance with its grant assurances at these commercial service airports.

In some cases, the FAA has found that through-the-fence access rights can interfere with the sponsor's ability to meet its obligations as sponsor of a federally assisted public use airport. This is discussed in detail at 75 FR 54946, 54948 (Sept. 9, 2010). As a result, the FAA believes that sponsors of commercial service airports with existing through-the-fence access agreements must adopt measures to substantially mitigate the potential problems with residential through-the-fence access where it exists to avoid future grant compliance issues. Therefore, the FAA, as a condition of continuing grants to commercial service airports with residential through-the-fence access, will require these sponsors adopt measures to substantially mitigate the potential problems with residential through-the-fence access to avoid future grant compliance issues.

Accordingly, the sponsor of a commercial service airport where residential through-the-fence access or access rights already exist will be considered in compliance with its grant assurances if the airport depicts the access on its airport layout plan (ALP), satisfies the terms and conditions contained in section 136 of Public Law

112–95, and meets certain standards for safety, efficiency, parity of fees, and mitigation of potential noncompatible land uses. Those standards are listed in section II, *Standards for compliance at commercial service airports with existing through-the-fence access.* The FAA's review of those standards will be detailed in a Compliance Guidance Letter which will be issued, in draft form, concurrently and published on the FAA's Web site at *www.faa.gov/airports.* An airport sponsor covered by this proposed final Policy would be required to seek FAA approval before entering into any agreement that would extend (including renewal of access) through-the-fence access. Sponsors are reminded that nearby homeowners possess no right to taxi aircraft across the airport's property boundary, and no off-airport property owner will have standing to file a formal complaint under 14 CFR part 16 with the FAA to challenge the sponsor's decision not to permit such access.

II. Standards for Compliance at Commercial Service Airports With Existing Through-the-Fence Access

The FAA understands that municipally-owned airports have varying degrees of zoning authority. For example, one sponsor may have strong zoning powers, while another may have none. Also, the nature of existing through-the-fence rights can greatly affect the sponsor's ability to implement measures to control access. Accordingly, the FAA does not expect every sponsor of an airport with existing residential through-the-fence access to adopt a uniform set of rules and measures to mitigate that access. However, the FAA does expect each such sponsor to adopt reasonable rules and implement measures that accomplish the following standards for compliance and satisfy the law, to the fullest extent feasible for that sponsor. In general, the greater the number of residential through-the-fence access points and users of the airport and the higher the number of aircraft operations, the more important it is to have formal measures in effect to ensure the sponsor retains its proprietary powers and mitigates adverse effects on the airport.

In order to satisfy the law, the sponsor and the property owner or an association representing property owners must have a written agreement that requires the property owner to:

- Pay access charges that the sponsor determines to be comparable to those fees charged to tenants and operators on-airport making similar use of the airport;
- Bear the cost of building and maintaining the infrastructure the sponsor determines is necessary to provide access to the airfield from property located adjacent to or near the airport;
- Maintain the property for residential, noncommercial use (the FAA interprets this limitation as a prohibition on commercial aeronautical services only) for the duration of the agreement;
- Prohibit access to the airport from other properties through the property of the property owner (the FAA interprets this limitation as a prohibition on access to the airport not authorized by the airport sponsor); and
- Prohibit any aircraft refueling from occurring on the property (the FAA interprets this as a prohibition on the sale of fuel from residential property).

The FAA's standards for compliance for any sponsor of a commercial service airport with existing residential through-the-fence access are as follows:

1. *General authority for control of airport land and access.* The sponsor has sufficient control of access points and operations across airport boundaries to maintain safe operations, and to make changes in airport land use to meet future needs.

2. *Safety of airport operations.* By rule, or by agreement with the sponsor, through-the-fence users are obligated to comply with the airport's rules and standards.

3. *Parity of access fees.* The sponsor can and does collect fees from through-the-fence users comparable to those charged to airport tenants.

4. *Protection of airport airspace.* Operations at the airport will not be affected by hangars and residences on the airport boundary, at present or in the future.

5. *Compatible land uses around the airport.* The potential for noncompatible land use adjacent to the airport boundary is minimized consistent with Grant Assurance 21, Compatible Land Use.

These standards will be applied, on a case-by-case basis, in the FAA's evaluation of whether each commercial service airport with existing residential through-the-fence access meets the above requirements to the fullest extent feasible for that airport. In situations when access can be legally transferred from one owner to another without the sponsor's review, the FAA will treat the access as existing. Because the ability of some sponsors to control access has been compromised as a result of legal rights previously granted to through-the-fence users, existing access locations may be evaluated under the alternative criteria for some standards as indicated below, if applicable to that airport.

In some cases, a sponsor may seek to relocate an existing access point. If the sponsor can demonstrate that this action will improve the airport's overall safety or better address issues associated with the sponsor's long-term planning needs, the FAA will not consider the access rights associated with the replacement access point to extend an access. In order to transfer the terms of the existing access point to a new access point without a change in compliance status, the former existing access point must be removed. Such requests should be coordinated with the FAA Airports District Office (ADO) or Regional Airports Division and clearly depicted on the sponsor's ALP.

III. Standards for Compliance at Commercial Service Airports Proposing To Extend Through-the-Fence Access

Once allowed, residential through-the-fence access is very difficult to change or eliminate in the future. This is because residential owners, more so than commercial interests, typically expect that their residential property will remain suitable for residential use and protected from adverse effects for a long time. Residential buyers and their mortgage lenders may ensure that the property is purchased with rights that guarantee no change in the access to the airport for decades, or indefinitely. Because each additional residential through-the-fence access location introduces the potential for problems for the airport in the future, and because this access is effectively permanent and resistant to change once permitted, the FAA will review extensions of existing residential through-the-fence access at public use airports carefully.

The following supplemental standards will be applied to the FAA's case-by-case review of sponsors' proposals to extend residential through-the-fence access. In situations when the transfer of access from one owner to another requires the sponsor's concurrence, the FAA will treat the access as an extension. The FAA will not approve requests to extend access that are inconsistent with the sponsor's grant assurances (excluding Grant Assurance 5, Preserving Rights and Powers, paragraph ''g'' as amended). Furthermore, the sponsor will be required to demonstrate the following standards for compliance:

- The new access agreement fully complies with the terms and conditions contained in section 136 of Public Law 112–95.
- The term of the access does not exceed 20 years.

• The sponsor provides a current (developed or revised within the last five years) airport master plan identifying adequate areas for growth that are not affected by the existence of through-the-fence access rights, or the sponsor has a process for amending or terminating existing through-the-fence access in order to acquire land that may be necessary for expansion of the airport in the future.

• The sponsor will impose and enforce safety and operating rules on through-the-fence residents utilizing this access while on the airport identical to those imposed on airport tenants and transient users.

• Through-the-fence residents utilizing this access will grant the sponsor a perpetual avigation easement for overflight, including unobstructed flight through the airspace necessary for takeoff and landing at the airport.

• Through-the-fence residents utilizing this access, by avigation easement; deed covenants, conditions or restrictions; or other agreement, have acknowledged that the property will be affected by aircraft noise and emissions and that aircraft noise and emissions may change over time.

• Through-the-fence residents utilizing this access have waived any right to bring an action against the sponsor for existing and future operations and activities at the airport associated with aircraft noise and emissions.

• The sponsor has a mechanism for ensuring through-the-fence residents utilizing this access will file FAA Form 7460–1, Notice of Proposed Construction or Alteration, if necessary and complying with the FAA's determination related to the review of Form 7460–1.

• The sponsor has a mechanism for ensuring through-the-fence residents do not create or permit conditions or engage in practices that could result in airport hazards, including wildlife attractants.

• Where available, the sponsor or other local government has in effect measures to limit future use and ownership of the through-the-fence properties to aviation-related uses (in this case, hangar homes), such as through zoning or mandatory deed restrictions. The FAA recognizes this measure may not be available to the sponsor in all states and jurisdictions.

• If the residential community has adopted restrictions on owners for the benefit of the airport (such as a commitment not to complain about aircraft noise), those restrictions are enforceable by the sponsor as a third-party beneficiary, and may not be cancelled without cause by the community association.

• The access agreement is subordinate to the sponsor's current and all future grant assurances.

• The sponsor has developed a process for educating through-the-fence residents about their rights and responsibilities.

IV. Proposed Process and Documentation

A. Existing Residential Through-the-Fence Access

1. *General.* The sponsor of a commercial service airport with existing residential through-the-fence access will be considered in compliance with its grant assurances, and eligible for future grants, if the FAA determines that the sponsor complies with the law and meets the applicable standards listed above under *Standards for compliance at commercial service airports with existing residential through-the-fence access.* The sponsor may demonstrate that it meets these standards by providing the ADO or regional division staff with a written description of the sponsor's authority and the controls in effect at the airport (''residential through-the-fence access plan'' or ''access plan''). Sponsors are encouraged to review the FAA's draft Compliance Guidance Letter on FAA Review of Existing and Proposed Residential-Through-Fence Access Agreements, which will be issued concurrently with this notice, prior to submitting their access plan. This draft guidance letter may be found on the FAA's Web site at *www.faa.gov/airports.* The ADO or regional division will review each access plan, on a case-by-case basis, to confirm that it addresses how the sponsor complies with the law and meets each of these standards at its airport. The ADO or regional division will forward recommendations regarding each access plan to the Manager of Airport Compliance. Only the Manager of Airport Compliance may accept a commercial service airport sponsor's residential through-the-fence access plan. In reviewing the access plan, the Manager of Airport Compliance may consult with the Transportation Security Administration (TSA). The FAA will take into account the powers of local government in each state, and other particular circumstances at each airport. In every case, however, the access plan must address the law and each of the basic requirements listed under section II of this proposed final Policy.

2. *Residential through-the-fence access plan.* The FAA will require evidence of compliance before issuing an AIP grant, beginning in Fiscal Year 2014. FY 2014 and later grants will include a special grant condition requiring the ongoing implementation of these access plans. Generally, the FAA will not award discretionary grants to the sponsor until the FAA accepts the sponsor's access plan as meeting the law and the standards to the extent feasible for that airport.

3. *Airport Layout Plan.* The FAA will require all residential through-the-fence access points to be identified on the airport's layout plan. A temporary designation may be added through a sponsor's pen and ink change to immediately identify the locations on the airport property that serve as points of access for off-airport residents. A formal ALP revision that fully depicts the scope of the existing residential through-the-fence agreements should be completed the next time the sponsor initiates an airport master plan study or update.

A sponsor's failure to depict all residential through-the-fence access points is a violation of the sponsor's grant assurances, and the agency may consider grant enforcement under 14 CFR part 16.

4. *FAA review.* The FAA's acceptance of the access plan represents an Agency determination that the commercial service airport has met the law and compliance standards for existing residential through-the-fence access for a period not to exceed 20 years. The following actions will trigger a commercial service airport sponsor to update its access plan prior to its 20-year expiration: Development of a new master plan or an update to an existing master plan, significant revisions to an ALP, requests for Federal financial participation in land acquisition, identification of a safety concern, or substantial changes to the access agreement. A commercial service airport sponsor's failure to implement its access plan could result in a violation of the special grant condition and potentially lead to a finding of noncompliance.

5. *Commercial Service Airports with existing residential through-the-fence access that do not meet the compliance standards.* The FAA recognizes that some commercial service airport sponsors may not be able to fully comply with the law and the standards listed above, due to limits on the powers of the sponsor and/or other local governments, or on other legal limits on the sponsor's discretion to adopt certain measures. Other sponsors have the capability to adopt measures to satisfy the compliance standards but have not done so. The FAA may consider a

commercial service airport sponsor's inability to comply with the law and/or the minimum compliance standards as a militating factor in its review of requests for discretionary funding.

6. *Commercial service airports that fail to submit an access plan.* The FAA expects commercial service airport sponsors with existing residential through-the-fence access to develop an access plan which addresses the law, preserves their proprietary rights and powers, and mitigates the inherent challenges posed by this practice. Beginning in Fiscal Year 2014, a sponsor's failure to comply with the Policy may jeopardize its ability to compete for AIP grant funding.

B. Requests To Extend Residential Through-the-Fence Access at Airports Covered by This Proposed Final Policy

As of the date of the enactment of Public Law 112–95 (February 14, 2012), a sponsor of a commercial service airport proposing to extend an access agreement must submit a current airport master plan and a revised residential through-the-fence access plan as detailed below. The ADO or regional division will forward its recommendations regarding each request to extend access to the Manager of Airport Compliance. Only the Manager of Airport Compliance may approve a sponsor's request to extend access. In reviewing the proposal, the Manager of Airport Compliance may consult with the TSA.

1. *Master Plan.* A sponsor of a commercial service airport wishing to extend an existing residential through-the-fence access agreement must submit a recent airport master plan to the ADO or regional division. The FAA considers a master plan to be recent if it was developed or updated within the past five years. The master plan should explain how the sponsor plans to address future growth, development, and use of the airport property over the next 20 years; sponsors should work with ADO or regional division staff to develop an appropriate scope of work for these master plans.

2. *Residential through-the-fence access plan.* The sponsor is responsible for revising its access plan, as discussed under section IV.A.2 of this proposed final Policy, to reflect how it will meet the standards for compliance for the extended access. Once the FAA has accepted the revised access plan, the FAA will condition future AIP grants upon its ongoing implementation.

3. *Continuing obligations.* Once the revised access plan is accepted by the FAA, and if required, the revised ALP, is approved by the FAA, the sponsor must continue to comply with obligations described in section IV.A of this proposed final Policy.

V. Eligibility for AIP Grants

A. *General.* Beginning in Fiscal Year 2014, a sponsor of a commercial service airport with existing residential through-the-fence access will be required to submit their residential through-the-fence access plan prior to notifying the FAA of its intent to apply for an AIP grant. The sponsor will not lose eligibility for entitlement grants on the basis of the through-the-fence access, but the FAA will consider the potential constraints on the utility of the airport to be a significant factor in future AIP funding decisions.

B. *Public infrastructure and facilities with substantial benefit to private through-the-fence users.* The FAA may be unable to justify the federal investment in a proposed project when private residential developments with through-the-fence access will receive substantial value from that federally assisted airport infrastructure and/or facility.

C. *Exclusive or primary private benefit.* On-airport infrastructure and facilities used exclusively or primarily for accommodation of through-the-fence users are considered private-use and are ineligible for AIP grants.

Issued in Washington, DC, on July 18, 2012.

Randall S. Fiertz,

Director, Airport Compliance and Management Analysis.

[FR Doc. 2012–18058 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2012–0559]

RIN 1625–AA08

Special Local Regulations; 2012 Ironman 70.3 Miami, Biscayne Bay; Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation on the waters of Biscayne Bay, east of Bayfront Park, in Miami, Florida during the 2012 Ironman 70.3 Miami, a triathlon. The Ironman 70.3 Miami is scheduled to take place on Sunday, October 28, 2012. Approximately 2500 participants are anticipated to participate in the swim. No spectators are expected to be present during the event. The special local regulation is necessary to provide for the safety of the participants, participant vessels, and general public on the navigable waters of the United States during the event. The special local regulation would establish an area that will encompass the event area. Persons and vessels will be prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before August 29, 2012. Requests for public meetings must be received by the Coast Guard on or before August 20, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0559 using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Mike H. Wu, Sector Miami Prevention Department, Coast Guard; telephone (305) 535–4317, email *Mike.H.Wu@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting

comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov*, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, type the docket number USCG–2012–0559 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½; by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type the docket number USCG–2012–0559 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.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before June 25, 2012 using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to provide for the safety of life on navigable waters of the United States during the Ironman 70.3 Miami.

C. Discussion of Proposed Rule

On October 28, 2012, Miami Tri Events is sponsoring the Ironman 70.3, a triathlon. The swim portion of the event will be held on the waters of Biscayne Bay, Miami, Florida. Approximately 2500 participants are anticipated to participate in the event. No spectator vessels are expected during the event.

The proposed rule would establish a special local regulation that will encompass certain waters of the Intracoastal Waterway and Biscayne Bay, Miami, Florida. The special local regulation will be enforced 6:45 a.m. until 9:45 a.m. on October 28, 2012. The special local regulation will establish an area around the event where all persons and vessels, except those persons and vessels participating in the event, are prohibited from entering, transiting though, anchoring in, or remaining within. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Miami via telephone at 305–535–4472, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the event area is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the special local regulations by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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 economic impact of this proposed rule is not significant for the following reasons: (1) The special local regulation will be enforced for only three hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the event area without authorization from the Captain of the Port Miami or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the event area during the enforcement period if authorized by the Captain of the Port Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

2. Impact on Small Entities

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

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

substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of Intracoastal Waterway and Biscayne Bay encompassed within the special local regulations from 6:45 a.m. until 9:45 a.m. on October 28, 2012. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

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

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a special local regulation issued in conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

2. Add a temporary § 100.35T07–0559 to read as follows:

§ 100.35T07–0559 Special Local Regulation; Ironman 70.3 Miami, Biscayne Bay; Miami, FL.

(a) *Regulated Area.* The following regulated area is a special local regulation. All waters of Biscayne Bay located east of Bayfront Park and encompassed within an imaginary line connecting the following points: starting

at Point 1 in position 25°46′44″ N, 080°10′59″ W; thence southeast to Point 2 in position 25°46′24″ N, 080°10′44″ W; thence southwest to Point 3 in position 25°46′18″ N, 080°11′05″ W; thence north to Point 4 in position 25°46′33″ N, 080°11′05″ W; thence northeast back to origin. All coordinates are North American Datum 1983.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.*

(1) Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Miami by telephone at 305–535–4472, or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(2) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement Date.* This rule will be enforced from 6:45 a.m. until 9:45 a.m. on October 28, 2012.

Dated: June 20, 2012.

C.P. Scraba,

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

[FR Doc. 2012–18455 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0470]

RIN 1625–AA09

Drawbridge Operation Regulation; Apalachicola River, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedules for two bridges that cross the Apalachicola River in Florida. First, the CSX Railroad requested to modify the operating schedule of their swing bridge at mile 105.9, at River Junction to require eight hours advanced notice at all times. Second, the Apalachicola and Northern Railroad (ANRR) requested to maintain the swing bridge at mile 4.5 (GIWW mile 347.0 East of Harvey Lock (EHL)), at Apalachicola, untended and in the open-to-navigation position at all times.

DATES: Comments and related material must reach the Coast Guard on or before September 28, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0470 using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

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

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

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email David Frank, Bridge Administration Branch; telephone 504–671–2128, email *David.M.Frank@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0470), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rules'' and insert ''USCG–2012–0470'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0470'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

The Code of Federal Regulations (CFR) under 33 CFR 117.5 requires that except as otherwise authorized by this part, drawbridges must open promptly and fully for the passage of vessels when a request or signal to open is given in accordance with this subpart. Presently, one bridge over the Apalachicola River is listed as having a special operating schedule under 33 CFR 117 Subpart B—Specific Requirements. Under 33 CFR 117.258, the draw of the CSX Railroad bridge at River Junction, mile 105.9 on the Apalachicola River, shall open on signal Monday through Friday from 8 a.m. until 4 p.m. At all other times the bridge will open on signal if at least four hours notice is given. This rule proposes to change the notice required for opening from four hours to eight hours for the CSX Railroad bridge.

A second bridge, the ANRR bridge at mile 4.5 on the Apalachicola River, (GIWW mile 347.0 EHL) in Apalachicola does not have a specific operating schedule, opening as required under 33 CFR 117.5. The Port of St. Joe, FL, owner of the bridge, has taken the rail line out of service and has an embargo to cease train operations for Port St. Joe and north of the Apalachicola River due to the absence of shipments coming in/out of Port St. Joe. While the embargo remains in effect, the operator of the bridge, ANRR, requests to maintain the swing bridge in the open-to-navigation position in accordance with 33 CFR 117.41. This rule proposes to add an operating schedule specific to the ANRR bridge under 33 CFR 117.258, stating that the bridge will be maintained in the open-to-navigation position.

Prior to the requests to change the operating schedules for these two bridges, no previous requests for changes have been received. These requests were initiated without consultation of waterway users but the USCG Bridge Administration Office in New Orleans was consulted for guidance on how to comply with the requirements of 33 CFR 117.41.

C. Basis and Purpose

The CSX swing bridge across the Apalachicola River, mile 105.9, presently opens on signal for the passage of vessels Monday through Friday from 8 a.m. until 4 p.m. At all other times, the bridge opens on signal if at least four hours advanced notice is given. The bridge owner has requested to change the operation regulations to reflect usage of the bridge by mariners. The request was made based upon a documented decrease in the number of requests for openings in the last three years. In 2010, the bridge opened 12 times for the passage of vessels. Eight of those openings were for either a United States Coast Guard (USCG) vessel or for a United States Army Corps of Engineers (USACE) vessel. In 2011, the bridge opened four times for the passage of vessels. Three of those openings were for either a USCG vessel or for a USACE vessel. Thus far in 2012, the bridge has only opened one time for a USACE vessel. It should be noted that all of the openings in the past three years have occurred between 8 a.m. and 4 p.m.; therefore, the bridge opened on signal for their passages. Information gathered regarding the decrease in vessel movements indicates that the lack of commercial facilities and the lack of maintenance on the waterway have contributed to the decline in traffic. While water elevations may return to their pre-drought levels, there is presently no evidence that the number of requests for bridge openings will increase in the future due to limited industrial development along the waterway. Accordingly, the bridge owner requested to change the operation regulations so that the bridge is allowed to open on signal at all times if at least eight hours advanced notification is given. USACE and USCG units using the waterway indicated that the proposed change to the operation of the bridge will not affect their ability to maintain the waterway and they have no objections to the proposed change.

The ANRR swing span bridge crosses the Apalachicola River at mile 4.5 (GIWW mile 347.0 EHL) and is required to open on signal for the passage of vessels. Since the bridge owner applied for and received an embargo for the suspension of train traffic on the line, the operation of the bridge is unnecessary and the operator of the bridge requested permission to leave the bridge in the open-to-navigation position and have the bridge untended. The bridge provides unlimited vertical clearance and 119 feet of horizontal clearance in the open-to-navigation position. Transit times for mariners should not be impeded with the bridge left in the open-to-navigation position. The bridge owner/operator will be required to maintain all bridge navigation lights in proper working order and will be required to periodically check the lights to see that they are working.

D. Discussion of Proposed Rule

The proposed rule for the CSX Railroad Bridge will require all vessels wishing to transit through the bridge site and needing the bridge to be opened for their passage to provide eight hours advanced notification. The proposed rule will require mariners to provide an additional four hours of advanced notification of arrival to transit through the bridge. For vessels wishing to transit through the bridge site between the hours of 8 a.m. and 4 p.m. Monday through Friday, these vessel operators will now be required to contact the bridge owner at least eight hours prior to transiting the bridge. As all openings in the past three years have been during the day, this requirement will be new to any vessels wishing to transit through the bridge site during these time frames. Several government vessels transit the waterway past the bridge site to conduct maintenance on the waterway. USACE and USCG units transiting the waterway indicated that the proposed change to the operation of the bridge will not affect their ability to maintain the waterway and they have no objections to the proposed change.

The proposed rule for the ANRR bridge should not cause any undue burden on any vessels as the bridge will remain in the open-to-navigation position and allow all vessels presently using the waterway at the bridge site to transit the bridge site without delay.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order

13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We consider the changes proposed in this rule to be minimal that a full Regulatory Evaluation is unnecessary. Very few vessels will be impacted by the proposed changes and those few vessels should be able to provide adequate advanced notification of their arrivals as is already done for the CSX Railroad bridge and vessels may transit through the ANRR bridge without delay as it will be maintained in the open-to-navigation position.

2. Impact on Small Entities

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

This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels needing to transit the Apalachicola River above mile 105.9. This action will not have a significant economic impact on a substantial number of small entities because these few vessels should be able to provide adequate advanced notification of their arrivals as is already done on this waterway for three other movable bridges located upstream and downstream of this bridge.

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

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 so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. 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 proposed rule would call for no 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 proposed rule under that Order and have determined that it 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 proposed 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 proposed rule would not affect 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 proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. This proposed rule involves the regulation of drawbridge operations. This rule is categorically excluded from further review under paragraph 32(e) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. In § 117.258, a new paragraph (a) is added and the current regulation is revised and redesignated as paragraph (b) to read as follows:

§ 117.258 Apalachicola River.

(a) The draw of the Apalachicola and Northern Railroad Bridge, mile 4.5 (GIWW mile 347.0 EHL), at Apalachicola, is maintained in the fully open-to-navigation position and untended. The bridge will not be returned to service until proper notification is published in **Federal Register**.

(b) The draw of the CSX Railroad Bridge, mile 105.9, at River Junction shall open on signal if at least eight hours notice is given.

Dated: July 13, 2012.

Peter Troedsson,

Captain, U.S. Coast Guard, Commander, Eighth Coast Guard District, Acting.

[FR Doc. 2012–18343 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG–2004–19621]

RIN 1625–AA89

Dry Cargo Residue Discharges in the Great Lakes

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes replacing its existing interim rule with a new rule to regulate the operation of U.S. and foreign vessels carrying bulk dry cargo such as limestone, iron ore, and coal on the U.S. waters of the Great Lakes, and the operation of U.S. bulk dry cargo vessels anywhere on the Great Lakes. Specifically, the Coast Guard proposes new requirements for the discharge of bulk dry cargo residue (DCR) on the U.S. waters of the Great Lakes. The Coast Guard also announces the availability of the tiered Draft Environmental Impact Statement (DEIS) prepared in support of this proposal. The proposed rule would continue to allow non-hazardous and non-toxic discharges of bulk DCR in limited areas of the Great Lakes. However, vessel owners and operators would need to minimize DCR discharges using methods they would be required to document in DCR management plans. The proposed rule would prohibit limestone and clean stone DCR discharges in some waters where they are now permitted. The proposed rule promotes the Coast Guard's strategic goals of maritime mobility and safety and protection of natural resources.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before October 29, 2012 or reach the Docket Management Facility by that date. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before October 29, 2012.

ADDRESSES: You may submit comments identified by docket number USCG-2004–19621 using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

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

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

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

Collection of Information Comments: If you have comments on the collection of information discussed in section VII.D. of this document, you must also send comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. To ensure that your comments to OIRA are received on time, the preferred methods are by email to *oira_submission@omb.eop.gov* (include the docket number and ''Attention: Desk Officer for Coast Guard, DHS'' in the subject line of the email) or fax at 202–395–6566. An alternate, though slower, method is by U.S. mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email John C. Morris, Office of Operating and Environmental Standards (CG–OES–3), U.S. Coast Guard; telephone 202–372–1433, email *John.C.Morris@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2004–19621), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing

address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2004–19621'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2004–19621'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

D. Public Meeting

We do not plan to hold a public meeting. But you may submit a request for one to the docket using one of the methods specified under ADDRESSES. In your request, explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

II. Abbreviations

AB Able Bodied Seaman
APPS Act to Prevent Pollution from Ships
CZMA Coastal Zone Management Act
DCR Dry Cargo Residue
DEIS Draft Environmental Impact Statement
DHS Department of Homeland Security
EIS Environmental Impact Statement
EPA Environmental Protection Agency
FEIS Final Environmental Impact Statement
FR **Federal Register**
ICR Information Collection Request
IR Interim Rule
MARPOL 73/78 International Convention for the Prevention of Pollution from Ships
NPRM Notice of Proposed Rulemaking
OIRA Office of Information and Regulatory Affairs, Office of Management and Budget
ROD Record of Decision
PIC Person in charge
SNPRM Supplemental Notice of Proposed Rulemaking
§ Section symbol
U.S.C. United States Code
VGP Vessel General Permit

III. Basis and Purpose

This supplemental notice of proposed rulemaking (SNPRM) proposes a rule to replace the interim rule (73 FR 56492, Sep. 29, 2008) now in effect. It also announces the availability of the tiered Draft Environmental Impact Statement (DEIS), which we previously announced we would prepare in support of this proposed rule (scoping notice, 73 FR 79496; Dec. 29, 2008). The legal basis for this rulemaking is section 623(b) of the Coast Guard and Maritime Transportation Act of 2004 (''the Act,'' Pub. L. 108–293). Section 623(b) of the Act gives the Coast Guard the authority, ''notwithstanding any other law * * * to promulgate regulations governing the discharge of dry bulk cargo residue on the Great Lakes.''

The purpose of this rulemaking, as a whole, is to exercise the authority conferred on the Coast Guard by the Act in a way that appropriately balances the needs of maritime commerce and environmental protection, by determining how, if at all, the discharge of dry cargo residue (DCR) can continue in the Great Lakes within a regulatory framework that imposes environmentally appropriate conditions on DCR discharges. The purpose of this SNPRM phase of the rulemaking is to propose a rule that would allow some DCR discharges to continue, under a regulatory framework that imposes additional conditions on the vessels from which those discharges take place.

IV. Background

Prior to opening this rulemaking, we published a notice of inquiry requesting information about the then-current status of dry cargo operations in the Great Lakes (69 FR 77147, Dec. 27, 2004; correction, 70 FR 1400, Jan. 5, 2005). The regulatory history for this rulemaking began with an announcement of our intent to prepare an Environmental Impact Statement (EIS) in support of the rulemaking and a request for public comments on the scope of the EIS (''scoping notice,'' 71 FR 12209, March 9, 2006). On June 8, 2006, we published a notice for a public meeting on the scope of the EIS, and again requested public comments (71 FR 33312). The scoping meeting was held in Cleveland, OH, on July 6, 2006. Our notice of proposed rulemaking (NPRM) and notice of the availability of the accompanying draft environmental impact statement appeared on May 23, 2008 (73 FR 30014). Public meetings on the NPRM and DEIS were announced on June 6, 2008 (73 FR 32273) and held in Duluth, MN, and Cleveland, OH, on July 15 and 17, 2008, respectively. Availability of the final environmental impact statement (FEIS) was announced on August 22, 2008, by the Environmental Protection Agency (73 FR 49667) and by the Coast Guard (73 FR 49694), and the Record of Decision (ROD) adopting the findings of the FEIS was signed September 23, 2008. An interim rule was published September 29, 2008 (73 FR 56492). On December 29, 2008 (73 FR 79496), we published a second scoping notice announcing our intent to prepare a new ''tiered'' (updated) EIS in support of a final rule, requested public comments, and announced a public scoping meeting, which was held in Chicago, IL, on January 28, 2009.

There are several factors that must be taken into account when addressing DCR discharges in the waters of the U.S. side of the Great Lakes. The Lakes support a significant volume of bulk dry cargo shipping that remains within the Great Lakes system. The Lakes are, in places, very deep and wide and either adjoin Canadian waters or are land-locked. Therefore, vessels that remain within the Great Lake system—unlike their East, West, or Gulf Coast counterparts—are continually subject to the navigable waters laws of both the United States and Canada.

The legislative conference report prepared in support of section 623(b) of the Act expressed Congress's expectation that in regulating Great Lakes DCR discharges, given these special characteristics, the U.S. Coast

Guard would adopt an approach ''that appropriately balances the needs of maritime commerce and environmental protection.'' House Report 108–617.

Our interim rule amended 33 CFR 151.66, a Coast Guard regulation that implements the Act to Prevent Pollution from Ships (APPS) 33 U.S.C. 1901 *et seq.* That regulation generally prohibits the discharge of DCR—an ''operational waste'' and, hence, ''garbage'' as both terms are defined in 33 CFR 151.05—in all U.S. navigable waters. The interim rule amended that prohibition with respect to the U.S. waters of the Great Lakes. It allows non-hazardous and non-toxic DCR discharges in limited areas of the Great Lakes, provided that carriers observe recordkeeping and reporting requirements, and it encourages carriers to adopt voluntary control measures for minimizing discharges. The interim rule applies to the owners and operators of U.S., Canadian, and other foreign vessels carrying bulk dry cargo on the U.S. waters of the Great Lakes, and also to the owners and operators of U.S. vessels carrying bulk dry cargo when they are on the Canadian waters of the Great Lakes. Non-self-propelled barges are excluded unless they are part of an integrated tug-and-barge unit.

Our Record of Decision in support of the interim rule concluded that the interim rule's only adverse environmental impacts would be minor and indirect, and that an outright ban of DCR discharges could cause an adverse economic impact for carriers and related industries in the Great Lakes region. Therefore, we found that allowing DCR discharges in the Great Lakes, under the conditions imposed by the interim rule, struck ''the best balance between economic and environmental concerns that can be achieved, given currently available information.'' ROD, p. 4. The conditions the interim rule imposed on DCR discharges were intended to limit even minor and indirect impacts of DCR discharges, and to give us the regulatory tools we needed to monitor discharges in the future.

We stated in the interim rule that, before taking action in this rulemaking, we would ''determine if, in the long term, the optimal balancing of commercial and environmental interests requires the mandatory use of DCR control measures, the adjustment of the geographical boundaries within which those discharges are currently allowed, or other regulatory changes.'' (73 FR at 56495.) We have now made a tentative determination of that issue and, in this SNPRM, we propose a rule based on that tentative determination. We request your comments on that determination and on the proposed rule.

V. Discussion of Comments on Interim Rule

In response to our September 2008 interim rule and December 2008 scoping notice, we received comments from 19 sources, including 5 State agencies (representing 4 States, with 1 State providing comments from 2 separate agencies, and 1 agency submitting multiple comments), 4 industry groups, 2 non-industry groups, 1 Indian Tribal group, and 7 individuals.

Three commenters expressed support for the interim rule or said DCR discharges should be permitted because of their low environmental impact and the high cost of eliminating discharges. Eight commenters expressed opposition to the interim rule or favored prohibiting all DCR discharges in the Great Lakes; one of the eight said our rule should move toward eliminating those discharges. These comments were unsupported by argument or evidence and therefore we can only acknowledge them.

Three State agency commenters said the interim rule is inconsistent with their State laws and with their coastal zone management plans. The interim rule states that it does not expressly preempt State laws and that it expressly cautions carriers that they must comply with all applicable Federal and State laws regulating DCR discharges. It also states that the Coast Guard will work with States and carriers to make sure carriers are informed of any State laws that could impose more restrictions on DCR discharges than the Coast Guard allows. 73 FR at 56497 col. 2.

Two State agency commenters said that DCR discharges are harmful because they provide favorable substrate conditions for invasive or exotic species. We acknowledge this as a legitimate concern, but point out that our tiered DEIS continues to support our 2008 ROD's finding that, with the mitigating measures the interim rule provides, any such adverse environmental impact is only minor and indirect. Furthermore, except for the Western Basin of Lake Erie, our proposed rule prohibits the discharge of any type of DCR within 3 miles of any shoreline in the Great Lakes. (The existing exception for the Western Basin recognizes that some vessels carrying limestone or clean stone never leave that area, so a complete prohibition on DCR discharges on those vessels could pose an extreme hardship on them.) This change to the interim rule would eliminate the introduction of any additional DCR substrate to shallower near-shore waters, the preferred habitat of several invasive species found in freshwater.

Two State agency commenters disagreed with our characterization of DCR as non-toxic and non-hazardous. Our tiered DEIS continues to support the interim rule's characterization of any DCR discharge it allows as non-toxic and non-hazardous.

Two State agency commenters pointed out that Lake Superior is the subject of a ''Demonstration Lake'' agreement between several States and the Province of Ontario, Canada, pursuant to which the parties commit themselves to the elimination of pollutants in Lake Superior. The International Joint Commission's 1990 designation of Lake Superior as a ''demonstration area'' led to a Binational Program to Restore and Protect the Lake Superior Basin, under which a zero-discharge standard applies, but only to particularly toxic heavy metals and organochlorine compounds. The Binational Program does not apply a zero discharge standard to other materials, such as DCR, so long as discharges of those other materials do not threaten identified key near-shore and wetland habitats. Our environmental analysis identified such habitats, based on all the data supplied to us by commenters or otherwise available to us. Both the interim rule and the proposed rule prohibit discharges in those habitats and other special protection areas.

Two State agency commenters said the interim rule is at odds with the EPA's Vessel General Permit (VGP) for discharges incidental to the normal operation of vessels. EPA requires VGP permittees to engage in specific behaviors or best management practices in order to minimize those discharges; the approach this SNPRM proposes for our rule. However, there is no conflict between the VGP and the interim rule, because the VGP specifically excludes from its coverage ''discharges of bulk dry cargo residues as defined at 33 CFR 151.66(b),'' citing the interim rule-amended version of 33 CFR 151.66. See VGP (Feb. 5, 2009), sec. 1.2.3.4; docket number EPA–HQ–OW–2008–0055–0717 (available at *http://www.regulations.gov*). One State agency commenter asked us to require specific technological and procedural measures for controlling DCR, pointing out for example that decks can be swept while cargo loading is in progress, and that shoreside facilities can stop their conveyor belts while a vessel repositions itself during loading operations. Another commenter offered information about specific control measures, recommended requiring the

use of best management practices to minimize DCR discharges, and recommended that we regulate shoreside facilities because vessels have no control over those facilities. Our proposed rule's ''broom clean'' requirement does not specify how to comply with that requirement, but one way would be to sweep the deck while loading takes place. We assume that the other control measures cited by these commenters would be among the voluntary options vessel owners and operators would consider in preparing the DCR management plans that we propose to require. With respect to shoreside facilities, we understand that vessels do not control those facilities, but they can voluntarily arrange with a facility to identify measures that the facility is willing to take to help the vessel comply with 33 CFR 151.66's requirements. As we subsequently discuss, we think that our regulatory focus needs to be on vessels rather than on shoreside facilities.

One State agency commenter said that we should voluntarily extend the interim rule's comment period and the period for consulting with States within the framework of the Coastal Zone Management Act (CZMA). The Coast Guard routinely grants State requests for additional time to evaluate Coast Guard CZMA consistency determinations, and both States and the general public will have that additional time to consider the Coast Guard's proposal for regulating DCR during the public comment period for this SNPRM, and therefore we do not see the need for additional extensions of time as requested by this commenter at this time.

One commenter, representing many States with coastal zone management plans, said that we should rely on States to provide us with information about developing port-based DCR control measures. As we subsequently discuss, we think that our regulatory focus needs to be on vessels, rather than on shoreside facilities. However, in proposing that vessels develop DCR management plans, we assume that a vessel's owner or operator will want to consult with shoreside facilities to assess what each facility can do to help the vessel comply with discharge minimization requirements.

Two commenters asked us to remove the quarterly reporting requirement as unnecessary, while two commenters recommended modifications to the Coast Guard recordkeeping form. We lack sufficient information to remove the reporting requirement at this time, and we specifically seek further public comment on the costs and benefits of indefinitely requiring the reporting to continue. Because the recommended modifications came from only two of the commenters and would require the costly revision of a commonly used standard form that provides the information we need, we also decline to modify the form at this time.

Another commenter, representing several associations, said that our reliance on the Act to regulate DCR discharges in the Great Lakes ''notwithstanding any other law'' was misplaced in the absence of a stronger showing of congressional intent to override international treaties like the International Convention for the Prevention of Pollution from Ships (MARPOL 73/78), or a stronger showing of the irreconcilability of MARPOL 73/78 and Great Lakes DCR regulations. MARPOL 73/78 is not irreconcilable with our interim rule or our proposed rule. Our interim rule already shares MARPOL Annex V's requirements for recordkeeping and for avoiding near-shore discharges, and our proposed rule would add an Annex V-like requirement for maintaining and following a DCR management plan. However, MARPOL 73/78 is inapplicable to the U.S. waters of the Great Lakes. APPS and the Act provide the statutory authority for 33 CFR 151.66. In the preamble to our interim rule, 73 FR at 56493, we extensively discussed the reasons why the zero-discharge approach to operational waste discharges (including DCR discharges) generally taken by APPS and Coast Guard regulations is not necessary for protecting the environment and could be disruptive for Great Lakes commerce. We also stated our interpretation that House Report 108–617, which accompanied passage of the Act, clearly expresses Congress's expectation that the Coast Guard will exercise its authority ''notwithstanding any other law'' to ''appropriately balance[e] the needs of maritime commerce and environmental protection.'' We believe the approach we took in the interim rule, and that we now propose strengthening in this rule, meets that expectation by adapting the pollution-preventing spirit of APPS to the special characteristics of the Great Lakes cited in our interim rule preamble's discussion.

The commenter representing several associations also called on the Coast Guard to review DCR control measures every three years. While we acknowledge that industry practices and technology may evolve over time, the Coast Guard declines to set a requirement for a three-year review. However, the Coast Guard will monitor that evolution and expects industry participants to do the same. In evaluating a vessel's compliance with the proposed DCR management plan requirement, the proposed rule would allow Coast Guard inspectors to take into account the extent to which the procedures described in the DCR management plan reflect current industry standard practices for vessels with comparable characteristics, cargoes, and operations. Furthermore, the Coast Guard is subject to statutes, executive orders, and agency policies that require the periodic reevaluation of existing regulations, including 33 CFR 151.66, to make sure that regulations continue to be appropriate despite changes in conditions.

Finally, the commenter representing several associations said that the Environmental Impact Statement (EIS) for the final rule should reevaluate DCR controls that affect special protected areas, and that we should add studies of discharge prohibitions under section 312 of the Clean Water Act, mandate complete discharge bans for new commercial operations and phased-in eliminations for existing operations, require mandatory discharge controls, and undertake additional studies of DCR toxicity. The interim rule already prohibits DCR discharges in special protected areas, and we have reevaluated that prohibition in the environmental analysis for this SNPRM. *www.regulations.gov.* Section 312 of the Clean Water Act seeks to address the dumping of untreated or inadequately treated sewage from vessels into U.S. navigable waters; DCR is not considered sewage waste and therefore this aspect of the comment is beyond the scope of our rulemaking. Our ongoing environmental analysis affirms our earlier assessment that ''any toxic components of DCR deposits in the Great Lakes do not exist in concentrations known to be toxic to organisms.'' 73 FR at 56494 col. 2; *www.regulations.gov.* We do not agree with the commenter's suggestion that mandatory discharge controls be imposed on all operations, but we do propose requiring each vessel to have a DCR management plan describing specifically how it will minimize discharges. This approach would require a vessel's owner or operator to determine and to implement those measures that best achieve discharge minimization, given the vessel's characteristics, cargoes, and operations. We also disagree with the commenter's suggestion that DCR discharge prohibitions be imposed on new operations and phased in for existing operations. We believe our proposal for discharge minimization, in accordance

with a vessel's DCR management plan, best achieves the balance of commercial and environmental considerations that Congress had in mind when it passed the Act.

One commenter said that the EIS for the final rule should study specific best management practices and technology. We agree, and our tiered DEIS reflects our evaluation of specific best management practices and technology.

One commenter, a Canadian association, said that we should harmonize our regulatory treatment of DCR with Canada's. We believe that our interim rule and our proposed rule are in harmony with Canadian DCR regulations for the Great Lakes, which may be found in Division 5, Subdivisions 1–4 of the Statutory Orders and Regulations of Canada (SOR)/2007–86, ''Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals.'' In promulgating these 2007 regulations, Transport Canada stated that its intent was to make Canadian regulations compatible with the then-current U.S. DCR enforcement policy. Like that policy, and like the interim rule and our proposed rule, the Canadian regulations prohibit the discharge of DCR in near-shore or special protected areas and require DCR discharge recordkeeping. In addition, Canadian regulations require that vessels carry and operate in accordance with a garbage management plan that covers its DCR procedures, and we are proposing a similar requirement with this rule.

The Canadian association also suggested some voluntary industry programs that could provide information about DCR control measures. We agree that owners and operators might find that such programs offer good advice on minimizing DCR discharges.

One commenter, representing Indian tribal interests, asked for consultation with the Coast Guard and asked that the EIS for the final rule add fish spawning grounds as a separate area of focus. Although we determined in the interim rule that Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, is not applicable to this rulemaking 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, 73 FR at 56496 col. 3, we have nevertheless engaged in consultation with this commenter. Documentation of that consultation appears in the docket as item USCG–2004–19621–0182. Fish spawning grounds have already been incorporated in our environmental analysis and DCR discharges in these areas are prohibited.

VI. Discussion of Proposed Rule

The context in which we developed this proposal. We stated in the interim rule that, before taking action in this rulemaking, we would ''determine if, in the long term, the optimal balancing of commercial and environmental interests requires the mandatory use of DCR control measures, the adjustment of the geographical boundaries within which those discharges are currently allowed, or other regulatory changes.'' 73 FR at 56495.

To help us achieve that long term balance, we analyzed the DCR discharge records reported to us in accordance with the interim rule. This helped us describe and quantify DCR discharges, and to determine what control measures were common and effective in controlling DCR discharges. This information is available in the appendices to the tiered DEIS. We also observed Great Lakes dry cargo operations firsthand. During the 2009 and 2010 shipping seasons, we visited vessels and facilities in the region, and observed cargo loading and unloading, and DCR discharge operations. This enabled us to gather DCR data using a known consistent set of metrics and a process that was completely independent of any used by vessel owners or operators to complete and submit their DCR discharge reports.

From this analysis and observation, we drew the following conclusions:

There is significant variation in the amount of DCR that vessels discharge; a finding that is supported by results reported by the regulated industry. However, most vessels appear to be minimizing the volume of DCR they discharge. They treat their cargo as a commodity to be conserved and not wasted. They deal with shoreside facilities that take the same practical view. These vessels and facilities use best practices to prevent cargo spillage in the first place, and to clean it up when it occurs. Most best practices are simple, intuitive, and cost little: For example, lining conveyor belts with fabric skirts, communicating with the shoreside facility to shut down loading chutes while moving from one hold to the next, and using brooms and shovels to clean up DCR and return it to the hold before the hold is sealed.

Deck spillage is a relatively minor source of DCR, and easily addressed through simple measures. By far the greater source of DCR is from cargo hold spillage into vessel tunnels. Tunnel spillage predominantly occurs during cargo unloading.

Within tunnels, large pieces of DCR that remain after unloading should be easy to recover while the vessel is underway, and to place on the conveyor belt with the rest of the cargo during the vessel's next unloading. Dust and small particles, however, inevitably make their way into the vessel's sump water. The sump must be pumped periodically, to preserve the vessel's trim and stability. Sump pumping can take several hours. If performed shoreside, this operation may delay the vessel, increasing its operating costs. It would be economically more rational to perform sump pumping only while the vessel is underway, though this would likely result in sump discharges being the main contributor to DCR discharges in the Great Lakes.

In this SNPRM, we propose a rule that would make three general changes to the current interim rule. (We also propose the non-substantive addition or amendment of two definitions, ''commercial vessel'' and ''mile,'' for stylistic purposes.) Our tiered DEIS supports all of these changes. The proposed rule would, like the interim rule, continue to apply to the owners and operators of U.S., Canadian, and other foreign vessels carrying bulk dry cargo on the U.S. waters of the Great Lakes, and also to the owners and operators of U.S. vessels carrying bulk dry cargo when they are on the Canadian waters of the Great Lakes. It would continue the interim rule's exclusion of non-self-propelled barges, unless they are part of an integrated tug and barge unit. The three proposed changes are as follows:

First, we would require the volume of DCR discharges to be minimized. Except for a new, objectively verifiable, ''broom clean'' standard applying to decks, discharge minimization would be achieved through methods of the vessel owner or operator's choice. ''Broom clean'' would be defined in 33 CFR 151.66(b)(2) as a condition in which deck residues ''consist only of dust, powder, or isolated and random pieces none of which exceeds 1 inch in diameter.'' ''Minimization'' would also be defined, as the ''reduction, to the greatest extent practicable, of any bulk dry cargo residue discharge from the vessel.'' Reinforcing the concept of minimization, we would also redefine bulk DCR to emphasize that DCR can exist ''regardless of particle size.''

Second, we would require discharge minimization methods to be documented in a vessel-specific DCR management plan, which we would

define as a written plan, subject to Coast Guard inspection, meeting at least the minimum criteria we would describe in 33 CFR 151.66(b)(5)

Third, limestone and clean stone DCR discharges would no longer be permitted within 3 miles of shore, except within a limited area of the Western Basin of Lake Erie.

Minimization and the DCR management plan. The proposed rule would require U.S. and foreign carriers conducting bulk dry cargo operations on the Great Lakes to minimize the amount of cargo residue discharged into the Great Lakes. Except for the new broom clean standard, our focus would be on discharge minimization, not on minimizing DCR. Nor would we require vessels to eliminate DCR discharges, because we continue to believe, as we did when we issued the interim rule, that a ''zero discharge'' requirement would be more costly than necessary to protect the environment against adverse impacts, and because the adverse impacts that can be associated with DCR discharges are only minor and indirect. Nevertheless, the elimination of DCR discharges remains the ideal, and we expect vessels to come as close to that ideal as practicable, given current industry standard practices for vessels of ''comparable characteristics, cargoes, and operations''—a term we would define in 33 CFR 151.66(b)(2) as meaning ''similar vessel design, size, age, crew complement, cargoes, operational routes, deck and hold configuration, and fixed cargo transfer equipment configuration.''

Discharge minimization would include keeping the vessel's deck in broom clean condition. All vessels should be able to achieve the broom clean standard on deck, by sweeping spilled cargo back into holds before they are sealed, if not by some other method. However, as noted, deck DCR only accounts for a relatively small proportion of overall DCR discharges. For the more significant tunnel sump discharges, it is not possible for us to define a similar standard that could be applied to all vessels. We believe that the degree of minimization that will be practicable for those discharges will depend on the variables of a vessel's characteristics, cargoes, and operations, and on the technology or procedures used to compensate for those variables.

Rather than mandating the use of specific procedures or technologies that may be ineffective or impracticable for some vessels, each vessel's owner or operator would select the method or methods best suited for minimizing that vessel's DCR discharges. We believe that the great majority of vessels affected by the proposed rule are already effectively minimizing those discharges. However, by making minimization a regulatory requirement, we would level the playing field to ensure that all affected vessels engage in responsible discharge minimization practices.

The proposed requirement for each vessel to carry its own vessel-specific DCR management plan on board, and to have that plan available for inspection, is central to the enforceability of a discharge minimization requirement.

Coast Guard inspectors would enforce discharge minimization by making sure that the vessel has a DCR management plan onboard, that the plan is complete and addresses all required items, and that the master or person in charge (PIC) ensures that the vessel and its crew operate according to the plan. The Coast Guard could infer the vessel's failure to minimize discharges from evidence such as:

- A missing plan;
- A plan that fails to address obvious DCR situations on the vessel that raise the probability of an eventual DCR discharge, such as obvious DCR buildup in the vessel's tunnels;
- Discharge minimization equipment that is called for in the plan but not maintained or operating properly; or
- A crewmember's inability to perform a discharge-minimization task for which the plan makes the crewmember responsible.

To ensure that the vessel's owner and operator exercise due diligence in writing the management plan, we would require the plan to describe:

- The equipment and procedures the vessel uses to minimize cargo spillage during loading and unloading;
- The equipment and procedures the vessel uses to recover spilled cargo and place it in holds or on unloading conveyances;
- How the owner or operator ensures crew familiarity with management plan procedures;
- Who has onboard responsibility for the vessel's discharge minimization procedures;
- What arrangements, if any, the vessel has with specific ports or cargo terminals for unloading and disposing of the vessel's DCR ashore; and
- How unavoidable DCR discharges will be conducted.

Our regulatory focus has been, and will remain, the vessels that carry bulk dry cargo—even though shoreside cargo loading and unloading facilities undoubtedly play a role in creating, or limiting the creation of, the shipboard DCR that is eventually discharged into the Great Lakes. Focusing on vessels makes sense because the Coast Guard's inspection infrastructure is more geared toward vessels than to shoreside facilities. We would expect each vessel's DCR management plan to describe how the vessel works with shoreside facilities to facilitate the vessel's compliance with the requirements of 33 CFR 151.66.

Another important aspect of the proposed management plan requirement is that the plan would need to be revised whenever there was a substantive change to the procedures or the equipment used to manage dry cargo residues on the vessel covered by the plan. Although regular or periodic revisions of the management plan are not required under this proposed rule, vessel owners would be required to maintain the plan in a manner that assures it accurately reflects the current procedures, practices, and technology employed in managing dry cargo residues on the vessel.

We expect that industry standard practices for the management of dry cargo residue will evolve as existing dry cargo conveyance technologies are supplanted by those that are more efficient, effective, and reliable. ''Industry standard practices'' would be specifically defined in 33 CFR 151.66(b)(2) and would include practices for installation, maintenance, operation, training, and supervision relating to bulk dry cargo transfer and DCR control measures. A primary premise of this proposed rule is that a vessel owner or operator will employ dry cargo residue management practices that are on par with the current industry standard for vessels of comparable characteristics, cargoes, and operations. ''Comparable characteristics, cargoes, and operations'' would be defined in 33 CFR 151.66 (b)(2) as meaning ''similar vessel design, size, age, crew complement, cargoes, operational routes, deck and hold configurations, and fixed cargo transfer equipment configurations''. A vessel's compliance with this requirement of the proposed rule would be determined in part by how well the vessel's DCR management practices, as outlined in its management plan, compare with the current industry standard practices employed by the majority of vessels with comparable characteristics, cargoes, and operations. If, for example, a vessel's plan continues to rely on technology or procedures that have been supplanted by more recent, affordable, and easily implemented industry standard practices, a Coast Guard inspector could consider this as evidence of failure to maintain the plan or failure to minimize DCR discharges.

Limestone and clean stone. While we propose to retain the interim rule's

approach toward the discharge of DCR in general, we propose a change with respect to limestone and clean stone DCR discharges. For most substances, DCR discharges have been and would remain subject to several geographic limitations, including a flat prohibition on discharges within a certain distance from shore and in special protected areas. For limestone and clean stone, however, the interim rule continued the prior policy, which allowed DCR from limestone and clean stone to be discharged close to shore, except where the nearest shore is in a special protected area or where the discharge would have an ''apparent impact'' on wetlands, fish spawning areas, or potable water intakes. We think this standard is too subjective and that it could be difficult for vessel crews to determine whether or not a stone DCR discharge would have an apparent impact on the local environment. Therefore, we propose making limestone and clean stone DCR discharges subject to the same 3 mile restriction we impose on other DCR discharges. Our 2009 and 2010 field research and the EIS indicated that limestone and clean stone vessels already avoid DCR discharges within 3 miles of shore because of near-shore operational hazards. Thus, those vessels should not incur any additional cost from the proposed extension of the exclusion zone. (We would preserve the existing exception for a limited portion of Lake Erie's Western Basin because some vessels carrying limestone or clean stone never leave that area, and if such a vessel wanted to discharge DCR it could be unusually and adversely affected by a complete prohibition on DCR discharges in the area.) Our proposed change would ensure that near-shore wetlands, fish spawning areas, and potable water intakes within the entire Great Lakes ecosystem are protected from DCR discharges, while simultaneously simplifying understanding and compliance with the rule for the regulated industry. It should also mitigate an environmental impact identified in the Final EIS for the interim rule; that is, possible changes in the physical structure of the lake bottom sediment, which may cause a less than 10% increase in zebra and quagga mussel attachment rates.

VII. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This SNPRM has not been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the SNPRM has not been reviewed by the Office of Management and Budget. A draft Regulatory Assessment follows:

The Coast Guard proposes a rule that would require vessels to minimize their DCR discharges, to document their DCR minimization methods, and to observe new restrictions on limestone and clean stone DCR discharges.

Table 1 compares components of the interim rule (baseline used for this rulemaking) and this SNPRM. It summarizes any changes in the component that we propose in the SNPRM.

TABLE 1—NO-ACTION (IR) AND PREFERRED ALTERNATIVE COMPARISON SUMMARY

Provision description	IR Provision	IR Provision synopsis	SNPRM Provision	SNPRM Provision synopsis	Change from IR to SNPRM
Record-keeping.	33 CFR 151.66(c)(1)(iv).	Vessels must record all DCR loading, unloading and sweeping on form CG–33.	NA		Recordkeeping requirement would remain in place. The industry would not incur any change in cost.
Reporting/ Certification.	33 CFR 151.66(c)(1)(iv).	The data collected are used to determine vessel practices in handling DCR, and the amount of DCR that is being managed by the vessels.	NA		Vessels will continue to certify and submit reports on a quarterly basis. The industry will not incur any change in cost.
Limestone & clean stone.	33 CFR 151.66(b)	Limestone and clean stone are exempt from the 3-mile near-shore sweeping boundary. Under the IR, these commodities can be discharged anywhere along the shoreline, provided there is no apparent impact on environmentally sensitive areas.	33 CFR 151.66(b)(2).	Limestone and clean stone DCR discharges, under the proposed rule, would not be allowed within 3 miles of shore.	There would be a no-cost change; our research indicates that vessels already avoid DCR discharges within 3 miles of shore because of near-shore operational hazards.
Voluntary minimization.	33 CFR 151.66(b)	Vessels are encouraged to minimize the amount of DCR going into the water and the use of control measures to reduce the amount of DCR falling on the decks and tunnels of vessels.	NA	The portion of 33 CFR 151.66(b) in the IR dealing with voluntary minimization would be removed in the SNPRM.	There is no cost associated with the removal of this IR requirement. (See the management plan below for details on mandatory minimization.)

TABLE 1—NO-ACTION (IR) AND PREFERRED ALTERNATIVE COMPARISON SUMMARY—Continued

Provision description	IR Provision	IR Provision synopsis	SNPRM Provision	SNPRM Provision synopsis	Change from IR to SNPRM
Broom clean standard.	NA		33 CFR 151.66(b)(3).	This requirement stipulates that vessels must show that decks have been swept to a standard that is in keeping with the mandatory minimization requirement of this proposed rule.	Vessels would realize a new cost for this requirement. We anticipate that vessels would see an annual cost increase ranging from $14,203 to $53,263 (non-discounted). Foreign vessels would incur an average annual cost of $28,847 (non-discounted). The benefit of this requirement is a reduction in the amount of discharge going into the waters of the Great Lakes.
Management plan.	NA		33 CFR 151.66(b)(4).	The plan must describe the specific measures the vessel employs to ensure the minimization of bulk dry cargo residue discharge.	The new requirement would have an initial year cost of $24,777 (non-discounted) to prepare a management plan. After the initial year, existing U.S. vessels would not incur additional cost (within the 10-year period of analysis) from this new requirement. Foreign vessels would incur a first year cost of $17,340 and an annual cost of $1,530 (all non-discounted) from this new requirement. This requirement would ensure that vessels are minimizing the amount of DCR going into the waters of the Great Lakes, and provide USCG with the means of policing DCR discharge.

Costs

The proposed rule has costs associated with having vessel owners and operators develop and maintain a management plan that describes the specific measures the vessel employs to ensure the minimization of bulk DCR discharges in the waters of the Great Lakes. The proposed rule would not impose any additional capital expenditures on the U.S. bulk dry cargo fleet operating exclusively on the Great Lakes, since we believe that vessels would use equipment already available onboard their vessels to comply with this proposed rule (for further information on specific measures currently being used, see DEIS).

We estimated the annualized costs of the SNPRM for the US fleet to range from $17,500 to $56,298 (with a per vessel average cost of $671), and the annualized costs of the SNPRM for the foreign fleet to range from $13,922 to $48,697 (with a per vessel average cost of $368), all costs are estimated using a 7 percent discount rate. The following table summarizes the affected population of vessels, costs and benefits of the proposed rule.

TABLE 2—SUMMARY OF AFFECTED POPULATION, COSTS AND BENEFITS OF THE SNPRM

Affected Population	
US	55 Vessels (14 owners).
Foreign	85 Vessels.
Total	140 Vessels.
Costs*	
US	Annualized = $17,500—$56,298. 10 year = $122,916—$395,413.
Foreign	Annualized = $13,922—$48,697. 10 year = $97,786—$342,029.
Total	Annualized = $31,423—$104,995. 10 year = $220,701—$737,444.
Benefits	
Minimizing the amount of DCR discharged into the waters of the Great Lakes would improve the aquatic environment. Promotion of environmental stewardship among owners and operators.	

* Costs are presented as ranges and estimated using a 7 percent discount rate.

The proposed rule would require all vessels loading or unloading bulk dry cargo at ports within the U.S. waters of the Great Lakes, and each U.S. bulk dry cargo vessel anywhere on the Great Lakes, to have a management plan

onboard and available for Coast Guard inspection that describes the specific measures the vessel employs to minimize DCR discharges. Foreign vessels greater than 400 GT can meet the management plan requirement under this proposed rule because they are required to meet the similar waste management plan requirement in Annex V of MARPOL 73/78. However, since Annex V of MARPOL 73/78 does not cover all of the requirements in 33 CFR 151.66(b)(4), foreign vessels would be required to address any additional management plan requirements under this proposed rule.

We estimate that the proposed rule would affect 14 entities that currently manage the 55 U.S. dry bulk carrier vessels, and 85 foreign dry bulk carrier vessels (70 Canadian and 15 non-Canadian) operating within U.S. jurisdictional waters of the Great Lakes in any given year. We anticipate that the controlling entities of U.S. vessels would write the management plans. We assume that a management plan for a foreign vessel operating in the U.S. waters of the Great Lakes would be written by the vessel master.

We estimate the affected population of foreign dry bulk carriers to be 85 vessels based on the data obtained from reporting requirements established by the 2009 interim rule. We originally estimated the foreign vessel population to be 219 vessels for 2008 NPRM and the 2009 interim rule. Our revised estimate of the foreign vessel population is based on recent data on foreign vessel dry cargo operations that was not available for the NPRM or the interim rule publications.

To maintain consistency with the cost methodology used in the interim rule, we continue to use Coast Guard reimbursable standard rates found in COMMANDANT INSTRUCTION 7310.1M (''COMDTINST'') to analyze the changes in wages for this rulemaking.[1] We have verified that the wages found in the COMDTINST are comparable to the loaded wages found in the Bureau of Labor Statistics. Therefore, that comparison between the interim rule and the SNPRM is straightforward.

Table 3 below shows estimated costs for developing the management plan required by proposed 33 CFR 151.66(b)(4) and for having onboard a hard copy of the plan available for inspection by the Coast Guard.

TABLE 3—COST OF COMPANY DEVELOPMENT OF A MANAGEMENT PLAN

[Non-discounted]

33 CFR 151.66 (b)(4)	Developer rating	Labor rate (loaded)	Time in hours	Cost per plan	Number of plans	Total initial cost	Recurring cost
US							
Company management plan ...	GS–12	$69	25	$1,725	14	$24,150	.....
Cost of copies	GS–3	28	.05	[a] 11.40	55	627	.....
Foreign							
Canadian Vessel	O–6	136	[b] 1.5	204	70	14,280	.....
Non-Canadian Foreign	O–6	136	[b] 1.5	204	15	3,060	[c] 1,530
Total	.....	.....	.....	.....	.....	42,117	1,530

Note: Values may not total due to rounding.

(a): Assumes that companies would spend $10 on supplies for each copy of the management plan. The $10 is added to the labor and time estimated to be $1.40 ($28 * 0.05 hrs), therefore the total cost of copies per plan is $11.40.

(b): We assume that foreign vessels greater than 400 GT would develop a modified management plan, since foreign vessels greater than 400 GT are required to have a waste management plan in accordance with Annex V of MARPOL 73/78. Therefore, the time required by foreign vessels greater than 400 GT to develop a management plan would be less than the time estimated for the U.S. fleet. Time required for foreign vessels developing a management plan was provided by the USCG Environmental Standards Division.

(c): The recurring cost of the management plan is only for half of the non-Canadian foreign vessels entering the Great Lakes in any given year. We anticipate that half the number of these vessels would return the following year, while the other half would be new visitors to the Great Lakes.

In addition to the management plan, the proposed rule would require that the deck be maintained in a broom clean condition whenever a vessel is in transit (33 CFR 151.66(b)(4)). We assume for the purpose of this regulatory analysis that an Able Body Seaman (AB) would be tasked with maintaining the broom clean standard as required under this proposed rule during loading and unloading operations, to the best of the AB's abilities under current vessel conditions. The requirement is intended to ensure that vessels are active in reducing the amount of DCR going into the waters of the Great Lakes. We do not expect that vessels would need to purchase additional brooms, shovels, etc., since these items are standard equipment on those vessels.

In order to determine the cost of maintaining decks in broom clean condition, we established that the surface area requiring broom cleaning would be those areas around the cargo hatches. During a site visit to the Great Lakes to observe vessel loading and unloading operations, we recorded the number of hatches for each vessel visited. We extrapolated the observed data to obtain an estimated number of total hatches for the Great Lakes bulk dry cargo fleet. We estimated the total number of hatches for the 55 U.S. vessels to be 1,169, while the total number of hatches for the 70 Canadian and 15 non-Canadian foreign vessels was estimated at 1,672. We estimate that 15 to 56 percent of the hatches would be affected by the broom clean standard after every loading and unloading event, and that it would take an AB three minutes per hatch (at a wage rate of $27 per hour) to meet the broom clean standard. Table 4 shows the annual estimated cost to the U.S. fleet for maintaining the broom clean standard. The cost range for this requirement is $14,203 to $53,001 (non-discounted). Costs are based on all vessels making an average of 60 trips per year.[2]

[1] COMMANDANT INSTRUCTION 7310.1M, ''COAST GUARD REIMBURSABLE STANDARD RATES'', FEB 28 2011, *http://www.uscg.mil/directives/ci/7000-7999/CI_7310_1M.PDF* (begins on page 3).

[2] Annual vessel trip information comes from the DEIS.

TABLE 4—U.S. FLEET COST FOR MEETING THE BROOM CLEAN STANDARD

33 CFR 151.66 (b)(3)	Crew member	Labor rate	Time req'd (%/Hr)	Total number of fleet hatches	% of Hatches swept	% Vessels broom clean	Avg number of trips/yr.	Number of crew	Total hrs/ yr.	Total cost
Broom Clean (Low)	Deckhand (AB)	$27	0.05	1,169	15	100	60	1	526	$14,203
Broom Clean (High)	Deckhand (AB)	27	0.05	1,169	56	100	60	1	1,963	53,001

Note: Values may not total due to rounding.

The cost to Canadian and non-Canadian foreign vessels is shown in Tables 5(a) and (b). The combined cost of the broom clean standard for foreign vessels is estimated to range from $69 to $45, 247 (non-discounted). Costs are based on Canadian vessels making an average of 45 trips per year and non-Canadian foreign vessels averaging only one trip per year.

TABLE 5(A)—CANADIAN FLEET COST FOR MEETING THE BROOM CLEAN STANDARD

33 CFR 151.66 (b)(3)	Crew member	Labor rate	Time req'd (%/Hr)	Total number of fleet hatches	% of Hatches swept	% Vessels broom clean	Avg number of trips/yr.	Number of crew	Total hrs/ yr.	Total cost
Broom Clean (Low)	Deckhand (AB)	$27	0.05	1,330	15	100	45	1	449	$12,120
Broom Clean (High)	Deckhand (AB)	27	0.05	1,330	56	100	45	1	1676	45,247

Note: Values may not total due to rounding.

TABLE 5(B) NON-CANADIAN FOREIGN FLEET COST FOR MEETING THE BROOM CLEAN STANDARD

33 CFR 151.66 (b)(3)	Crew member	Labor rate	Time req'd (%/Hr)	Total number of fleet hatches	% of Hatches swept	% Vessels broom clean	Avg number of trips/yr.	Number of crew	Total hrs/ yr.	Total cost
Broom Clean (Low)	Deckhand (AB)	$27	0.05	342	15	100	1	1	3	$69
Broom Clean (High)	Deckhand (AB)	27	0.05	342	56	100	1	1	10	259

Note: Values may not total due to rounding.

The cost of complying with the management plan and broom clean requirements for the U.S. fleet is estimated to have a first-year cost range of $38,982 to $77,778 (non-discounted) and recurring annual costs ranging from $14,203 to $53,001 (non-discounted). Table 6 shows the U.S. fleet cost estimate for the 10-year period of analysis.

TABLE 6—U.S. VESSELS HIGH AND LOW COST ESTIMATES

Year	High Cost Estimate			Low Cost Estimate		
	Undiscounted	3%	7%	Undiscounted	3%	7%
1	$77,778	$75,513	$72,690	$38,982	$37,846	$36,432
2	53,001	49,959	46,293	14,203	13,388	12,406
3	53,001	48,503	43,265	14,203	12,998	11,594
4	53,001	47,091	40,434	14,203	12,619	10,836
5	53,001	45,719	37,789	14,203	12,252	10,127
6	53,001	44,388	35,317	14,203	11,895	9,464
7	53,001	43,095	33,006	14,203	11,549	8,845
8	53,001	41,839	30,847	14,203	11,212	8,266
9	53,001	40,621	28,829	14,203	10,886	7,726
10	53,001	39,438	26,943	14,203	10,569	7,220
Total Cost	554,787	476,165	395,413	166,812	145,214	122,916
Annualized Cost	.....	55,821	56,298	.....	17,024	17,500

Note: Values may not total due to rounding.

In addition, we estimate that foreign vessels would incur a first-year cost that ranges from $15,249 to $59,527 (non-discounted). All foreign vessels would incur an annual cost due to the broom clean standard; however, half of the 15 non-Canadian foreign vessels entering the U.S. waters of the Great Lakes would be anticipated to incur an additional cost for developing a management plan since the same non-Canadian foreign vessel is not expected to make the same trip every year. We estimate recurring cost of all foreign vessels to range from $13,719 to $47,035 (non-discounted). Table 7 shows the U.S. fleet cost estimate for the 10-year period of analysis.

TABLE 7—FOREIGN VESSELS HIGH AND LOW COST ESTIMATES

Year	High Cost Estimate			Low Cost Estimate		
	Undiscounted	3%	7%	Undiscounted	3%	7%
1	$59,527	$57,793	$55,632	$15,249	$14,805	$14,251
2	47,035	44,335	41,082	13,719	12,391	11,983
3	47,035	43,044	38,395	13,719	12,555	11,199
4	47,035	41,790	35,883	13,719	12,189	10,466
5	47,035	40,573	33,535	13,719	11,834	9,781
6	47,035	39,391	31,342	13,719	11,489	9,141
7	47,035	38,244	29,291	13,719	11,155	8,543
8	47,035	37,130	27,375	13,719	10,830	7,985
9	47,035	36,049	25,584	13,719	10,514	7,462
10	47,035	34,999	23,910	13,719	10,208	6,974
Total Cost	482,843	413,347	342,029	138,719	118,510	97,786
Annualized Cost	.....	48,457	48,697	.....	13,893	13,922

Note: Values may not total due to rounding.

The proposed rule would also prohibit all near-shore limestone and clean stone DCR discharges, except in the Western Basin of Lake Erie. Our research found that vessels carrying limestone and clean stone already avoid DCR discharges within 3 miles of shore because of near-shore operational hazards. Therefore, the proposed prohibition of these discharges would not incur any additional cost to the fleet.

We estimate the total annualized cost to industry (US and foreign) of the SNPRM to be $31,423 to $104,995 and the total discounted 10-year costs to industry to be $220,701 to $737,444 (values discounted at 7 percent). We do not expect there would be additional government costs required to implement the changes from this SNPRM.

Benefits

We examined the benefits of the proposed rule and concluded that the benefits are qualitative. The requirement of the management plan causes all vessel owners and operators to become more active in preserving the Great Lakes' aquatic environment. The proposed rule sets a performance standard that allows the industry to determine its most efficient methods to minimize DCR discharges.

We anticipate that the proposed rule would change the current industry behavior of discharging DCR into the waters of the Great Lakes. The proposed requirement for vessels to have and follow DCR management plans should increase overall compliance levels with today's industry best practices for preventing or minimizing DCR discharges. In enforcing the DCR management plan requirement, the Coast Guard would be able to consider how well a vessel's plan reflects then-current industry standard practices. This would ensure that if, over time, there is an improvement in most vessels' ability to manage DCR, all vessels will be measured against the improved standard. Although our environmental analysis has shown only minor and indirect adverse environmental impacts from DCR discharges, we assume that any reduction in those impacts would provide at least a qualitative benefit. In addition, the vessel owners and operators themselves could realize efficiency gains from maintaining and gradually improving their DCR management practices. The proposed rule would not impose a rigid prescriptive standard, but would give the industry the flexibility to develop vessel-specific performance standards that achieve the regulatory objectives in the most cost-effective way.

Alternatives

Alternative 1: no action. This alternative would simply keep the current DCR interim rule in place. We have re-evaluated the interim rule and concluded that our proposed rule would do more to minimize the volume of DCR discharge going into the waters of the Great Lakes and would reduce the interim rule's regulatory costs. Therefore we reject this alternative.

Alternative 2: modified regulations with DCR management plan requirement. This is the preferred alternative described in this SNPRM and evaluated here.

Alternative 3: baseline control measures. This alternative would enforce the existing DCR management baseline. Each vessel would be required to maintain its current practices or equipment for managing DCR. We closely evaluated this alternative but reject it because over time a vessel's baseline operational equipment will wear out and need replacement, and it would be difficult for inspectors to gauge how well the replacement equipment replicates the operational state attained by the original equipment. Moreover, this alternative provides inferior environmental protection, by locking vessels into today's baseline. By contrast, the preferred alternative assumes that DCR management practices and technology will improve over time, and we want the regulatory compliance of vessels in the future to be measured against the best practices and technology then available, and not against today's baseline, which we assume will represent a lower level of DCR management capability.

B. Small Entities

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

The Coast Guard analysis did not find any non-profit or governmental small entities. However, we did find 9 small entities affected by this rule classified under one of the following North American Industry Classification System (NAICS) 6-digit codes for water transportation: 238910—Site Preparation Constructor; 483113—Coastal and Great Lakes Freight Transportation; 484110—General Freight Trucking Local; 487210—Scenic & Sightseeing Transportation Water;

483212—Inland Water Passenger Transportation; and 483211—Inland Water Freight. According to the Small Business Administration's size standards, a U.S. company classified under these NAICS codes with annual revenues of less than $7 million is considered a small business. We estimate the cost of this rule to be less than 1 percent of revenue for 100 percent of the small entities for both initial and recurring costs. The estimated annualized costs per small entity complying with the proposed rule would range from a high estimate of $7,327 to a low estimate of $2,267 with both discounted at 7 percent respectively.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. Comments submitted in response to this finding will be evaluated under the criteria in the ''Regulatory Information'' section of this preamble.

We are interested in the potential impacts from this proposed rule on small businesses and we request public comment on these potential impacts. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the docket where indicated under the ''Public Participation and Request for Comments'' section of this SNPRM, or see *www.regulations.gov,* docket number USCG–2004–19621, for additional instruction.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult John C. Morris of the Office of Operating and Environmental Standards (CG–OES–3) at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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).

D. Collection of Information

The proposed rule would call for a revision to an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1310.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of those who must collect the information, and an estimate of the total annual burden can be found under, ''The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.''

Title: Waste Management Plans, Refuse Discharge Logs, and Letters of Instruction for Certain Persons in Charge (PIC).

Summary of the Collection of Information

The Information Collection Request (ICR) is a collection of recordkeeping requirements that documents management of waste onboard vessels. It also requires that persons on non-inspected vessels must carry a letter verifying the credential of the PIC, and that they have had instruction on the management of waste. Currently, the ICR covers Waste Management Plans and Refuse Discharge Logs for The International Convention for the Prevention of Pollution from Ships letters of instruction for certain PIC and the DCR recordkeeping.

This proposed rule deals with section D of the current ICR, which addresses all dry bulk carrier vessels (foreign and domestic) operating on the Great Lakes. Under the interim rule, this population is required to report DCR quantities and the location of discharges into U.S. waters of the Great Lakes, in accordance with 33 CFR 151.66(c). We used the information collected from these reports to analyze and determine how best to regulate vessels in handling/managing DCR. The proposed rule would require U.S. and foreign vessels to develop and maintain a management plan that describes the specific measures the vessel employs to ensure the minimization of bulk DCR discharges.

Need for Information: Since there is no uniformity as to the types of equipment used throughout the fleet, the management plan would provide a description of how the individual vessel ensures the minimization of DCR discharges.

Proposed Use of Information: The information in the management plan would provide the Coast Guard with the means to monitor how individual operators are effectively managing and minimizing their DCR discharges. In addition, the management plan would be used by Coast Guard inspectors to enforce the minimization requirement.

Description of the Respondents: We estimate that all U.S. bulk dry cargo vessels operating anywhere in the Great Lakes, and foreign commercial bulk dry cargo vessels operating on the U.S. waters of the Great Lakes, would be affected by the management plan requirement.

Number of Respondents: The management plan would have a total number of 140 [3] (55 U.S. vessels + 70 Canadian vessels + 15 non–Canadian foreign vessels) respondents, which account for the total number of bulk dry cargo vessels operating on the waters of the Great Lakes in any given year.

Frequency of the Response: All vessels carrying bulk dry cargo on the Great Lakes are required to develop a management plan. The frequency in the development of the management plan would be subject to vessels modifying their vessels and/or equipment. We do not anticipate vessels modifying or adding major equipment during the 10-year period of this analysis. We therefore assume that the development of the management plan would occur once for U.S. and Canadian vessels. However, a percentage (50%) of non-Canadian foreign vessels would be required to develop a management plan each year, since we estimate that this percentage would be entering the Great Lakes for the first time. Therefore, we estimate that in the first year there would be 140 (55 U.S. vessels + 70 Canadian vessels + 15 non-Canadian foreign vessels) total management plans developed by all bulk dry cargo vessels operating in U.S. waters, and 8 (rounded) reoccurring responses by non-Canadian foreign vessels.

Burden of Response: We estimate that there would be 55 management plans developed for the entire U.S. dry cargo vessel fleet operating on the Great

[3] The number of foreign vessels affected has been updated (from the interim rule) due to information being provided by Form CG–33.

Lakes, and that it would only affect the burden of response in the first year that the proposed rule is in effect. The total estimated burden hours for the U.S. fleet is 352.75 (350 hours company section + 2.75 hours copies), at a cost to the fleet of $24,150 (non-discounted). The total foreign vessel fleet would have a burden of response in the first year of 128 hours (1.5 hours for management plan × 85 vessels), at a cost of $17,340 (non-discounted).

Estimate of Total Annual Burden: The proposed rule would not have an annual cost burden after the first year of this rule being implemented for U.S. and Canadian vessels (see ''BURDEN OF RESPONSE,'' above). After the first year, non-Canadian foreign vessels would incur an annual burden. We anticipate non–Canadian vessels would incur an annual burden of 11 hours for management plan development at a cost of $1,530 (non-discounted).

As required by the Paperwork Reduction Act of 1995, we have submitted a copy of this proposed rule to OMB for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining the burden are; how we can improve the quality, usefulness, and clarity of the information, and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated under **ADDRESSES**, by the date under **DATES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this proposed rule, OMB would need to approve the Coast Guard's request to collect this information.

E. 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 proposed rule under that Order and have determined that it does not have implications for federalism. As we discussed at length in part V of this preamble, we received comments from several States in response to our interim rule and are aware that some agencies in some States bordering the Great Lakes disagree with the Coast Guard's approach to the discharge of DCR in those waters. We encourage all such States, and any of their agencies with a stake in the outcome of this rulemaking, to continue sharing their input with us. We believe neither the interim rule, nor the rule proposed by this document, necessarily preempts or conflicts with State laws that may prohibit DCR discharges or impose conditions on those discharges that differ from those imposed by the Coast Guard. We do not take the position that such State laws facially frustrate an overriding Federal purpose. Until such time as a cognizant court rules to the contrary, we caution carriers that they must comply with all applicable Federal and State laws regulating DCR discharges. We encourage States to make us aware of laws they think are applicable. As we are so informed, we will share that information with the public by placing it in the docket for this rulemaking.

F. Unfunded Mandates Reform Act

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

G. Taking of Private Property

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

H. Civil Justice Reform

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

I. Protection of Children

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

J. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. However, a group representing tribal interests requested consultation, and the Coast Guard agreed to brief that group on the rulemaking. The briefing is described in the docket (see docket item USCG–2004–19621–0182).

K. Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National

Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). A draft ''Environmental Impact Statement'' (EIS) is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. We encourage the public to submit comments on the draft EIS.

List of Subjects in 33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 151 as follows:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

1. The authority citation for part 151 continues to read as follows:

Authority: 33 U.S.C. 1321, 1902, 1903, 1908; 46 U.S.C. 6101; Pub. L. 104–227 (110 Stat. 3034); Pub. L. 108–293 (118 Stat. 1063), § 623; E.O. 12777, 3 CFR, 1991 Comp. p. 351; DHS Delegation No. 0170.1, sec. 2(77).

2. Amend § 151.66 by revising paragraph (b) to read as follows:

§ 151.66 Operating requirements: Discharge of garbage in the Great Lakes and other navigable waters.

* * * * *

(b)(1) On the U.S. waters of the Great Lakes, commercial vessels may discharge bulk dry cargo residues in accordance with and subject to the conditions imposed by this paragraph

(2) As used in this paragraph—

Apostle Islands National Lakeshore means the site on or near Lake Superior administered by the National Park Service, less Madeline Island, and including the Wisconsin shoreline of Bayfield Peninsula from the point of land at 46°57′19.7″ N, 090°52′51.0″ W southwest along the shoreline to a point of land at 46°52′56.4″ N, 091°3′3.1″ W.

Broom clean means a condition in which the vessel's deck shows that care has been taken to prevent or eliminate any visible concentration of bulk dry cargo residues, so that any remaining bulk dry cargo residues consist only of dust, powder, or isolated and random pieces, none of which exceeds 1 inch in diameter.

Bulk dry cargo residues means non-hazardous and non-toxic residues, regardless of particle size, of dry cargo carried in bulk, including limestone and other clean stone, iron ore, coal, salt, and cement. It does not include residues of any substance known to be toxic or hazardous, such as nickel, copper, zinc, lead, or materials classified as hazardous in provisions of law or treaty.

Caribou Island and Southwest Bank Protection Area means the area enclosed by rhumb lines connecting the following coordinates, beginning on the northernmost point and proceeding clockwise:

47°30.0′ N, 085°50.0′ W
47°24.2′ N, 085°38.5′ W
47°04.0′ N, 085°49.0′ W
47°05.7′ N, 085°59.0′ W
47°18.1′ N, 086°05.0′ W

Commercial vessel means a commercial vessel loading, unloading, or discharging bulk dry cargo in the U.S. waters of the Great Lakes, or a U.S. commercial vessel transporting bulk dry cargo and operating anywhere on the Great Lakes; but the term does not include a non-self-propelled barge unless it is part of an integrated tug and barge unit.

Comparable characteristics, cargoes, and operations means similar vessel design, size, age, crew complement, cargoes, operational routes, deck and hold configuration, and fixed cargo transfer equipment configuration.

Detroit River International Wildlife Refuge means the U.S. waters of the Detroit River bound by the area extending from the Michigan shore at the southern outlet of the Rouge River to 41°54.0′ N 083°06.0′ W along the U.S.-Canada boundary southward and clockwise connecting points:

42°02.0′ N, 083°08.0′ W
41°54.0′ N, 083°06.0′ W
41°50.0′ N, 083°10.0′ W
41°44.52′ N, 083°22.0 ′ W
41°44.19′ N, 083°27.0′ W

Dry cargo residue (or DCR) management plan means the plan required by paragraph (b)(5) of this section.

Grand Portage National Monument means the site on or near Lake Superior, administered by the National Park Service, from the southwest corner of the monument point of land at 47°57.521′ N, 089°41.245′ W to the northeast corner of the monument point of land, 47°57.888′ N, 089°40.725′ W.

Indiana Dunes National Lakeshore means the site on or near Lake Michigan, administered by the National Park Service, from a point of land near Gary, Indiana at 41°42′59.4″ N, 086°54′59.9″ W eastward along the shoreline to 41°37′08.8″ N, 087°17′18.8″ W near Michigan City, Indiana.

Industry standard practices means practices that ensure the proper installation, maintenance, and operation of shipboard cargo transfer and DCR removal equipment, proper crew training in DCR minimization procedures and cargo transfer operations, and proper supervision of cargo transfer operations to minimize DCR accumulation on or in a commercial vessel.

Integrated tug and barge unit means any tug-barge combination which, through the use of special design features or a specially designed connection system, has increased sea-keeping capabilities relative to a tug and barge in the conventional pushing mode.

Isle Royale National Park means the site on or near Lake Superior, administered by the National Park Service, where the boundary includes any submerged lands within the territorial jurisdiction of the United States within 4½ miles of the shoreline of Isle Royale and the surrounding islands, including Passage Island and Gull Island.

Mile means a statute mile.

Milwaukee Mid-Lake Special Protection Area means the area enclosed by rhumb lines connecting the following coordinates, beginning on the northernmost point and proceeding clockwise:

43°27.0′ N, 087°14.0′ W
43°21.2′ N, 087°02.3′ W
43°03.3′ N, 087°04.8′ W
42°57.5′ N, 087°21.0′ W
43°16.0′ N, 087°39.8′ W

Minimization means the reduction, to the greatest extent practicable, of any bulk dry cargo residue discharge from the vessel.

Northern Refuge means the area enclosed by rhumb lines connecting the coordinates, beginning on the northernmost point and proceeding clockwise:

45°45.0′ N, 086°00.0′ W

western shore of High Island, southern shore of Beaver Island:

45°30.0′ N, 085°30.0′ W
45°30.0′ N, 085°15.0′ W
45°25.0′ N, 085°15.0′ W
45°25.0′ N, 085°20.0′ W
45°20.0′ N, 085°20.0′ W
45°20.0′ N, 085°40.0′ W
45°15.0′ N, 085°40.0′ W
45°15.0′ N, 085°50.0′ W
45°10.0′ N, 085°50.0′ W
45°10.0′ N, 086°00.0′ W

Pictured Rocks National Lakeshore means the site on or near Lake Superior, administered by the National Park Service, from a point of land at

46°26′21.3″ N, 086°36′43.2″ W eastward along the Michigan shoreline to 46°40′22.2″ N, 085°59′58.1″ W.

Six Fathom Scarp Mid-Lake Special Protection Area means the area enclosed by rhumb lines connecting the following coordinates, beginning on the northernmost point and proceeding clockwise:

44°55.0′ N, 082°33.0′ W
44°47.0′ N, 082°18.0′ W
44°39.0′ N, 082°13.0′ W
44°27.0′ N, 082°13.0′ W
44°27.0′ N, 082°20.0′ W
44°17.0′ N, 082°25.0′ W
44°17.0′ N, 082°30.0′ W
44°28.0′ N, 082°40.0′ W
44°51.0′ N, 082°44.0′ W
44°53.0′ N, 082°44.0′ W
44°54.0′ N, 082°40.0′ W

Sleeping Bear Dunes National Lakeshore means the site on or near Lake Michigan, administered by the National Park Service, that includes North Manitou Island, South Manitou Island and the Michigan shoreline from a point of land at 44°42′45.1″ N, 086°12′18.1″ W north and eastward along the shoreline to 44°57′12.0″ N, 085°48′12.8″ W.

Stannard Rock Protection Area means the area within a 6-mile radius from Stannard Rock Light, at 47°10′57″ N, 087°13′34″ W.

Superior Shoal Protection Area means the area within a 6-mile radius from the center of Superior Shoal, at 48°03.2′ N, 087°06.3′ W.

Thunder Bay National Marine Sanctuary means the site on or near Lake Huron designated by the National Oceanic and Atmospheric Administration as the boundary that forms an approximately rectangular area by extending along the ordinary high water mark between the northern and southern boundaries of Alpena County, cutting across the mouths of rivers and streams, and lakeward from those points along latitude lines to longitude 83 degrees west. The coordinates of the boundary are:

45°12′25.5″ N, 083°23′18.6″ W
45°12′25.5″ N, 083°00′00″ W
44°51′30.5″ N, 083°00′00″ W
44°51′30.5″ N, 083°19′17.3″ W

Waukegan Special Protection Area means the area enclosed by rhumb lines connecting the following coordinates, beginning on the northernmost point and proceeding clockwise:

42°24.3′ N, 087°29.3′ W
42°13.0′ N, 087°25.1′ W
42°12.2′ N, 087°29.1′ W
42°18.1′ N, 087°33.1′ W
42°24.1′ N, 087°32.0′ W

Western Basin means that portion of Lake Erie west of a line due south from Point Pelee.

(3) Discharges of bulk dry cargo residue under paragraph (b) of this section are allowed, subject to the conditions listed in Table 151.66(b)(3) of this section.

TABLE 151.66(B)(3)—BULK DRY CARGO RESIDUE DISCHARGES ALLOWED ON THE GREAT LAKES

Location	Cargo	Discharge allowed except as noted
Tributaries, their connecting rivers, and the St. Lawrence River.	Limestone and other clean stone.	Prohibited within 3 miles from shore.
	All other cargoes	Prohibited.
Lake Ontario	Limestone and other clean stone.	Prohibited within 3 miles from shore.
	Iron ore	Prohibited within 6 miles from shore.
	All other cargoes	Prohibited within 13.8 miles from shore.
Lake Erie	Limestone and other clean stone.	Prohibited within 3 miles from shore; prohibited in the Detroit River International Wildlife Refuge; prohibited in Western Basin, except that a vessel operating exclusively within Western Basin may discharge limestone or clean stone cargo residues over the dredged navigation channels between Toledo Harbor Light and Detroit River Light.
	Iron ore	Prohibited within 6 miles from shore; prohibited in the Detroit River International Wildlife Refuge; prohibited in Western Basin, except that a vessel may discharge residue over the dredged navigation channels between Toledo Harbor Light and Detroit River Light if it unloads in Toledo or Detroit and immediately thereafter loads new cargo in Toledo, Detroit, or Windsor.
	Coal, salt	Prohibited within 13.8 miles from shore; prohibited in the Detroit River International Wildlife Refuge; prohibited in Western Basin, except that a vessel may discharge residue over the dredged navigation channels between Toledo Harbor Light and Detroit River Light if it unloads in Toledo or Detroit and immediately thereafter loads new cargo in Toledo, Detroit, or Windsor.
	All other cargoes	Prohibited within 13.8 miles from shore; prohibited in the Detroit River International Wildlife Refuge; prohibited in Western Basin.
Lake St. Clair	Limestone and other clean stone.	Prohibited within 3 miles from shore.
	All other cargoes	Prohibited.
Lake Huron, except Six Fathom Scarp Mid-Lake Special Protection Area.	Limestone and other clean stone.	Prohibited within 3 miles from shore; prohibited in the Thunder Bay National Marine Sanctuary.
	Iron ore	Prohibited within 6 miles from shore and in Saginaw Bay; prohibited in the Thunder Bay National Marine Sanctuary; prohibited for vessels upbound along the Michigan thumb as follows: (i) Between 5.8 miles northeast of entrance buoys 11 and 12 to the track line turn abeam of Harbor Beach, prohibited within 3 miles from shore. (ii) For vessels bound for Saginaw Bay only, between the track line turn abeam of Harbor Beach and 4 nautical miles northeast of Point Aux Barques Light, prohibited within 4 miles from shore and not less than 10 fathoms of depth.

TABLE 151.66(B)(3)—BULK DRY CARGO RESIDUE DISCHARGES ALLOWED ON THE GREAT LAKES—Continued

Location	Cargo	Discharge allowed except as noted
	Coal, salt	Prohibited within 13.8 miles from shore and in Saginaw Bay; prohibited in the Thunder Bay National Marine Sanctuary; prohibited for vessels upbound from Alpena into ports along the Michigan shore south of Forty Mile Point within 4 miles from shore and not less than 10 fathoms of depth.
	All other cargoes	Prohibited within 13.8 miles from shore and in Saginaw Bay; prohibited in the Thunder Bay National Marine Sanctuary.
Lake Michigan	Limestone and other clean stone.	Prohibited within 3 miles from shore; prohibited within the Milwaukee Mid-Lake and Waukegan Special Protection Areas; prohibited within the Northern Refuge; prohibited within 3 miles of the shore of the Indiana Dunes and Sleeping Bear National Lakeshores; prohibited within Green Bay.
	Iron ore	Prohibited in the Northern Refuge; north of 45°N, prohibited within 12 miles from shore and in Green Bay; south of 45°N, prohibited within 6 miles from shore, and prohibited within the Milwaukee Mid-Lake and Waukegan Special Protection Areas, in Green Bay, and within 3 miles of the shore of Indiana Dunes and Sleeping Bear National Lakeshores; except that discharges are allowed at: (a) 4.75 miles off Big Sable Point Betsie, along established Lake Carriers Association (LCA) track lines; and (b) Along 056.25° LCA track line between due east of Poverty Island to a point due south of Port Inland Light.
	Coal	Prohibited in the Northern Refuge; prohibited within 13.8 miles from shore and prohibited within the Milwaukee Mid-Lake and Waukegan Special Protection Areas, in Green Bay, and within 3 miles of the shore of Indiana Dunes and Sleeping Bear National Lakeshores; except that discharges are allowed— (i) Along 013.5° LCA track line between 45°N and Boulder Reef, and along 022.5° LCA track running 23.25 miles between Boulder Reef and the charted position of Red Buoy #2; (ii) Along 037° LCA track line between 45°20′N and 45°42′N; (iii) Along 056.25° LCA track line between points due east of Poverty Island to a point due south of Port Inland Light; and (iv) At 3 miles from shore for coal carried between Manistee and Ludington along customary routes.
	Salt	Prohibited in the Northern Refuge; prohibited within 13.8 miles from shore and prohibited within the Milwaukee Mid-Lake and Waukegan Special Protection Areas, in Green Bay, and within 3 miles of the shore of Indiana Dunes and Sleeping Bear National Lakeshores, and in Green Bay.
	All other cargoes	Prohibited in the Northern Refuge; prohibited within 13.8 miles from shore and prohibited within the Milwaukee Mid-Lake and Waukegan Special Protection Areas, in Green Bay, and within 3 miles of the shore of Indiana Dunes and Sleeping Bear National Lakeshores.
Lake Superior	Limestone and other clean stone.	Prohibited within 3 miles from shore; and prohibited within Isle Royale National Park and the Caribou Island and Southwest Bank, Stannard Rock, and Superior Shoal Protection Areas, and within 3 miles of the shore of the Apostle Islands and Pictured Rocks National Lakeshores or the Grand Portage National Monument.
	Iron ore	Prohibited within 6 miles from shore (within 3 miles off northwestern shore between Duluth and Grand Marais); and prohibited within Isle Royale National Park and the Caribou Island and Southwest Bank, Stannard Rock, and Superior Shoal Protection Areas, and within 3 miles of the shore of the Apostle Islands and Pictured Rocks National Lakeshores or the Grand Portage National Monument.
	Coal, salt	Prohibited within 13.8 miles from shore (within 3 miles off northwestern shore between Duluth and Grand Marais); and prohibited within Isle Royale National Park and the Caribou Island and Southwest Bank, Stannard Rock, and Superior Shoal Protection Areas, and within 3 miles of the shore of the Apostle Islands and Pictured Rocks National Lakeshores or the Grand Portage National Monument.
	Cement	Prohibited within 13.8 miles from shore (within 3 miles offshore west of a line due north from Bark Point); and prohibited within Isle Royale National Park and the Caribou Island and Southwest Bank, Stannard Rock, and Superior Shoal Protection Areas, and within 3 miles of the shore of the Apostle Islands and Pictured Rocks National Lakeshores or the Grand Portage National Monument.
	All other cargoes	Prohibited within 13.8 miles from shore; and prohibited within Isle Royale National Park and the Caribou Island and Southwest Bank, Stannard Rock, and Superior Shoal Protection Areas, and within 3 miles of the shore of the Apostle Islands and Pictured Rocks National Lakeshores or the Grand Portage National Monument.

(4) The master, owner, operator, or person in charge of any commercial vessel must ensure that the vessel's deck is kept broom clean whenever the vessel is in transit.

(5) The master, owner, operator, or person in charge of any commercial vessel must ensure that a dry cargo residue management plan is onboard the vessel, kept available for Coast Guard inspection, and that all operations are

conducted in accordance with the plan. A waste management plan meeting the requirements of 33 CFR 151.57 satisfies this requirement, so long as it provides all the information required by this paragraph (b)(5). If the plan is maintained electronically, at least one paper copy of the plan must be onboard for use during inspections. The plan must describe the specific measures the vessel employs to ensure the minimization of bulk dry cargo residue discharges, and, at a minimum, must list or describe—

(i) Equipment onboard the vessel that is designed to minimize bulk dry cargo spillage during loading and unloading;

(ii) Equipment onboard the vessel that is available to recover spilled cargo from the decks and transfer tunnels and return it to the holds or to unloading conveyances;

(iii) Operational procedures employed by the vessel's crew during the loading or unloading of bulk dry cargoes to minimize cargo spillage onto the decks and into the transfer tunnels and to achieve and maintain the broom clean deck condition required by paragraph (b)(4) of this section;

(iv) Operational procedures employed by the vessel's crew during or after loading or unloading operations to return spilled bulk dry cargo residue to the vessel's holds or to shore via an unloading conveyance;

(v) How the vessel's owner or operator ensures that the vessel's crew is familiar with any operational procedures described by the plan;

(vi) The position title of the person onboard who is in charge of ensuring compliance with procedures described in the plan;

(vii) Any arrangements between the vessel and specific ports or terminals for the unloading and disposal of the vessel's bulk dry cargo residues ashore; and

(viii) The procedures used and the vessel's operating conditions to be maintained during any unavoidable discharge of bulk dry cargo residue into the Great Lakes.

(6) In determining whether a commercial vessel or person is in compliance with this paragraph (b), Coast Guard personnel may consider—

(i) The extent to which the procedures described in the vessel's DCR management plan reflect current industry standard practices for vessels of comparable characteristics, cargoes, and operations;

(ii) The crew's demonstrated ability to perform tasks for which the DCR management plan holds them responsible;

(iii) Whether equipment described in the DCR management plan is maintained in proper operating condition; and

(iv) The extent to which the crew adheres to the vessel's DCR management plan during actual dry cargo loading and unloading operations and DCR discharge operations.

* * * * *

J.G. Lantz,

Director of Commercial Regulations and Standards, United States Coast Guard.

[FR Doc. 2012–18399 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0427]

RIN 1625–AA00

Safety Zone; Gilmerton Bridge Center Span Float-In, Elizabeth River; Norfolk, Portsmouth, and Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Coast Guard is withdrawing its proposed rule concerning the Gilmerton Bridge Center Span Float-in and bridge construction of span placement. The original proposal had a start date of July 31, 2012, and must be rescheduled to start on September 5, 2012, due to unforeseen circumstances with span lift construction.

DATES: The proposed rule is withdrawn on July 6, 2012.

ADDRESSES: The docket for this withdrawn rulemaking is available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2012–0427 in the ''Keyword'' box, and then clicking ''Search.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call or email Hector Cintron, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5581, email *Hector.L.Cintron@uscg.mil.* If you have questions on viewing material in the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2012, we published a notice of proposed rulemaking entitled ''Safety Zone; Gilmerton Bridge Center Span Float-in, Elizabeth River; Norfolk, Portsmouth, and Chesapeake, Virginia'' in the **Federal Register** (77 FR 43557). The rulemaking concerned establishing a safety zone on the navigable waters of the Elizabeth River in Norfolk, Portsmouth, and Chesapeake, VA, in order to provide for the safety of life on navigable waters during the Gilmerton Bridge Center Span Float-in and bridge construction of span placement.

Withdrawal

The proposed rule is being withdrawn due to unforeseen circumstances in the construction timeline of the Center Span, which has caused a 5 week delay in the project.

Authority: We issue this notice of withdrawal under the authority of 5 U.S.C. 552(a), 44 U.S.C. 1505(a)(3), and 33 CFR 1.05–1.

Dated: July 17, 2012.

John K. Little,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2012–18559 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2012–0446; FRL–9703–9]

Approval and Promulgation of Air Quality Implementation Plans; Utah; Determination of Clean Data for the 1987 PM_{10} Standard for the Ogden Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to determine that the Ogden City nonattainment area in Utah is currently attaining the National Ambient Air Quality Standard (NAAQS) for particulate matter with an aerodynamic diameter of less than or equal to a nominal ten micrometers (PM_{10}) based on certified, quality-assured ambient air monitoring data for the years 2009 through 2011. The State of Utah submitted a letter dated March 30, 2000, requesting EPA to make a clean data

determination for the nonattainment area of Ogden City. Based on our proposed determination that the Ogden City nonattainment area is currently attaining the PM_{10} NAAQS, EPA is also proposing to determine that Utah's obligation to make submissions to meet certain Clean Air Act (CAA) requirements related to attainment of the NAAQS is not applicable for as long as the Ogden City nonattainment area continues to attain the NAAQS. This action is being taken under the CAA.

DATES: Comments must be received on or before August 29, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2012–0446, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: freeman.crystal@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Carl Daly, Director, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Carl, Daly, Director, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2012–0446. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, U.S. Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Crystal Freeman, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6602, *freeman.crystal@epa.gov.*

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Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The initials *AQS* mean or refer to EPA's Air Quality System database.

(iii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iv) The initials *NAAQS* mean or refer to National Ambient Air Quality Standard.

(v) The initials *NSR* mean or refer to new source review.

(vi) The initials $PM_{2.5}$ mean or refer to particulate matter with an aerodynamic diameter equal to or less than 2.5 micrometers (fine particulate matter).

(vii) The initials PM_{10} mean or refer to particulate matter with an aerodynamic diameter equal to or less than 10 micrometers (coarse particulate matter).

(viii) The initials *RACM* mean or refer to reasonably available control measures.

(ix) The initials *RFP* mean or refer to reasonable further progress.

(x) The initials *SIP* mean or refer to State Implementation Plan.

(xi) The initials *SLAMS* mean or refer to state and local air monitoring stations.

(xii) The words *State* or *Utah* mean the State of Utah, unless the context indicates otherwise.

(xiii) The initials *UDEQ* mean or refer to Utah Department of Environmental Quality.

I. General Information

A. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the

public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. PM_{10} NAAQS

EPA sets the NAAQS for certain ambient air pollutants at levels required to protect public health and welfare. Particulate matter with an aerodynamic diameter less than or equal to a nominal ten micrometers, or PM_{10}, is one of these ambient air pollutants for which EPA has established health-based standards. On July 1, 1987, EPA promulgated two primary standards for PM:$_{10}$ a 24-hour standard of 150 micrograms per cubic meter (μg/m^3); and, an annual PM_{10} standard of 50 μg/m^3. EPA also promulgated secondary PM_{10} standards that were identical to the primary standards. See 52 FR 24634 (July 1, 1987).

Effective December 18, 2006, EPA revoked the annual PM_{10} standard but retained the 24-hour PM_{10} standard. See 71 FR 61144 (October 17, 2006). An area attains the 24-hour PM_{10} standard when the expected number of days per calendar year with a 24-hour concentration in excess of the standard (referred to herein as an ''exceedance''), as determined in accordance with 40 CFR part 50, appendix K, is equal to or less than one.[1] See 40 CFR 50.6 and 40 CFR part 50, appendix K.

B. Designation and Classification of Ogden City PM_{10} Nonattainment Area

The Ogden City nonattainment area was designated nonattainment for PM_{10} and classified as moderate under section 107(d)(3) of the CAA, on July 28, 1995. See 60 FR 38726 (July 28, 1995) and 40 CFR Part 81.345 (Ogden Area Weber County (part) City of Ogden). The Ogden City designation became effective on September 26, 1995.

C. How does EPA make attainment determinations?

Generally, EPA determines whether an area's air quality is meeting the PM_{10} NAAQS based on complete,[2] quality-assured, and certified data gathered at established state and local air monitoring stations (SLAMS) in the nonattainment area, and entered into the EPA Air Quality System (AQS) database. Data from air monitors operated by State, local, or Tribal agencies in compliance with EPA monitoring requirements must be submitted to AQS. These monitoring agencies certify annually that these data are accurate to the best of their knowledge. Accordingly, EPA relies primarily on data in AQS when determining the attainment status of an area. See 40 CFR 50.6; 40 CFR part 50, appendix J and K; 40 CFR part 53; and, 40 CFR part 58, appendices A, C, D, and E. EPA will also consider air quality data from other air monitoring stations in the nonattainment area provided those stations meet the Federal monitoring requirements for SLAMS, including the quality assurance and quality control criteria in 40 CFR part 58, appendix A. See 40 CFR 58.14 (2006) and 58.20 (2007);[3] 71 FR 61236, 61242 (October 17, 2006). All valid data are reviewed to determine the area's air quality status in accordance with 40 CFR part 50, appendix K.

Attainment of the 24-hour PM_{10} standard is determined by calculating the expected number of exceedances of the standard in a year. The 24-hour PM_{10} standard is attained when the expected number of exceedances averaged over a three-year period is less than or equal to one at each monitoring site within the nonattainment area. Generally, three consecutive years of complete air quality data are required to show attainment of the 24-hour PM_{10} standard. See 40 CFR part 50 and appendix K.[4]

To demonstrate attainment of the 24-hour PM_{10} standard at a monitoring site, the monitor must provide sufficient data to perform the required calculations in 40 CFR part 50, appendix K. The amount of data required varies with the sampling frequency, data capture rate, and the number of years of record. In all cases, three years of representative monitoring data that meet the 75 percent criterion discussed earlier should be utilized, if available. More than three years may be considered, if all additional representative years of data meeting the 75 percent criterion are utilized. Data not meeting these criteria may also suffice to show attainment; however, such exceptions must be approved by the appropriate Regional Administrator in accordance with EPA guidance. See 40 CFR part 50, appendix K, section 2.3.

III. EPA's Analysis

A. What is the Ogden City nonattainment area monitoring network?

The Utah Department of Environmental Quality (UDEQ) has operated PM_{10} monitors in Ogden City since 1987. The first monitor in Ogden City was operated by the Ogden Health Department at 2570 Grant Avenue until February 15, 2000. The monitor was replaced by the Ogden Number 2 monitoring site at 228 32nd Street, which began operation on July 2, 2001. Both sites were selected to read maximum concentration values near the center of the Ogden City urbanized area.

B. Does the Ogden City nonattainment area monitor meet minimum federal ambient air quality monitoring requirements?

Annually, UDEQ submits monitoring network plan reports to EPA on compliance with the applicable reporting requirements in 40 CFR 58.10. These reports discuss the status of the

[1] An exceedance is defined as a daily value that is above the level of the 24-hour standard, 150 μg/m^3, after rounding to the nearest 10 μg/m^3 (i.e., values ending in five or greater are to be rounded up). Thus, a recorded value of 154 μg/m^3 would not be an exceedance since it would be rounded to 150 μg/m^3; whereas, a recorded value of 155 μg/m^3 would be an exceedance since it would be rounded to 160 μg/m^3. See 40 CFR part 50, appendix K, section 1.0.

[2] For PM_{10}, a ''complete'' set of data includes a minimum of 75 percent of the scheduled PM_{10} samples per quarter. See 40 CFR part 50, appendix K, section 2.3(a).

[3] EPA promulgated amendments to the ambient air monitoring regulations in 40 CFR parts 53 and 58 on October 17, 2006. (See 71 FR 61236.) The requirements for Special Purpose Monitors were revised and moved from 40 CFR 58.14 to 40 CFR 58.20.

[4] Because the annual PM_{10} standard was revoked effective December 18, 2006, this document discusses only attainment of the 24-hour PM_{10} standard. See 71 FR 61144 (October 17, 2006).

air monitoring network, as required under 40 CFR part 58. With respect to PM_{10}, UDEQ's annual network plans meet the applicable requirements under 40 CFR part 58. The Ogden Number 2 monitor samples on a daily schedule, which meets the requirements of 40 CFR 58.12(e) for monitoring frequency. Also, UDEQ annually certifies that the data it submits to AQS are quality-assured.

C. What does the air quality data show for the Ogden City nonattainment area?

Since 1995, when Ogden City was designated as a nonattainment area, the data from AQS indicate that six exceedances of the PM_{10} standard have been measured in the Ogden City nonattainment area at the Ogden Number 2 monitor. From the six total exceedances, one was observed in 2002, two were in 2003, one was in 2009, and two were in 2010. All these exceedances have been flagged by UDEQ as exceptional events involving either July 4th fireworks, high winds, or wildfires. These exceedances resulted in expected numbers of exceedances of 1.0 for the period 2001 through 2003, 2002 through 2004, 2008 through 2010, and 2009 through 2011, showing that the Ogden City nonattainment area has attained the PM_{10} NAAQS in all years containing complete monitoring data from 1995 to present. The available data shows attainment of the PM_{10} standard continuously since 2002, even if EPA takes no action to exclude data flagged as exceptional events.

Between 1995 and 2011, an interruption of monitoring occurred between February 16, 2000 until July 2, 2001. This prevented EPA from determining that Ogden had attained the NAAQS via a clean data determination until 3 years of complete monitoring data had been collected after 2001. Beginning in 2002, complete data showing attainment of the PM_{10} standard has been collected in AQS for the Ogden City PM_{10} nonattainment area.

For the purposes of this proposed action, we have reviewed the data for the most recent three-year period (2009 through 2011). Table 1 summarizes the PM_{10} concentration data collected at the Ogden Number 2 monitor over the past three years. As shown in Table 1, three exceedances, but no violations, were recorded within the Ogden City nonattainment area over the 2009 through 2011 period.

TABLE 1—SUMMARY OF 2009–2011 PM_{10} MONITORING DATA FOR OGDEN CITY NONATTAINMENT AREA [A]

Monitoring site	Highest 24-hour PM_{10} concentration ($\mu g/m^3$)			Expected exceedances per year
	2009	2010	2011	2009–2011
Ogden No. 2	181	216	79	1.0

PM_{10} NAAQS = 150 $\mu g/m^3$

[a] Source: AQS AMP350 report dated June 8, 2012.

Table 2 expands on Table 1's expected exceedance per year for Ogden City's PM_{10} monitor for years 2009 through 2011. For the years 2009 and 2010, there were three exceedances that were flagged as exceptional events. However, even though there were exceedances within these two years, the Ogden City monitor did not violate the PM_{10} NAAQS.

TABLE 2—SUMMARY OF OGDEN CITY'S PM_{10} MONITOR DATA (49–057–0002), 2009–2011 EXPECTED EXCEEDANCES PER YEAR

Year	Monitor 49–057–0002
2009	1.0 (Wildfire Exceptional Event Flag).
2010	2.0 (High Wind Exceptional Event Flag).
2011	0.0.
2009–2011 Three Year Average.	1.0.

During the 2009 through 2011 time period, the data collected by UDEQ meets the completeness criterion for all quarters at the Ogden Number 2 monitor. As noted above, to be considered ''complete,'' valid measurements must be made for 75 percent of all the scheduled sampling dates in each quarter of the year, and generally, three years of representative monitoring data that meets the 75 percent criterion should be utilized, where available.

Based on our review of the certified, quality-assured data for 2009 through 2011, we find that the expected number of exceedances per year for the Ogden City nonattainment area for the most recent three-year period (i.e., 2009 to 2011) was 1.0 day per year. With an annual expected exceedance rate for the 24-hour PM_{10} NAAQS of 1.0, these data show attainment of the PM_{10} standard. The EPA proposes to determine that the Ogden City nonattainment area is attaining the PM_{10} NAAQS. Prior to taking final action on this proposal, we will review any preliminary data for 2012 submitted by UDEQ to AQS for the Ogden City nonattainment area to ensure that such preliminary data show continued attainment of the standard.

IV. EPA's Clean Data Policy and the Applicability of the Clean Air Act Planning Requirements to the Ogden City Nonattainment Area

The air quality planning requirements for moderate PM_{10} nonattainment areas, such as the Ogden City nonattainment area, are set out in part D, subparts 1 and 4, of title I of the Act. EPA has issued guidance in a General Preamble describing how we will review state implementation plans (SIPs) and SIP revisions submitted under title I of the Act, including those containing moderate PM_{10} nonattainment area SIP provisions.[5]

The subpart 1 requirements include, among other things, provisions for reasonably available control measures or ''RACM'', reasonable further progress or ''RFP'', emissions inventories, a permit program for construction and operation of new or modified major stationary sources in the nonattainment area or ''NSR'', contingency measures, conformity, and additional SIP revisions providing for attainment where EPA determines that the area has failed to attain the standard by the applicable attainment date.

Subpart 4 requirements in CAA section 189 apply specifically to PM_{10} nonattainment areas. The requirements for moderate PM_{10} nonattainment areas include: (1) An attainment demonstration; (2) provisions for

[5] ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' (57 FR 13498 (April 16, 1992), and supplemented at 57 FR 18070 (April 28, 1992)); hereafter referred to as the General Preamble.

RACM; (3) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date; and, (4) provisions ensuring that the control requirements applicable to an area's major stationary sources of PM_{10} also apply to major stationary sources of PM_{10} precursors, except where the Administrator has determined that such sources do not contribute significantly to PM_{10} levels exceeding the NAAQS.

For nonattainment areas where EPA determines that monitored data show that the NAAQS have already been achieved, EPA's interpretation, upheld by the Courts, is that the obligation to submit certain requirements of part D, subparts 1, 2, and 4 of the Act are suspended for so long as the area continues to attain. These include requirements for attainment demonstrations, RFP, RACM, and contingency measures, because these provisions have the purpose of helping achieve attainment of the NAAQS. Certain other obligations for PM_{10} nonattainment areas, however, are not suspended, such as the NSR requirements.

This interpretation of the CAA is known as the Clean Data Policy. It is the subject of several EPA memoranda and regulations, and numerous rulemakings that have been published in the **Federal Register** over more than fifteen years. EPA finalized the statutory interpretation set forth in the Clean Data Policy as part of its ''Final Rule to Implement the 8-hour Ozone National Ambient Air Quality Standard—Phase 2'' (Phase 2 Final Rule); see 40 CFR 51.918 and discussion in the preamble to the rule at 70 FR 71612, 71645–71646 (November 29, 2005). The DC Circuit Court upheld this Clean Data regulation as a valid interpretation of the CAA; see *NRDC* v. *EPA,* 571 F. 3d 1245 (D.C. Cir. 2009). EPA also finalized its interpretation in an implementation rule for the NAAQS for particulate matter of 2.5 microns or less ($PM_{2.5}$); see 40 CFR 51.1004(c). Thus, EPA has codified the Clean Data Policy when it established final rules governing implementation of new or revised NAAQS. See 70 FR 71612, 71644–46 (November 29, 2005); 72 FR 20586, 20665 (April 25, 2007) ($PM_{2.5}$ Implementation Rule). Otherwise, EPA applies the Clean Data Policy in individual rulemakings related to specific nonattainment areas. See, e.g., 75 FR 27944 (May 19, 2010), the determination of attainment of the PM_{10} standard in Coso Junction, California, and 75 FR 6571 (February 10, 2010), the determination of attainment of the 1-hour ozone standard in Baton Rouge, Louisiana.

In its many applications of the Clean Data Policy interpretation to PM_{10}, EPA has explained that the legal bases set forth in detail in our Phase 2 Final Rule; our May 10, 1995 memorandum from John S. Seitz, entitled ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard;'' our $PM_{2.5}$ Implementation Rule; and our December 14, 2004 memorandum from Stephen D. Page entitled ''Clean Data Policy for the Fine Particle National Ambient Air Quality Standards,'' are equally pertinent to the interpretation of provisions of subparts 1 and 4 applicable to PM_{10}. See, e.g., 71 FR 6352 (February 8, 2006) (Ajo, Arizona area); 71 FR 13021 (March 14, 2006) (Yuma, Arizona area); 71 FR 40023 (July 14, 2006) (Weirton, West Virginia area); 71 FR 44920 (August 8, 2006) (Rillito, Arizona area); 71 FR 63642 (October 30, 2006) (San Joaquin Valley, California area); 72 FR 14422 (March 28, 2007) (Miami, Arizona area); 75 FR 27944 (May 19, 2010) (Coso Junction, California area); and 76 FR 21807 (April 19, 2011) (Truckee Meadows, Nevada area). EPA's interpretation that the obligation to submit an attainment demonstration, RACM, RFP, contingency measures, and other measures related to attainment under part D of title I of the CAA is suspended while the area is attaining the NAAQS, applies whether the standard is PM_{10}, ozone, or $PM_{2.5}$.

In EPA's proposed and final rulemakings determining that the San Joaquin Valley nonattainment area attained the PM_{10} standard, EPA set forth at length its rationale for applying the Clean Data Policy to PM_{10}. The Ninth Circuit Court subsequently upheld this rulemaking, and specifically EPA's Clean Data Policy, in the context of the PM_{10} standard. See *Latino Issues Forum* v. *EPA,* Nos. 06–75831 and 08–71238 (9th Cir.), Memorandum Opinion, March 2, 2009. In rejecting petitioner's challenge to the Clean Data Policy for $PM_{10,}$ the Court stated:

> As the EPA rationally explained, if an area is in compliance with PM_{10} standards, then further progress for the purpose of ensuring attainment is not necessary.

EPA noted in its prior PM_{10} rulemakings that the reasons for relieving an area that has attained the relevant standard of certain obligations under part D, subparts 1 and 2, apply equally to part D, subpart 4, which contains specific attainment demonstration and RFP provisions for PM_{10} nonattainment areas. In EPA's Phase 2 Final Rule and ozone (Seitz) and $PM_{2.5}$ Clean Data (Page) memoranda, EPA established that it is reasonable to interpret provisions regarding RFP and attainment demonstrations, along with related requirements, so as not to require SIP submissions if an area subject to those requirements is already attaining the NAAQS (i.e., attainment of the NAAQS is demonstrated with three consecutive years of complete, quality-assured, and certified air quality monitoring data). Every U.S. Circuit Court of Appeals that has considered the Clean Data Policy has upheld EPA rulemakings applying its interpretation, for both ozone and PM_{10}. See *Sierra Club* v. *EPA,* 99 F.3d 1551 (10th Cir. 1996); *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004); *Our Children's Earth Foundation* v. *EPA,* No. 04–73032 (9th Cir. June 28, 2005) (memorandum opinion), *Latino Issues Forum,* supra.

It has been EPA's longstanding interpretation that the general provisions of part D, subpart 1 of the Act (sections 171 and 172) do not require the submission of SIP revisions concerning RFP for areas already attaining the ozone NAAQS. In the General Preamble, we stated:

> [R]equirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point.

See 57 FR 13564 (April 16, 1992). EPA's prior determinations of attainment for PM_{10}, *e.g.,* for the San Joaquin Valley and Coso Junction areas in California, make clear that the same reasoning applies to the PM_{10} provisions of part D, subpart 4. See 71 FR 40952 and 71 FR 63642 (proposed and final determination of attainment for San Joaquin Valley) and 75 FR 13710 and 75 FR 27944 (proposed and final determination of attainment for Coso Junction).

With respect to RFP, section 171(1) states that, for purposes of part D of title I, RFP ''means such annual incremental reductions in emissions of the relevant air pollutant as are required by this part or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable date.'' Thus, whether dealing with the general RFP requirement of section 172(c)(2), the ozone-specific RFP requirements of sections 182(b) and (c), or the specific RFP requirements for PM_{10} areas of part D, subpart 4, section 189(c)(1), the stated purpose of RFP is to ensure

attainment by the applicable attainment date. Section 189(c)(1) states that:

> Plan revisions demonstrating attainment submitted to the Administrator for approval under this subpart shall contain quantitative milestones which are to be achieved every 3 years until the area is redesignated attainment and which demonstrate reasonable further progress, as defined in section 7501(1) of this title, toward attainment by the applicable date.

Although this section states that revisions shall contain milestones which are to be achieved until the area is redesignated to attainment, such milestones are designed to show reasonable further progress ''toward attainment by the applicable attainment date,'' as defined by section 171. Thus, it is clear that once the area has attained the standard, no further milestones are necessary or meaningful. This interpretation is supported by language in section 189(c)(3), which mandates that a State that fails to achieve a milestone must submit a plan that assures that the State will achieve the next milestone or attain the NAAQS if there is no next milestone. Section 189(c)(3) assumes that the requirement to submit and achieve milestones does not continue after attainment of the NAAQS.

In the General Preamble, we noted with respect to section 189(c) that the purpose of the milestone requirement ''is 'to provide for emission reductions adequate to achieve the standards by the applicable attainment date' (H.R. Rep. No. 490, 101st Cong., 2d Sess. 267 (1990)).'' See 57 FR 13539 (April 16, 1992). If an area has in fact attained the standard, the stated purpose of the RFP requirement will have already been fulfilled.[6] EPA took this position with respect to the general RFP requirement of section 172(c)(2) in the General Preamble and also in the Seitz memorandum with respect to the requirements of sections 182(b) and (c). In our prior applications of the Clean Data Policy to PM_{10}, we have extended that interpretation to the specific provisions of part D, subpart 4. See, e.g., 71 FR 40952 and 71 FR 63642, the proposed and final determination of attainment for San Joaquin Valley, and 75 FR 13710 and 75 FR 27944, the proposed and final determination of attainment for Coso Junction.

In the General Preamble, we stated, in the context of a discussion of the requirements applicable to the evaluation of requests to redesignate nonattainment areas to attainment, that the ''requirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point.'' See 57 FR 13564 (April 16, 1992). See also our September 4, 1992 memorandum from John Calcagni, entitled ''Procedures for Processing Requests to Redesignate Areas to Attainment'' (Calcagni memorandum), at page 6.

Similarly, the requirements of section 189(c)(2) with respect to milestones no longer apply so long as an area has attained the standard. Section 189(c)(2) provides in relevant part that:

> Not later than 90 days after the date on which a milestone applicable to the area occurs, each State in which all or part of such area is located shall submit to the Administrator a demonstration * * * that the milestone has been met.

Where the area has attained the standard and there are no further milestones, there is no further requirement to make a submission showing that such milestones have been met. As noted above, this is consistent with the position that EPA took with respect to the general RFP requirement of section 172(c)(2) in the General Preamble and also in the Seitz memorandum with respect to the requirements of section 182(b) and (c). In the Seitz memorandum, EPA also noted that section 182(g), the milestone requirement of subpart 2, which is analogous to provisions in section 189(c), is suspended upon a determination that an area has attained. The Seitz memorandum, also citing additional provisions related to attainment demonstration and RFP requirements, stated:

> Inasmuch as each of these requirements is linked with the attainment demonstration or RFP requirements of section 182(b)(1) or 182(c)(2), if an area is not subject to the requirement to submit the underlying attainment demonstration or RFP plan, it need not submit the related SIP submission either.

See Seitz memorandum at page 5.

With respect to the attainment demonstration requirements of section 189(a)(1)(B), an analogous rationale leads to the same result. Section 189(a)(1)(B) requires that the plan provide for ''a demonstration (including air quality modeling) that the [SIP] will provide for attainment by the applicable attainment date * * *.'' As with the RFP requirements, if an area is already monitoring attainment of the standard, EPA believes there is no need for an area to make a further submission containing additional measures to achieve attainment. This is also consistent with the interpretation of the section 172(c) requirements provided by EPA in the General Preamble, the Page memorandum, and the section 182(b) and (c) requirements set forth in the Seitz memorandum. As EPA stated in the General Preamble, no other measures to provide for attainment would be needed by areas seeking redesignation to attainment since ''attainment will have been reached.'' See 57 FR at 13564 (April 16, 1992).

Other SIP submission requirements are linked with these attainment demonstration and RFP requirements, and similar reasoning applies to them. These requirements include the contingency measure requirements of sections 172(c)(9) and 182(c)(9). We have interpreted the contingency measure requirements of sections 172(c)(9) and 182(c)(9) as no longer applying when an area has attained the standard because those ''contingency measures are directed at ensuring RFP and attainment by the applicable date.'' See 57 FR 13564 (April 16, 1992) and Seitz memorandum, pages 5–6.

Both sections 172(c)(1) and 189(a)(1)(C) require ''provisions to assure that reasonably available control measures'' (i.e., RACM) are implemented in a nonattainment area. The General Preamble states that EPA interprets section 172(c)(1) so that RACM requirements are a ''component'' of an area's attainment demonstration. See 57 FR 13560 (April 16, 1992). Thus, for the same reason the attainment demonstration no longer applies by its own terms, the requirement for RACM no longer applies. EPA has consistently interpreted this provision to require only implementation of potential RACM measures that could contribute to reasonable further progress or to attainment. See the General Preamble at 57 FR 13498 (April 16, 1992). Thus, where an area is already attaining the

[6] Thus, we believe that it is a distinction without a difference that section 189(c)(1) speaks of the RFP requirement as one to be achieved until an area is ''redesignated attainment,'' as opposed to section 172(c)(2), which is silent on the period to which the requirement pertains, or the ozone nonattainment area RFP requirements in sections 182(b)(1) or 182(c)(2), which refer to the RFP requirements as applying until the ''attainment date,'' since section 189(c)(1) defines RFP by reference to section 171(1) of the Act. Reference to section 171(1) clarifies that, as with the general RFP requirements in section 172(c)(2) and the ozone-specific requirements of section 182(b)(1) and 182(c)(2), the PM-specific requirements may only be required ''for the purpose of ensuring attainment of the applicable national ambient air quality standard by the applicable date.'' 42 U.S.C. section 7501(1). As discussed in the text of this rulemaking, EPA interprets the RFP requirements, in light of the definition of RFP in section 171(1), and incorporated in section 189(c)(1), to be a requirement that no longer applies once the standard has been attained.

standard, no additional RACM measures are required.[7] EPA is interpreting section 189(a)(1)(C) consistent with its interpretation of section 172(c)(1).

We emphasize that the suspension of the obligation to submit SIP revisions concerning these RFP, attainment demonstration, RACM, and other related requirements exists only for as long as the Ogden City nonattainment area continues to monitor attainment of the PM_{10} standard. If EPA determines, after notice-and-comment rulemaking, that the area has monitored a violation of the PM_{10} NAAQS, the basis for suspending the requirements would no longer exist. As a result, the Ogden City nonattainment area would again be subject to a requirement to submit the pertinent SIP revision or revisions and would need to address those requirements. Thus, a final determination that the area need not submit one of the pertinent SIP submittals amounts to no more than a suspension of the requirements for so long as the area continues to attain the standard. Only after EPA redesignates the area to attainment would the area be relieved of these attainment-related submission obligations. Attainment determinations under the Clean Data Policy do not suspend an area's obligations unrelated to attainment in the area, such as provisions to address pollution transport.

Based on our proposed determination that the Ogden City nonattainment area is currently attaining the PM_{10} NAAQS (*see* section III.C above) and as set forth above, we propose to find that Utah's obligations to submit planning provisions to meet the requirements for an attainment demonstration, reasonable further progress plans, reasonably available control measures, and contingency measures, no longer apply for so long as the Ogden City nonattainment area continues to monitor attainment of the PM_{10} NAAQS. In the future, after notice-and-comment rulemaking, if EPA determines that the area again violates the PM_{10} NAAQS, then the basis for suspending the attainment demonstration, RFP, RACM, and contingency measure requirements would no longer exist. In that event, we would notify Utah that we have determined that the Ogden City nonattainment area is no longer attaining the PM_{10} standard and provide notice to the public in the **Federal Register**.

[7] The EPA's interpretation that the statute only requires implementation of RACM measures that would advance attainment was upheld by the United States Court of Appeals for the Fifth Circuit (*Sierra Club* v. *EPA, 314 F.3d 735, 743–745 (5th Cir. 2002)*), and by the United States Court of Appeals for the D.C. Circuit (*Sierra Club* v. *EPA, 294 F.3d 155, 162–163 (D.C. Cir. 2002)*).

V. EPA's Proposed Action

Based on the most recent three-year period of certified, quality-assured data meeting the requirements of 40 CFR part 50, appendix K, and for the reasons discussed above, we propose to find that the Ogden City nonattainment area is currently attaining the 24-hour PM_{10} NAAQS.

In conjunction with and based upon our proposed determination that the Ogden City nonattainment area is currently attaining the standard, EPA proposes to determine that Utah's obligation to submit the following CAA requirements is not applicable for so long as the Ogden City nonattainment area continues to attain the PM_{10} standard: An attainment demonstration under CAA section 189(a)(1)(B); RACM provisions under CAA section 189(a)(1)(C); RFP provisions under CAA section 189(c); and, the attainment demonstration, RACM, RFP and contingency measure provisions under CAA section 172 of the Act.

Any final action resulting from this proposal would not constitute a redesignation to attainment under CAA section 107(d)(3) because we have neither received nor approved a maintenance plan for the Ogden City nonattainment area as meeting the requirements of section 175A of the CAA, nor have we determined that the area has met the other CAA requirements for redesignation. The classification and designation status in 40 CFR part 81 would remain moderate nonattainment for the Ogden City nonattainment area until such time as EPA determines that Utah has met the CAA requirements for redesignating the Ogden City nonattainment area to attainment.

VI. Statutory and Executive Order Reviews

With this action, we propose to make a determination regarding attainment of the PM_{10} NAAQS based on air quality data and, if finalized, this proposed action would result in suspension of certain Federal requirements, and would not impose additional requirements beyond those imposed by State law or by the CAA. For that reason, this proposed action:

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

In addition, this proposed action does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249; November 9, 2000), because the SIP obligations discussed herein do not apply to Indian Tribes and thus will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: July 10, 2012.

Howard Cantor,

Acting Regional Administrator, Region 8.

[FR Doc. 2012–18389 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0398; FRL–9707–4]

Approval of Air Quality Implementation Plans; Arizona; Interstate Transport of Fine Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Arizona on October 14, 2009 and to determine that the existing SIP is adequate to address the requirements of section 110(a)(2)(D)(i)(I) of the Clean Air Act (CAA) for the 2006 National Ambient Air Quality Standard (NAAQS or standard) for fine particulate matter ($PM_{2.5}$). Section 110(a)(2)(D)(i)(I) of the CAA requires that each SIP contain adequate provisions to prohibit air emissions from adversely affecting air quality in other states through interstate transport. EPA is proposing to approve the SIP revision submitted by Arizona and to conclude that additional control measures in Arizona are not necessary under CAA section 110(a)(2)(D)(i)(I) because emissions from Arizona sources do not contribute significantly to nonattainment or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in any other state. We are taking comments on this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before August 29, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2012–0398, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: vagenas.ginger@epa.gov.*
3. *Fax:* 415–942–3964.
4. *Mail or deliver:* Ginger Vagenas (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes 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 *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. 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: Ginger Vagenas, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3964 *vagenas.ginger@epa.gov.*

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

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I. Background

A. 2006 24-Hour $PM_{2.5}$ NAAQS Infrastructure Requirements

On September 21, 2006, EPA promulgated a final rule revising the 1997 24-hour primary and secondary NAAQS for $PM_{2.5}$ from 65 micrograms per cubic meter ($\mu g/m^3$) to 35 $\mu g/m^3$. 71 FR 61144 (October 17, 2006).

Section 110(a)(1) of the CAA requires each state to submit to EPA, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a primary or secondary NAAQS or any revision thereof, a SIP that provides for the ''implementation, maintenance, and enforcement'' of such NAAQS. EPA refers to these specific submissions as ''infrastructure'' SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS. For the 2006 24-hour $PM_{2.5}$ NAAQS, these infrastructure SIPs were due on September 21, 2009.[1] Section 110(a)(2) includes a list of specific elements that each such plan submission must meet, including section 110(a)(2)(D)(i), which pertains to interstate transport of certain emissions.

The transport SIP provisions in section 110(a)(2)(D)(i) (also called ''good neighbor'' provisions) require each state to submit a SIP that prohibits emissions that adversely affect another state in the ways contemplated in the statute. Section 110(a)(2)(D)(i) identifies four distinct elements related to the evaluation of impacts of interstate transport of air pollutants. In this action, EPA is addressing the first two elements of this section (*i.e.,* the requirements in section 110(a)(2)(D)(i)(I) to prohibit emissions activity within a state that will significantly contribute to nonattainment or interfere with maintenance of the NAAQS in any other state) for the 2006 24-hour $PM_{2.5}$ NAAQS.[2]

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

[1] The rule establishing the revised $PM_{2.5}$ NAAQS was signed by the Administrator and publically disseminated on September 21, 2006. Because EPA did not prescribe a shorter period for section 110(a) ''infrastructure'' SIP submittals for these NAAQS, these submittals were due on September 21, 2009, three years from the September 21, 2006 signature date pursuant to section 110(a)(1) of the CAA. *See* 42 U.S.C. 7410(a)(1).

[2] This proposed action does not address the remaining two elements of the transport SIP provision (in CAA section 110(a)(2)(D)(i)(II)) regarding interference with measures required to prevent significant deterioration of air quality or to protect visibility in another state. We intend to evaluate and act upon Arizona's SIP submissions addressing these additional requirements of CAA section 110(a)(2)(D)(i) in separate rulemakings. We proposed action on Arizona's provisions regarding interference with other states' measures to prevent significant deterioration of air quality on June 27, 2012. *See* 77 FR 38239.

B. NO_X SIP Call, Clean Air Interstate Rule (CAIR) and the Transport Rule

EPA has previously addressed the requirements of section 110(a)(2)(D)(i)(I) in past regulatory actions such as the 1998 NO_X SIP call,[3] the 2005 Clean Air Interstate Rule (''CAIR''),[4] and the 2011 Transport Rule (also known as the ''Cross-State Air Pollution Rule'' or ''CSAPR'').[5] In the NO_X SIP call, EPA took action to remediate emissions of nitrogen oxides (NO_X) that significantly contributed to nonattainment of, or interfered with maintenance of, the then applicable ozone NAAQS through interstate transport of NO_X and the resulting ozone.[6] Through this rule, EPA evaluated whether or not the ozone-season NO_X emissions in certain states had prohibited interstate impacts, and if they had such impacts, required the states to adopt substantive SIP revisions to eliminate the NO_X emissions, whether through participation in a regional cap and trade program or by other means.[7]

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

In 2008, the U.S. Court of Appeals for the D.C. Circuit found that CAIR and the related CAIR federal implementation plans were unlawful. *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), modified on rehearing, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (D.C. Cir. 2008). Among other issues, the court held that EPA had not correctly addressed the second element of section 110(a)(2)(D)(i)(I) in CAIR and noted that ''EPA gave no independent significance to the 'interfere with maintenance' prong of section 110(a)(2)(D)(i)(I) to separately identify upwind sources interfering with downwind maintenance.'' 531 F.3d at 909. EPA's approach, the court reasoned, would leave areas that are ''barely meeting attainment'' with ''no recourse'' to address upwind emissions sources. *Id.* The court therefore concluded that a plain language reading of the statute requires EPA to give independent meaning to the interfere with maintenance requirement of section 110(a)(2)(D)(i) and that the approach used by EPA in CAIR failed to do so.

To address the judicial remand of CAIR and to replace it, on August 8, 2011, EPA published the final Transport Rule. 76 FR 48208. The Transport Rule addresses interstate transport pursuant to CAA section 110(a)(2)(D)(i)(I) in the eastern United States with respect to the 1997 8-hour ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 24-hour $PM_{2.5}$ NAAQS.[9] As part of this rulemaking, EPA specifically reexamined the section 110(a)(2)(D)(i)(I) requirements to prohibit emissions from sources in a state that ''contribute significantly to nonattainment'' or ''interfere with maintenance'' of the NAAQS in other states and developed an approach to identify (1) areas that it predicts to be violating the NAAQS, and (2) areas that it predicts to be close to the level of these NAAQS and therefore at risk to become nonattainment unless emissions from sources in other states are appropriately controlled. This approach starts by identifying those specific geographic areas for which further evaluation is appropriate and differentiates between areas where the concern is significant contribution to nonattainment as opposed to interference with maintenance. EPA then conducts state-specific analyses of multiple factors related to pollution levels at the identified ''receptors'' (monitoring sites) of concern to evaluate significant contribution to nonattainment and interference with maintenance of the NAAQS in other states.

On December 30, 2011, the U.S. Court of Appeals for the D.C. Circuit issued an order addressing the status of the Transport Rule and CAIR in response to motions filed by numerous parties seeking a stay of the Transport Rule pending judicial review.[10] In that order, the court stayed the Transport Rule pending resolution of these petitions for review of the rule. The court also stated that EPA is expected to continue to administer CAIR in the interim until the court rules on these petitions for review of the Transport Rule.

C. EPA Guidance

On September 25, 2009, after the court remanded CAIR and while EPA was working on its replacement, EPA issued a guidance memorandum that provides recommendations to states for making submissions to meet the requirements of CAA section 110(a)(2)(D)(i) for the 2006 $PM_{2.5}$ standards (''2006 $PM_{2.5}$ NAAQS Infrastructure Guidance'' or ''Guidance'').[11] With respect to the requirement in section 110(a)(2)(D)(i)(I) to prohibit emissions that would contribute significantly to nonattainment of the NAAQS in any other state, the 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance essentially reiterated the recommendations for western states made by EPA in previous guidance addressing the 110(a)(2)(D)(i) requirements for the 1997 8-hour Ozone and 1997 $PM_{2.5}$ NAAQS.[12] The 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance advised states outside of the CAIR region to include in their section 110(a)(2)(D)(i)(I) SIPs adequate technical analyses to support their conclusions regarding interstate pollution transport, *e.g.,* information concerning emissions in the state, meteorological conditions in the state and in potentially impacted states, monitored ambient pollutant concentrations in the state and in potentially impacted states, distances to

[3] *See* ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone,'' 63 FR 57356 (October 27, 1998) (''NO_X SIP Call'').

[4] *See* ''Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call,'' 70 FR 25162 (May 12, 2005) (''CAIR'').

[5] *See* ''Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals; Final Rule,'' 76 FR 48208 (August 8, 2011) (''Transport Rule'').

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

[7] *Ibid.*

[8] *See* 70 FR 25162 at 25263–69 (May 12, 2005).

[9] CAIR did not address the 2006 24-hour $PM_{2.5}$ NAAQS.

[10] *See* Order dated December 30, 2011, *EME Homer City Generation, L.P.* v. *EPA* (No. 11–1302 and consolidated cases) (D.C. Circuit).

[11] *See* Memorandum from William T. Harnett entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS),'' September 25, 2009.

[12] *See* Memorandum from William T. Harnett entitled ''Guidance for State Implementation Plan (SIP) Submission to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-hour ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' August 15, 2006.

the nearest areas not attaining the NAAQS in other states, and air quality modeling. *See* 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance at 3.[13] With respect to the requirement in section 110(a)(2)(D)(i)(I) to prohibit emissions that would interfere with maintenance of the NAAQS by any other state, the Guidance stated that SIP submissions must address this independent requirement of the statute and provide technical information appropriate to support the state's conclusions, such as information concerning emissions in the state, meteorological conditions in the state and in potentially impacted states, monitored ambient concentrations in the state and in potentially impacted states, and air quality modeling. *See* 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance at 3, 4.

In this action, EPA is maintaining the conceptual approach to evaluating interstate pollution transport under CAA section 110(a)(2)(D)(i)(I) that the Agency provided in the 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance and the Transport Rule.

As described more fully in our Technical Support Document (TSD), EPA evaluated data from existing monitors over three overlapping 3-year periods (i.e., 2006–2008, 2007–2009, and 2008–2010) to determine which areas are expected to be violating the 2006 24-hour $PM_{2.5}$ NAAQS and which areas are predicted to potentially have difficulty maintaining attainment. In essence, if a monitoring site shows a violation of the 2006 24-hour $PM_{2.5}$ NAAQS during the most recent 3-year period (2008–2010), then this monitor location is appropriate for evaluation for purposes of the significant contribution to nonattainment element of section 110(a)(2)(D)(i)(I). If, on the other hand, a monitoring site shows attainment of the 2006 24-hour $PM_{2.5}$ NAAQS during the most recent 3-year period (2008–2010) but a violation in at least one of the previous two 3-year periods (2006–2008 or 2007–2009), then this monitor location is appropriate for evaluation for purposes of the interfere with maintenance element of the statute.

By this method, EPA has identified those areas with monitors that are appropriate ''nonattainment receptors'' or ''maintenance receptors'' for evaluating whether the emissions from sources in another state could significantly contribute to nonattainment in, or interfere with maintenance in, that particular area. EPA believes that this approach for identifying areas that are predicted to be nonattainment and significantly impacted by other states, or have difficulty maintaining the NAAQS, is appropriate to evaluate a state's submission in relation to the elements of CAA section 110(a)(2)(D)(i)(I) pertaining to significant contribution to nonattainment and interference with maintenance.

EPA continues to believe that the more widespread and serious transport problems in the eastern United States are analytically distinct.[14] For the 2006 $PM_{2.5}$ NAAQS, EPA believes that nonattainment and maintenance problems in the western United States are relatively local in nature with only limited impacts from interstate transport. In the Transport Rule, EPA did not calculate the portion of any downwind state's predicted $PM_{2.5}$ concentrations that would result from emissions from individual western states, such as Arizona. Accordingly, EPA believes that section 110(a)(2)(D)(i)(I) SIP submissions for states outside the geographic area analyzed to develop the Transport Rule may be evaluated using a ''weight of the evidence'' approach that takes into account available relevant information, such as that recommended by EPA in the 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance. Such information may include, but is not limited to, the amount of emissions in the state relevant to the NAAQS in question, the meteorological conditions in the area, the distance from the state to the nearest monitors in other states that are appropriate receptors, or such other information as may be probative to consider whether sources in the state may contribute significantly to nonattainment or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in other states. These submissions can rely on modeling when acceptable modeling technical analyses are available, but EPA does not believe that modeling is necessarily required if other available information is sufficient to evaluate the presence or degree of interstate transport in a given situation.

II. The State's Submittal

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

On October 14, 2009, the Arizona Department of Environmental Quality (ADEQ) submitted the ''Arizona State Implementation Plan Revision under Clean Air Act Section 110(a)(1) and (2); 2006 $PM_{2.5}$ NAAQS, 1997 $PM_{2.5}$ NAAQS and 1997 8-hour Ozone NAAQS,'' to address the requirements of CAA section 110(a)(2)(D)(i)(I) for the 2006 $PM_{2.5}$ NAAQS, among other requirements (''2009 Infrastructure Analysis'').[15] Within that submittal, Appendix B, ''Clean Air Act Section 110(a)(2)(D)(i)—Interstate Transport Analysis for the 2006 $PM_{2.5}$ National Ambient Air Quality Standards'' (referred to herein as ''$PM_{2.5}$ Transport Analysis'') addresses the CAA section 110(a)(2)(D)(i)(I) interstate transport requirements that are the subject of this proposed rule.

ADEQ's October 14, 2009 submittal includes public process documentation for the 2009 Infrastructure Analysis, including the $PM_{2.5}$ Transport Analysis. In addition, the SIP revision includes documentation of a duly noticed public hearing held on September 16, 2009, on the proposed 2009 Infrastructure Analysis.

We find that the process followed by ADEQ in adopting the $PM_{2.5}$ Transport Analysis complies with the procedural requirements for SIP revisions under CAA section 110 and EPA's implementing regulations.

III. EPA's Evaluation

To determine whether the CAA section 110(a)(2)(D)(i)(I) requirement is satisfied, EPA must determine whether a state's emissions contribute significantly to nonattainment or

[13] The 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance stated that EPA was working on a new rule to replace CAIR that would address issues raised by the court in the *North Carolina* case and that would provide guidance to states in addressing the requirements related to interstate transport in CAA section 110(a)(2)(D)(i)(I) for the 2006 $PM_{2.5}$ NAAQS. It also noted that states could not rely on the CAIR rule for section 110(a)(2)(D)(i)(I) submissions for the 2006 24-hour $PM_{2.5}$ NAAQS because the CAIR rule did not address this NAAQS. *See* 2006 $PM_{2.5}$ NAAQS Infrastructure Guidance at 3.

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

[15] ADEQ intended for this SIP submittal to also address all other requirements of CAA section 110(a), excepting section 110(a)(2)(G), for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS and the 2006 $PM_{2.5}$ NAAQS. *See* letter dated October 14, 2009, from Eric C. Massey, Air Quality Director, ADEQ, to Laura Yoshii, Acting Regional Administrator, EPA Region 9, with enclosures. EPA has proposed to act on this submittal for purposes of addressing the other ''infrastructure'' requirements of CAA section 110(a) in a separate proposed rule published on June 27, 2012 (77 FR 38239).

interfere with maintenance in downwind areas. If this factual finding is in the negative, then section 110(a)(2)(D)(i)(I) does not require any changes to a state's SIP. If, however, the evaluation reveals that emissions from sources within the state do contribute significantly to nonattainment or interfere with maintenance in other states, then the state must adopt substantive provisions to eliminate those emissions. The state could achieve any required reductions through traditional command and control programs, or at its own election, through participation in a cap and trade program. Consistent with EPA's approach in the 1998 NO_X SIP call, the 2005 CAIR, and the 2011 Transport Rule,[16] EPA is evaluating these impacts with respect to specific monitors identified as having nonattainment and/or maintenance problems, which we refer to as ''receptors.'' EPA notes that no single piece of information is by itself dispositive of the issue. Instead, the total weight of all the evidence taken together is used to evaluate significant contributions to nonattainment or interference with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in another state.

This proposed approval addresses the requirements of CAA section 110(a)(2)(D)(i)(I) for the 2006 24-hour $PM_{2.5}$ NAAQS in several ways. It takes into account Arizona's $PM_{2.5}$ Transport Analysis, which explains that meteorological and other characteristics in Arizona and in the surrounding areas reduce the likelihood that Arizona's emissions contribute significantly to nonattainment or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in any downwind state. In addition, EPA has supplemented its evaluation of Arizona's submittal with a review of the monitors in other states that are appropriate ''nonattainment receptors'' or ''maintenance receptors,'' consistent with EPA's approach in the Transport Rule, and additional technical information to consider whether sources in Arizona contribute significantly to nonattainment or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in other states.

Our Technical Support Document (TSD) contains a more detailed evaluation and is available in the public docket for this rulemaking, which may be accessed online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0398. We provide below a summary of our analysis.

A. Evaluation of Significant Contribution to Nonattainment

EPA reviewed the State of Arizona's $PM_{2.5}$ Transport Analysis and additional technical information to evaluate the potential for Arizona emissions to contribute significantly to nonattainment of the 2006 $PM_{2.5}$ NAAQS at specified monitoring sites in the western United States.[17] EPA first identified as ''nonattainment receptors'' all monitoring sites in the western states that had recorded $PM_{2.5}$ design values above the level of the 2006 24-hour $PM_{2.5}$ NAAQS (35 $\mu g/m^3$) during the years 2008–2010.[18] See Section III of the TSD for more a more detailed description of EPA's methodology for selection of nonattainment receptors. Because geographic distance is a relevant factor in the assessment of potential pollution transport, EPA focused its review on information related to potential transport of $PM_{2.5}$ pollution from Arizona to nonattainment receptors in the states bordering Arizona: Utah, Nevada, and California.[19] With respect to Utah and Nevada, as detailed in the TSD, EPA believes that the following factors support a finding that emissions from Arizona do not significantly contribute to nonattainment of the 2006 24-hour $PM_{2.5}$ NAAQS in either of these states: (1) Technical information indicating that elevated $PM_{2.5}$ levels at nonattainment receptors are predominantly caused by local emission sources, (2) air quality data indicating that regional background levels of $PM_{2.5}$ are generally low during the time periods of elevated $PM_{2.5}$ at these receptors, and (3) the presence of significant terrain, which creates a physical impediment to pollution transport. Similarly and again as detailed in the TSD, with respect to California, technical information indicating that elevated $PM_{2.5}$ levels at the nonattainment receptors are predominantly caused by local emission sources and that the dominant air flows across California are from the west to the east support a finding that emissions from the state of Arizona do not significantly contribute to nonattainment of the 2006 24-hour $PM_{2.5}$ standards in California.

EPA also evaluated potential $PM_{2.5}$ transport to nonattainment receptors in the more distant western states of Oregon, Washington, Idaho, and Montana.[20] EPA believes that the following factors support a finding that emissions from Arizona do not significantly contribute to nonattainment of the 2006 24-hour $PM_{2.5}$ NAAQS in any of these states: (1) The significant distance from the State of Arizona to the nonattainment receptors in these states, (2) technical information indicating that elevated $PM_{2.5}$ levels at nonattainment receptors in these states are predominantly caused by local emission sources, (3) air quality data indicating that regional background levels of $PM_{2.5}$ are generally low during the time periods of elevated $PM_{2.5}$ at these receptors, and (4) the presence of significant terrain, which creates a physical impediment to pollution transport.

Based on this evaluation of Arizona's $PM_{2.5}$ Transport Analysis and additional technical information, EPA proposes to conclude that emissions of direct $PM_{2.5}$ and $PM_{2.5}$ precursors from sources in the State of Arizona do not significantly contribute to nonattainment of the 2006 24-hour $PM_{2.5}$ standards in any other state and that CAA section 110(a)(2)(D)(i)(I) therefore does not require Arizona to adopt additional controls for purposes of implementing the 2006 24-hour $PM_{2.5}$ standards.

B. Evaluation of Interference With Maintenance

EPA reviewed the State of Arizona's $PM_{2.5}$ Transport Analysis and additional technical information to evaluate the potential for Arizona emissions to interfere with maintenance of the 2006 24-hour $PM_{2.5}$ standards at specified monitoring sites in the western U.S. EPA first identified as ''maintenance

[16] *See* NO_X SIP Call, 63 FR 57371 (October 27, 1998); CAIR, 70 FR 25172 (May 12, 2005); and Transport Rule or Cross-State Air Pollution Rule, 76 FR 48208 (August 8, 2011).

[17] EPA has also considered potential $PM_{2.5}$ transport from Arizona to the nearest nonattainment and maintenance receptors located in the eastern, midwestern and southern states covered by the Transport Rule and believes it is reasonable to conclude that, given the significant distance from Arizona to the nearest such receptor (in Illinois) and the relatively insignificant amount of emissions from Arizona that could potentially be transported such a distance, emissions from Arizona sources do not significantly contribute to nonattainment or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS at this location. These same factors also support a finding that emissions from Arizona sources neither contribute significantly to nonattainment nor interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS at any location further east. *See* TSD at Section I.B.3.

[18] Because CAIR did not cover states in the western United States, these data are not significantly impacted by the remanded CAIR and thus could be considered in this analysis. In contrast, recent air quality data in the eastern, midwestern and southern states are significantly impacted by reductions associated with CAIR and because the Transport Rule was developed to replace CAIR, EPA could not consider reductions associated with the CAIR in the base case transport analysis for those states. *See* 76 FR at 48223–24.

[19] EPA did not identify any nonattainment receptors in New Mexico or Colorado.

[20] EPA did not identify any nonattainment receptors in Wyoming.

receptors'' all monitoring sites in the western states that had recorded $PM_{2.5}$ design values above the level of the 2006 24-hour $PM_{2.5}$ NAAQS (35 μg/m^3) during the 2006–2008 and/or 2007–2009 periods but below this standard during the 2008–2010 period. See section IV of the TSD for more information regarding EPA's methodology for selection of maintenance receptors. All of the maintenance receptors in the western states are located in California, Utah, and Arizona. EPA therefore evaluated the potential for transport of Arizona emissions to the maintenance receptors located in California and Utah.[21] As detailed in the TSD, EPA believes that the following factors support a finding that emissions from Arizona do not interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in either state: (1) Technical information indicating that elevated $PM_{2.5}$ levels at these maintenance receptors are predominantly caused by local emission sources, and (2) technical information indicating that the dominant air flows across California are from the west to the east.

Based on this evaluation of Arizona's $PM_{2.5}$ Transport Analysis and additional technical information, EPA proposes to conclude that emissions of direct $PM_{2.5}$ and $PM_{2.5}$ precursors from sources in the State of Arizona do not interfere with maintenance of the 2006 24-hour $PM_{2.5}$ standards in any other state and that CAA section 110(a)(2)(D)(i)(I) therefore does not require Arizona to adopt additional controls for purposes of implementing the 2006 24-hour $PM_{2.5}$ standards.

C. Section 110(l) of the Act

Section 110(l) of the Act prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress (RFP) or any other applicable requirement of the Act. The $PM_{2.5}$ Transport Analysis contains no regulatory provisions and does not affect any requirement in Arizona's applicable implementation plan. We propose to determine that our approval of the $PM_{2.5}$ Transport Analysis would comply with CAA section 110(l) because the proposed SIP revision would not interfere with the on-going process for ensuring that requirements for RFP and attainment of the NAAQS are met. The SIP revision does not alter any provisions in the SIP as EPA has concluded, based on its supplemental analysis, that the existing SIP is sufficient to meet the requirements of 110(a)(2)(D)(i)(I). Our TSD contains a more detailed discussion of our evaluation.

[21] As this analysis focused on *interstate* transport, EPA did not evaluate the impact of Arizona emissions on maintenance receptors within Arizona. (EPA has not identified any nonattainment receptors in Arizona.)

IV. Proposed Action

Under section 110(k) of the Clean Air Act, EPA is proposing to approve a SIP revision submitted by the State of Arizona on October 14, 2009 and to determine, based on that submission and additional EPA analysis, that emissions from Arizona sources do not contribute significantly to nonattainment of the 2006 24-hour $PM_{2.5}$ NAAQS in any other state or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS by any other state. Accordingly, we propose to conclude that the existing SIP is adequate to address the requirements of section 110(a)(2)(D)(i)(I) of the Clean Air Act (CAA) for the 2006 National Ambient Air Quality Standard (NAAQS or standard) for fine particulate matter ($PM_{2.5}$) and that additional control measures in Arizona are not necessary for this purpose.

EPA is soliciting public comments on this proposal and will accept comments until the date noted in the **DATES** section above.

V. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: July 20, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2012–18545 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0398; FRL–9707–5]

Partial Approval and Disapproval of Air Quality Implementation Plans; Arizona; State Board Requirements for Ozone and Fine Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove a State

Implementation Plan (SIP) revision submitted by the State of Arizona to address the requirements of section 110(a)(2)(E)(ii) of the Clean Air Act (CAA) for the 1997 8-hour ozone national ambient air quality standards (NAAQS) and the 1997 and 2006 NAAQS for fine particulate matter ($PM_{2.5}$). EPA is proposing to approve the state's provisions regarding disclosure of potential conflicts of interest under 128(a)(2), but is proposing to disapprove, on narrow grounds, their 128(a)(1) provisions regarding board composition because these provisions do not apply to enforcement orders. We encourage the State to submit a revised SIP to address this very narrow deficiency, and we stand ready to work with the State to develop a revised plan. We are taking comments on this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before August 29, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2012–0398, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: r9_airplanning@epa.gov.*
3. *Fax:* 415–947–3579.
4. *Mail or deliver:* Rory Mays (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes 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 *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. 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: Rory Mays, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3227, *mays.rory@epa.gov.*

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

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I. Background

A. Regulatory History

On July 18, 1997, EPA issued a revised NAAQS for ozone[1] and a new NAAQS for fine particulate matter ($PM_{2.5}$).[2] EPA subsequently revised the 24-hour $PM_{2.5}$ NAAQS on September 21, 2006.[3] Each of these actions triggered a requirement for states to submit an infrastructure SIP to address the applicable requirements of section 110(a)(2) within three years of issuance of the new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that each such plan submission must meet, including section 110(a)(2)(E)(ii), which requires compliance with the requirements of section 128 of the CAA.

On March 10, 2005, EPA entered into a Consent Decree with EarthJustice that obligated EPA to make official findings in accordance with section 110(k)(1) of the CAA as to whether states had made required complete SIP submissions, pursuant to sections 110(a)(1) and (2), by December 15, 2007 for the 1997 8-hour ozone NAAQS and by October 5, 2008 for the 1997 $PM_{2.5}$ NAAQS. EPA made such findings for the 1997 8-hour ozone NAAQS on March 27, 2008 (73 FR 16205) and for the 1997 $PM_{2.5}$ NAAQS on October 22, 2008 (73 FR 62902). In each case, EPA found that Arizona had failed to make a complete submittal to satisfy the requirements of section 110(a)(2)(E)(ii).

The State board SIP provisions in section 128 require each state to submit a SIP that contains requirements that (1) any board or body which approves permits or enforcement orders under the CAA shall have at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to permits or enforcement orders under the CAA; and (2) any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed. 42 U.S.C. 7428.

B. EPA Guidance

In 1978, EPA issued a guidance memorandum recommending ways States could meet the requirements of section 128 (''1978 Guidance''), including suggested interpretations of certain terms in section 128.[4] EPA has not issued further guidance or regulations of general applicability on the subject since that time. However, as part of our proposals on other recent infrastructure actions, EPA has proposed certain interpretations of section 128 and invited comment on these interpretations. See, e.g., EPA's proposed rule on infrastructure SIP requirements for Hawaii (77 FR 21913, April 12, 2012). We are now proposing these same interpretations in relation to the Arizona infrastructure SIP.[5]

II. The State's Submittals

On October 14, 2009, ADEQ submitted the ''Arizona State Implementation Plan Revision under Clean Air Act Section 110(a)(2) and (2); 2006 $PM_{2.5}$ NAAQS, 1997 $PM_{2.5}$ NAAQS

[1] The 8-hour averaging period replaced the previous 1-hour averaging period, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm (62 FR 38856).

[2] The annual $PM_{2.5}$ standard was set at 15 micrograms per cubic meter ($\mu g/m^3$), based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors and the 24-hour $PM_{2.5}$ standard was set at 65 $\mu g/m^3$, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area (62 FR 38652).

[3] The final rule revising the 24-hour NAAQS for $PM_{2.5}$ from 65 $\mu g/m^3$ to 35 $\mu g/m^3$ was published in the **Federal Register** on October 17, 2006 (71 FR 61144).

[4] *See* Memorandum from David O. Bickart to Regional Air Directors, ''Guidance to States for Meeting Conflict of Interest Requirements of Section 128,'' Suggested Definitions, March 2, 1978.

[5] If EPA finalizes this action, the proposed interpretations will supersede (to the extent that they are inconsistent with) interpretations suggested in the 1978 guidance, at least for Arizona's SIP.

and 1997 8-hour Ozone NAAQS,'' to address all of the CAA section 110(a)(2) requirements except for section 110(a)(2)(G) [6] for these three NAAQS (''2009 Infrastructure Submittal'').[7] The 2009 Infrastructure Submittal includes public process documentation (including public comments) and evidence of adoption.

On June 1, 2012, ADEQ submitted the ''Proposed Supplement to the Arizona State Implementation Plan under Clean Air Act Section 110(a)(1) and (2): Implementation of [1997 $PM_{2.5}$ and 8-hour ozone NAAQS and 2006 $PM_{2.5}$ NAAQS], Parallel Processing Version'' (''2012 Supplement''). The 2012 Supplement includes a number of statutes and regulations that are currently effective under State law but that have not been adopted specifically for submittal to EPA as a SIP revision under CAA section 110. By letter dated June 1, 2012, ADEQ submitted unofficial copies of these statutes and regulations to EPA with a request for ''parallel processing'' [8] and stated its intention to submit these statutes and regulations as a formal SIP submittal, following reasonable notice and public hearings, by late August 2012.[9] ADEQ amended this request by letter dated June 14, 2012, to remove several statutes and regulations from the 2012 Supplement.[10]

We are proposing to act on the 2009 Infrastructure Submittal, as supplemented and amended by the 2012 Supplement. We refer to the 2009 Infrastructure Submittal and 2012 Supplement collectively as the ''2009 Infrastructure SIP.''

III. EPA's Evaluation

To determine whether the CAA section 110(a)(2)(E)(ii) requirements are satisfied, EPA must determine whether the State SIP has adequate board composition and disclosure requirements under section 128 of the CAA. In their 2009 Infrastructure Submittal and 2012 Supplement, Arizona submitted unofficial copies of Title 38, Chapter 3, Article 8 Conflict of Interest of Officers and Employees provisions to address the section 128 requirements. The June 2012 Supplement also included Arizona Revised Statute § 49–478, which addresses compositional requirements for county hearing boards. We are proposing to approve these statutory provisions into the SIP as non-regulatory materials.[11]

A. Evaluation of 128(a)(1) Board Composition Requirements

As explained further in our Technical Support Document (TSD),[12] Arizona has four heads of executive agencies that approve permits and enforcement orders under the Clean Air Act: the Director of Arizona Department of Environmental Quality (ADEQ), and the Control Officer of each of the following three agencies: Maricopa County Air Quality Department (AQD), Pima County Department of Environmental Quality (DEQ), and Pinal County Air Quality Control District (AQCD). Permit and enforcement order appeals at the state level are heard by an administrative law judge in Arizona's Office of Administrative Hearings, while those at the county level are heard by an Air Quality Hearing Board in each respective county (Maricopa, Pima, and Pinal). The only boards in Arizona that approve permits and enforcement orders are the Air Quality Hearing Boards in Maricopa, Pima, and Pinal counties, which may hear permit and enforcement order appeals and take actions to sustain, modify, or reverse (for permits) or affirm or modify (for enforcement orders) the actions of each county's respective Control Officer. These boards are subject to the board membership requirements of section 128(a)(1).

ARS 49–478(B) establishes the compositional requirements of the county Air Quality Hearing Boards, namely that they consist of five members and that ''[a]t least three members shall not have a substantial interest, as defined in section 38–502, in any person required to obtain a permit pursuant to [Title 49, Chapter 3 (''Air Quality''), Article 3 (''County Air Pollution Control'')].'' It is important to note that while this statute explicitly addresses interests in persons required to obtain permits, it does not address ''substantial interest'' with respect to interests in persons subject to enforcement orders.

Pima County Code 17.04.190 (''Composition'') generally mirrors the language or ARS 49–478 but also includes the following requirement in subsection B: ''At least a majority of the hearing board members shall not individually have a substantial interest in an emission source subject to permits or enforcement orders issued pursuant to this title. Substantial interest means any interest other than a remote interest as defined in A.R.S. 38–502, paragraph 10.'' Thus, this local regulation extends the majority membership requirement of ARS 49–478 to interests in persons subject to enforcement orders. However, this regulation has not been submitted for incorporation into the Arizona SIP.

Maricopa County Air Pollution Control Regulation, Rule 100, Section 108 also mirrors the language of ARS 49–478 but its majority membership requirement is limited to substantial interests ''in any person required to obtain an air pollution permit'' (i.e., it does not address persons subject to enforcement orders). Arizona's 2009 Infrastructure Submittal and 2012 Supplement did not cite any such provisions for Pinal County.

ARS 49–478 in conjunction with the definitions of ''substantial interest'' and ''remote interest'' in ARS 38–502, which we propose to approve into the Arizona SIP, satisfy the ''public interest'' and ''significant income'' requirements of CAA section 128(a)(1) for the county boards, but only with respect to interests in persons subject to permits. ARS 49–478 does not specifically reference interests in persons subject to enforcement orders. We view this as a very narrow deficiency in the State SIP but one that nonetheless compels disapproval of the State's 128(a)(1) board composition provisions.

EPA takes very seriously a proposal to disapprove a state plan, as we believe that it is preferable, and preferred in the provisions of the Clean Air Act, that

[6] In a separate rulemaking, EPA proposed to fully approve Arizona's SIP to address the requirements regarding air pollution emergency episodes in CAA section 110(a)(2)(G) for the 1997 8-hour ozone NAAQS. 77 FR 21911 (April 12, 2012).

[7] *See* letter dated October 14, 2009, from Eric C. Massey, Air Quality Director, ADEQ, to Laura Yoshii, Acting Regional Administrator, EPA Region 9.

[8] Under EPA's ''parallel processing'' procedure, EPA proposes rulemaking action concurrently with the State's proposed rulemaking. If the State's proposed plan is changed, EPA will evaluate that subsequent change and may publish another notice of proposed rulemaking. If no significant change is made, EPA will publish a final rulemaking on the plan after responding to any submitted comments. Final rulemaking action by EPA will occur only after the plan has been fully adopted by Arizona and submitted formally to EPA for approval into the SIP. See 40 CFR part 51, appendix V, section 2.3. We note that because ADEQ's rulemaking process here is solely for purposes of adopting the 2012 Supplement as a SIP revision under CAA section 110 and not for purposes of revising any of the statutes or regulations contained therein, we do not expect any significant changes between the proposed and final plans.

[9] *See* letter dated June 1, 2012, from Eric C. Massey, Air Quality Director, ADEQ, to Jared Blumenfeld, Regional Administrator, EPA Region 9.

[10] *See* letter dated June 14, 2012, from Eric C. Massey, Air Quality Director, ADEQ, to Jared Blumenfeld, Regional Administrator, EPA Region 9.

[11] Copies of these Arizona statutes are included in the 2012 Supplement, which is available in the docket for this action and online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0398.

[12] Our Technical Support Document (TSD) describes our evaluation in more detail and is available in the public docket for this rulemaking, which may be accessed online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0398.

these requirements be implemented through state plans. A state plan need not contain exactly the same provisions that EPA might require, but EPA must be able to find that the state plan is consistent with the requirements of the Act. Further, EPA's oversight role requires that it assure consistent implementation of Clean Air Act requirements by states across the country, even while acknowledging that individual decisions from source to source or state to state may not have identical outcomes. In this instance, we believe that the 2009 Infrastructure SIP mostly meets the requirements of 128(a)(1) with respect to significant income and representing the public interest, except that the submitted provisions do not specifically address ''substantial interest'' with respect to interests in persons subject to enforcement orders. As a result, EPA believes this proposed disapproval is the only path that is consistent with the Act at this time. Based on the content of Pima County Code 17.04.190, we believe that this narrow deficiency can be cured by Maricopa and Pinal counties amending their regulations to mirror Pima County Code 17.04.190, and by ADEQ submitting such amended regulations for Pima, Maricopa, and Pinal counties as a SIP revision.

B. Evaluation of 128(a)(2) Disclosure Requirements

Arizona's statutes governing disclosure of interests are found in ARS Title 38, Chapter 3, Article 8, which ADEQ submitted as a revision to the Arizona SIP. As further explained in our TSD, the conflict of interest requirements under Article 8 apply to all those individuals that approve permits and enforcement orders in the first instance or on appeal, including the Director of ADEQ, the administrative law judges of the state Office of Administrative Hearings, the Air Pollution Control Officers of the three relevant counties (Maricopa, Pima, and Pinal), and the members of the Air Quality Hearing Boards in each of the three counties.

ARS 38–503 is the heart of the disclosure provisions in Article 8. In particular, ARS 38–503(B) reads as follows: ''Any public officer or employee who has, or whose relative has, a substantial interest in any decision of a public agency shall make known such interest in the official records of such public agency and shall refrain from participating in any manner as an officer or employee in such decision.'' We interpret ''any decision of a public agency'' to include both permit and enforcement order approvals. ARS 38–502(3) defines ''make known'' as filing a paper or a copy of relevant meeting minutes that fully discloses a substantial interest and such filings must be maintained in a special file open to public inspection pursuant to ARS 38–509.

The disclosure of ''a substantial interest in any decision of a public agency'' covers a wide array of potential conflicts, because ''remote interest'' is narrowly defined, and Article 8 applies to all individuals that approve permits and enforcement orders under the CAA. Thus, upon Article 8 being approved into the Arizona SIP, the State and counties of Arizona will meet the CAA section 128(a)(2) requirement that ''any potential conflicts of interest * * * be adequately disclosed.''

IV. Proposed Action

EPA has evaluated the 2009 Infrastructure SIP and the existing provisions of the Arizona SIP for compliance with the CAA section 110(a)(2)(E)(ii) requirements for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS and the 2006 $PM_{2.5}$ NAAQS. Our TSD contains more detailed evaluations and is available in the public docket for this rulemaking, which may be accessed online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0398.

Based upon this analysis, EPA proposes to approve Arizona's 2009 Infrastructure SIP with respect to the following infrastructure SIP requirements:

- Section 110(a)(2)(E)(ii) (in part): 128(a)(2) relating to potential conflicts of interest by members of any state board or body.

In addition, we are proposing to approve into the SIP certain statutory provisions included in the 2009 Infrastructure SIP, as discussed in the TSD: [13]

- ARS Title 38, Chapter 3, Article 8 (''Conflict of Interest of Officers and Employees'')
- ARS 49–435 (''Hearings on orders of abatement'')
- ARS 49–461 (''Violations; order of abatement'')
- ARS 49–478 (''Hearing board'')
- ARS 49–482 (''Appeals to hearing board'')
- ARS 49–490 (''Hearings on orders of abatement'')

Simultaneously, we are proposing to disapprove Arizona's 2009 Infrastructure SIP with respect to the following infrastructure SIP requirements:

- Section 110(a)(2)(E)(ii) (in part): 128(a)(1) relating to ''significant income'' and representing the ''public interest'' board composition requirements for Pima, Maricopa, and Pinal counties.

As explained more fully in the TSD, we are proposing to disapprove the 2009 Infrastructure SIP with respect to this requirement of CAA section 110(a)(2)(E)(ii) because the Arizona SIP does not fully satisfy the statutory requirements for board composition under section 128(a)(1) of the Act.

Section 110(l) of the Act prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress (RFP) or any other applicable requirement of the Act. The portion of 110(a)(2)(E)(ii) of the 2009 Infrastructure SIP that we are proposing to approve, as explained in the TSD, would improve the SIP by replacing obsolete statutes or regulations and by updating the state and local agencies' SIP implementation and enforcement authorities. We propose to determine that our approval of this element of the 2009 Infrastructure SIP would comply with CAA section 110(l) because the proposed SIP revision would not interfere with the on-going process for ensuring that requirements for RFP and attainment of the NAAQS are met, and the submitted SIP revision clarifies and updates the SIP. Our TSD contains a more detailed discussion of our evaluation.

Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of part D, title I of the CAA (CAA sections 171–193) or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP Call) starts a sanctions clock. The 2009 Infrastructure SIP was not submitted to meet either of these requirements. Therefore, any action we take to finalize the described partial disapprovals will not trigger mandatory sanctions under CAA section 179.

In addition, CAA section 110(c)(1) provides that EPA must promulgate a Federal Implementation Plan (FIP) within two years after finding that a State has failed to make a required submission or disapproving a State implementation plan submission in whole or in part, unless EPA approves a SIP revision correcting the deficiencies within that two-year period.

[13] Copies of these Arizona statutes and regulations are included in the 2012 Supplement, which is available in the docket for this action and online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0398.

V. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq, because this proposed partial approval and partial disapproval of SIP revisions under CAA section 110 will not in-and-of itself create any new information collection burdens but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. 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. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this proposed action will not have a significant impact on a substantial number of small entities. This proposed rule does not impose any requirements or create impacts on small entities. This proposed partial SIP approval and partial SIP disapproval under CAA section 110 will not in-and-of itself create any new requirements but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector.'' EPA has determined that the proposed partial approval and partial disapproval action 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 action proposes to approve certain pre-existing requirements, and to disapprove certain other 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 proposed action.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires 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.''

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP on which EPA is proposing action would not apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this proposed action.

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

EPA interprets EO 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 EO has the potential to influence the regulation. This proposed action is not subject to EO 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed partial approval and partial disapproval under CAA section 110 will not in-and-of itself create any new regulations but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP.

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

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

I. National Technology Transfer and Advancement Act

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

available and applicable voluntary consensus standards.

The EPA believes that this proposed action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

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

Executive Order (EO) 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.

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Particulate matter, Volatile organic compounds.

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

Dated: July 20, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2012–18547 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0556; FRL–9706–7]

Revisions to the Nevada State Implementation Plan, Washoe County Air Quality District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Washoe County District Board of Health (WCDBOH) portion of the Nevada State Implementation Plan (SIP) that EPA expects to be submitted by the Nevada Division of Environmental Protection (NVDEP). These revisions concern regulations regarding compliance with permit conditions, recordkeeping, source sampling and testing, and statements of compliance with 40 CFR part 70 permits. These regulations generally regulate emissions of criteria pollutants such as volatile organic compounds (VOC), oxides of nitrogen (NO_X), and particulate matter (PM). This proposed approval is based upon proposed regulations submitted by NVDEP and an accompanying request that EPA proceed with SIP review while the State and local agencies complete their public review and agency adoption processes. EPA will not take final action on these regulations until NVDEP submits the final adopted versions to EPA as a revision to the Nevada SIP. Final EPA approval of the regulations and incorporation of them into the Nevada SIP would make them federally enforceable under the Clean Air Act (CAA). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by August 29, 2012.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2012–0556, 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.

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: Cynthia Allen, EPA Region IX, (415) 947–4120, *allen.cynthia@epa.gov.*

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

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I. The State's Submittal

A. What rules did the State submit?

By letter dated July 5, 2012, NVDEP submitted to EPA on behalf of WCDBOH, unofficial copies of several rules, with a request for approval of these provisions into the SIP by parallel processing.[1] See July 5, 2012 letter to Jared Blumenfeld, Regional Administrator, EPA Region 9, from Colleen Cripps, Administrator, NVDEP. Table 1 lists the four rules addressed by this proposal.

[1] Under EPA's ''parallel processing'' procedure, EPA proposes rulemaking action concurrently with the State's proposed rulemaking. If the State's proposed rule is changed, EPA will evaluate that subsequent change and may publish another notice of proposed rulemaking. If no significant change is made, EPA will publish a final rulemaking on the rule after responding to any submitted comments. Final rulemaking action by EPA will occur only after the rule has been fully adopted by Nevada and submitted formally to EPA for incorporation into the SIP. See 40 CFR part 51, appendix V.

TABLE 1—RULES SUBMITTED BY NEVADA FOR PARALLEL PROCESSING

Local agency	Rule No.	Rule title
WCDBOH	030.218	Demonstration of Compliance.
WCDBOH	030.230	Record Keeping.
WCDBOH	030.235	Requirements for Source Sampling and Testing.
WCDBOH	030.970A	Part 70 Permit Monitoring and Compliance.

The above rules have been adopted locally but have not been adopted specifically for purposes of approval into the federally enforceable SIP under CAA section 110. NVDEP has requested that WCDBOH adopt these regulations following public process for purposes of SIP approval and thereafter submit the rules to NDEP for transmittal to EPA as SIP revisions. Concurrent with these county processes, NVDEP anticipates that it will schedule a public hearing in August on its proposal to submit these rules to EPA for incorporation into the SIP, and intends to submit the final SIP revision to EPA by late August. We note that because the state and county rulemaking processes here are solely for purposes of adopting these regulations as SIP revisions under CAA section 110 and not for purposes of revising any of the regulations, we do not expect any substantive changes between the proposed and final submittals. Final approval of these rules, however, is contingent upon EPA's receipt of fully adopted rules that satisfy state and local procedural requirements for SIP submittals.

B. Are there other versions of these rules?

There are no SIP-approved versions of WCDBOH Rules 030.218, 030.230, 030.235, and 030.970.

C. What is the purpose of the submitted rules?

The submitted rules govern demonstrating compliance with permit conditions, recordkeeping, source sampling and testing, and statements of compliance with 40 CFR Part 70 permits. These regulations generally regulate, among other things, emissions of criteria pollutants such as VOCs, NO_X and PM. VOCs help produce ground-level ozone and smog, which harm human health and the environment. NO_X helps produce ground-level ozone, smog and particulate matter, which harm human health and the environment. PM contributes to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires States to submit regulations that control VOC, NO_X, and PM emissions.

- Section 030.218, Demonstration of Compliance, states that the Control Officer may require the operator of a source to provide any applicable data to demonstrate compliance with the conditions of the Permit to Operate.
- Section 030.230, Record Keeping, states that the Control Officer may require any holder of a Permit to Operate to keep adequate records concerning contaminant emissions for any equipment or process for which the permit was issued.
- Section 030.235, Requirement for Source Sampling and Testing, requires the APCO to determine the exact quantity and effect of emissions produced by stationary sources. The APCO may require source stack testing, or other types of source testing including, but not limited to, mass balance types of analysis, be made by the operator.
- Section 030.970A, Part 70 Permit Monitoring and Compliance, requires sources subject to 40 CFR Part 70 permitting requirements to submit an annual statement of compliance covering certain specified items.

EPA's technical support document (TSD) has more information about these rules.

II. EPA's Evaluation and Proposed Action

A. How is EPA evaluating the rules?

Generally, SIP rules must be enforceable (see section 110(a) of the Act) and must not relax existing requirements (see sections 110(l) and 193). Guidance and policy documents that we use to evaluate enforceability requirements consistently include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).
2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
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) (''General Preamble'').

B. Do the rules meet the evaluation criteria?

We believe these rules are consistent with the applicable requirements and guidance regarding enforceability and SIP relaxations. The TSD has more information on our evaluation.

C. Public Comment and Proposed Action

Because EPA believes the submitted rules fulfill all applicable CAA requirements, we are proposing to fully approve them under section 110(k)(3) of the Act. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period or NVDEP does not submit the adopted SIP revisions as expected, we intend to publish a final approval action that will incorporate these rules into the federally enforceable SIP.

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: July 19, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2012–18500 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[FRL–9708–1]

Public Meeting: Potential Regulatory Implications of the Reduction of Lead in Drinking Water Act of 2011

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is hosting a public meeting on August 16, 2012, to discuss and solicit input from States, manufacturers, drinking water systems, other interested groups and consumers on the implementation of the Reduction of Lead in Drinking Water Act of 2011 (''the Act''). The Act was signed on January 4, 2011, and will be effective on January 4, 2014. The Act amended Section 1417 of the Safe Drinking Water Act (SDWA), which prohibits the use of certain plumbing products that are not ''lead free'' (as defined by SDWA), and makes it unlawful to introduce into commerce products that are not ''lead free.''

DATES: The public meeting will be held at the Environmental Protection Agency Conference Center (lobby level-room 1204). One Potomac Yard (South Building) 2777 S. Crystal Drive, Arlington, VA 22202 on Thursday, August 16, 2012, from 1:00 p.m. to 4:30 p.m., Eastern Daylight Time (EDT). All attendees must go through a metal detector, sign in with the security desk, and show government issued photo identification to enter the building. Teleconference and webcast attendance will be available. Instructions for registration for the meeting are located in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: For general information about this meeting, contact Lameka Smith, Standards and Risk Management Division, Office of Ground Water and Drinking Water; by phone (202) 564–1629 or by email *smith.lameka@epa.govmailto:*. For the full text of the Reduction of Lead in Drinking Water Act of 2011, please visit: *www.gpo.gov/fdsys/pkg/PLAW.../pdf/PLAW-111publ380.pdf*. For additional information about the Lead and Copper Rule, please visit: *http://water.epa.gov/lawsregs/rulesregs/sdwa/lcr/index.cfm*.

SUPPLEMENTARY INFORMATION:

Registration: Individuals planning to attend in person, by teleconference, or via webcast must register for the meeting by contacting Junie Percy of IntelliTech at (937) 427–4148 ext. 210, or by email *junie.percy@itsysteminc.com* no later than August 15, 2012. There is no charge for attending this public meeting, but seats and phone lines are limited, so please register as soon as possible.

Reduction of Lead in Drinking Water Act: The Act made several key changes to Section 1417: First, the Act changed the definition of ''lead-free'' under SDWA by reducing the lead content to a weighted average of not more than 0.25% in the wetted surface material. Second, the Act also amended the definition of ''lead free'' by adding a specific formula for calculating lead content. Third, the Act created two separate exemptions to the prohibitions on the use and introduction into commerce of products that are not ''lead-free.'' Some of the changes the Act makes to SDWA Section 1417 raise implementation challenges and issues that may warrant regulatory changes beyond codification of the statutory changes into the Code of Federal Regulations. EPA would make any needed regulatory changes as part of the Lead and Copper Rule long-term revisions (LCR–LTR). However, because the final LCR–LTR will be published after the effective date of the Act, EPA intends to provide information to assist plumbing manufacturers, States, water systems, plumbing retailers and other affected parties in implementing the provisions of the Act starting in 2014. Information from this stakeholder meeting will help inform regulatory revisions that will be included in the LCR–LTR.

Special Accommodations: For information on access or to request special accommodations for individuals with disabilities, please contact Lameka Smith, Standards and Risk Management Division, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency; by telephone (202) 564–1629 or email *smith.lameka@epa.govmailto:*. Please allow at least five business days prior to the meeting to provide EPA with time to process your request.

Dated: July 24, 2012.

Pamela S. Barr,

Acting Director, Office of Ground Water and Drinking Water.

[FR Doc. 2012–18525 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 206

[Docket ID FEMA–2010–0035]

RIN 1660–AA68

Housing Assistance Due to Structural Damage

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Under the authority of section 408 of the Robert T. Stafford Disaster

Relief and Emergency Assistance Act (Stafford Act), the Federal Emergency Management Agency (FEMA) provides grants to individuals and households to repair or replace their homes after a Presidentially-declared major disaster or emergency. FEMA proposes to revise its repair, replacement, and housing construction assistance regulations to clarify the eligibility criteria for assistance and implement changes to section 408 of the Stafford Act that were made by the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA).

DATES: Comments must be received on or before September 28, 2012.

ADDRESSES: You may submit comments, identified by docket ID FEMA–2010–0035, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail/Hand Delivery/Courier: Regulatory Affairs Division, Office of Chief Counsel, 500 C Street SW., Room 840, Washington, DC 20472–3100.

Instructions: All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal e-Rulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the Privacy Notice link on the homepage of *www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2010–0035'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.'' Submitted comments may also be inspected at the Office of Chief Counsel, Federal Emergency Management Agency, 500 C Street SW., Room 835, Washington, DC 20472–3100.

FOR FURTHER INFORMATION CONTACT: Lumumba T. Yancey, FEMA, Individual Assistance Division, 500 C Street SW., Washington, DC 20472–3100, (phone) 202–212–1000, (facsimile) (202) 212–1005, or (email) *FEMA-IA-Regulations@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) provides the Federal Emergency Management Agency (FEMA) with the authority to administer the Individuals and Households grant program (IHP). *See* 42 U.S.C. 5174. Through the IHP, FEMA provides grants and/or direct assistance to help survivors recover from Presidentially-declared emergencies and major disasters. This help may be in the form of housing assistance as well as assistance to meet ''other needs'' such as medical, dental, funeral, fuel, or clothing costs.

Specifically, FEMA provides the following types of housing assistance:

Temporary Housing: Money is available to rent a different place to live for a limited period of time. When rental properties are not available, FEMA may provide direct assistance in the form of a temporary housing unit.

Housing Repair: Money is available to homeowners to repair disaster damage to their primary residence. Assistance is only available to repair damage that is not covered by insurance. The goal is to make the damaged home safe, sanitary, and functional.

Housing Replacement: Money is available to homeowners to replace their home if it was destroyed in the disaster. Assistance is only available for damage that is not covered by insurance.

Permanent and Semi-Permanent Housing Construction: In exceptional circumstances, FEMA is authorized to provide permanent and semi-permanent housing construction. If FEMA exercises its discretion to offer this form of disaster assistance, FEMA may provide money for the construction of a home, or may construct the new permanent or semi-permanent housing unit for an individual or household. This type of assistance is currently provided only in remote and insular areas or locations specified by FEMA where no other type of housing assistance is available, feasible, or cost-effective. Assistance is provided only for damage that is not covered by insurance.

The regulations establishing the types of IHP assistance available, the eligibility requirements for assistance, and the procedures for obtaining assistance are in 44 CFR part 206, subparts D and F.

On September 30, 2002, FEMA published an interim rule in the **Federal Register**, identified by Regulation Identifier Number (RIN) 1660–AA18, which revised its regulations implementing the IHP. *See* 67 FR 61446. FEMA published a correction to the interim rule on October 9, 2002. *See* 67 FR 62896. Among other things, the interim rule established the housing repair, replacement, and construction eligibility regulations in 44 CFR 206.117. These regulations are currently in effect.

This proposed rule addresses the public comments received on the interim rule related to housing repair and replacement, and proposes revisions that are intended to clarify and improve FEMA's eligibility requirements for housing repair assistance. These proposed changes are intended to restate the existing requirements more clearly and in greater detail. They are not intended to create new eligibility requirements or add an additional burden on applicants.

In addition, the proposed rule implements and codifies legislative changes made after the interim rule was published. On October 4, 2006, the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA) amended section 408 of the Stafford Act which affected housing repair, replacement, and construction assistance. First, it amended subsection 408(c)(2) of the Stafford Act by removing the subcaps that had limited the amount of IHP funds that could be used for housing repair and replacement. *See* 42 U.S.C. 5174(c) and section 686 of Public Law 109–295. This was a self-implementing statutory change, which went into effect immediately. FEMA no longer applies the housing repair and replacement subcaps. Individuals and households may use up to the full amount of IHP funds ($31,400 for fiscal year 2012) for repair and replacement assistance. *See* 76 FR 63940 (Oct. 14, 2011). This figure is adjusted annually to reflect changes in the Consumer Price Index (CPI).

Second, PKEMRA amended subsection 408(c)(4) of the Stafford Act by removing the word ''remote'' and adding the word ''semi-permanent.'' While FEMA already had authority to provide ''permanent housing construction'' assistance, this statutory change provides FEMA with authority to provide assistance for the construction of ''semi-permanent'' housing. Prior to this statutory change, FEMA only had the authority to provide construction assistance to locations that were insular (outside the continental United States) or in remote areas where the other types of housing assistance were unavailable, infeasible, or not cost effective. The removal of the statutory requirement that a location be ''remote'' allows FEMA greater flexibility to provide construction assistance in other locations, when FEMA determines that the stringent statutory requirements are satisfied. *See* 42 U.S.C. 5174(c)(4) and section 685 of Public Law 109–295. Although this change would likely provide more flexibility for FEMA to meet the housing needs of disaster

survivors, FEMA expects to exercise this authority only rarely. Typically, within the continental United States, alternative housing resources and/or other types of temporary housing are available and feasible (e.g., rental housing or FEMA-provided temporary housing units).

II. Discussion of the Proposed Rule

This rule proposes to do four things. First, it proposes to address the public comments received on the 2002 interim rule related to housing repair and replacement and proposes revisions to the interim rule as a result of those comments. Second, it proposes changes which are intended to restate the existing requirements more clearly and in greater detail, without substantively changing the underlying requirements. The changes should clarify IHP housing repair assistance requirements for potential applicants and make it easier for the public to understand why damage to their residence is (or is not) eligible for IHP assistance. These proposed changes are not intended to create new eligibility requirements or add an additional burden on applicants. Third, this rule proposes to revise the regulations to align with PKEMRA's removal of the housing repair and replacement subcaps. This is a non-discretionary conforming amendment that aligns the regulation with changes in the Stafford Act and FEMA's current operations. Finally, it proposes to add the term ''semi-permanent'' and to remove the term ''remote'' with respect to the eligibility requirements for housing construction, as authorized by PKEMRA.

When appropriate, FEMA will provide financial assistance to individuals and households to repair eligible real property components that are a part of their primary residence and were damaged by the event. To be eligible for repair assistance, the damage to the component must have been caused by the declared event and the component must have been functional before the event. Also, repair or replacement of the component must be necessary to ensure the safety or health of the occupant or to make the residence functional. These eligibility requirements are currently in effect. *See* 44 CFR 206.117(b)(2), (c)(1). This rule proposes language that would revise the repair assistance regulations to restate the eligibility requirements more clearly.

If an individual or household's primary residence is damaged, and repair is not feasible, the individual or household may apply for housing replacement assistance. If FEMA awards replacement assistance, FEMA provides the individual or household financial assistance for the reasonable costs to replace their home, up to the maximum assistance set by law. The Disaster Mitigation Act of 2000 set a cap of $5,000 for repair assistance, and $10,000 for replacement assistance that an individual could use out of their maximum assistance award. *See* section 206 of Public Law 106–390. An individual was previously not allowed to use any additional funds from their maximum assistance award for the reasonable costs to repair or replace their home.

Under the current regulations, FEMA will provide replacement assistance if there is at least $10,000 of disaster-related damage (as adjusted annually to reflect changes in the CPI). *See* 44 CFR 206.117(b)(3). If awarded replacement assistance, under the current regulations, the applicant can either (1) replace the dwelling in its entirety for $10,000 (as adjusted annually to reflect changes in the CPI) or (2) use the assistance towards the cost of acquiring a new permanent residence that costs more than $10,000. *See* 44 CFR 206.117(b)(3). This $10,000 eligibility structure is no longer appropriate since PKEMRA removed the repair and replacement subcaps from the Stafford Act. FEMA proposes to remove the $10,000 subcap and eligibility threshold from the regulations, but maintain the underlying concept that replacement assistance is only available when the applicant must replace the damaged dwelling in its entirety. To accomplish this, FEMA proposes that to be eligible for housing replacement assistance, all parts of the dwelling's structure must have been compromised and deemed not repairable.

FEMA also proposes to remove the $5,000 subcap for repair assistance from the regulations, to reflect current law and FEMA policy. With the $5,000 subcap for repair assistance removed, individuals and households continue to be granted up to the full amount of IHP funds ($30,200 for fiscal year 2011) for repairs, when repairs are feasible and replacement assistance is not warranted. This change does not reduce available repair assistance funds.

In exceptional circumstances, FEMA is authorized to provide permanent or semi-permanent housing construction assistance. If FEMA exercises its discretion to offer this form of housing assistance in a specific disaster, FEMA may fund the construction of a permanent or semi-permanent dwelling for an individual or household. This type of assistance is only provided in those situations where the other types of FEMA housing assistance are unavailable, infeasible, or not cost effective. This limitation exists in FEMA's current regulations and is not changed by this proposed rule. *See* 44 CFR 206.117(b)(4). FEMA proposes to revise the regulatory language to conform to changes to the Stafford Act. The Stafford Act now provides that housing construction may be permanent or semi-permanent and the requirement that FEMA provides assistance only in remote areas has been removed. FEMA proposes to define ''semi-permanent housing'' as housing with a life expectancy of more than 5 years, but less than 25 years. Housing with a life expectancy of less than 5 years would be deemed temporary housing and that over 25 years would be deemed permanent housing. FEMA has the authority to provide this type of assistance in insular areas outside the continental United States, as well as in other locations where no alternative housing resources are available or where other types of FEMA housing assistance are unavailable, infeasible, or not cost-effective. *See* 42 U.S.C. 5174(c) and section 685 of Public Law 109–295.

The basic eligibility requirements for housing assistance are not changed by this proposed rule. To be eligible for housing assistance, the damage must not be covered by insurance, the damage must be to a dwelling owned and occupied by the applicant, and it must have served as the applicant's pre-disaster primary residence. Just as fundamentally, section 408 requires that all assistance be for ''necessary expenses and serious needs'' that arose as a ''direct result'' of the disaster; thus, repair and replacement assistance are provided only to applicants whose residences were ''damaged by'' the disaster. *See* 42 U.S.C. 5174(a)(1), (b), (c); 42 U.S.C. 5155; 44 CFR 206.113, 206.117(b). To provide greater clarity to the requirement that the damage is a direct result of the disaster, FEMA proposes to make changes to 44 CFR 206.117(a), (b)(2), (b)(3), (b)(4), and remove paragraph (c). The following discussion will address the proposed revisions to 44 CFR 206.117, paragraph by paragraph.

44 CFR 206.117—Paragraph (a) Definitions

As with all of FEMA's IHP housing assistance regulations in 44 CFR part 206 subpart D, the definitions in 44 CFR 206.111 apply to 44 CFR 206.117. However, FEMA finds that to provide clarity to the housing assistance regulations additional definitions may be necessary. FEMA proposes to revise 44 CFR 206.117(a) to define particularly

important terms applicable to the housing repair, replacement and construction requirements. These proposed definitions would be applicable to 44 CFR 206.117 only. In paragraph (a), FEMA proposes to add new definitions for ''Caused by the disaster''; ''Real property component'' and ''component''; and ''Semi-permanent housing.'' Each of these terms is particularly important in the interpretation of FEMA's housing repair assistance regulations.

44 CFR 206.117—Paragraph (b)(2) Repair Assistance

Paragraph (b) addresses repair assistance. In paragraph (b)(2)(i), FEMA proposes to clearly notify applicants that the eligibility criteria for individuals and households who apply for IHP assistance set forth in 44 CFR 206.113 also apply to 206.117(b)(2). Not only must the component be eligible, but the applicant must be eligible. FEMA proposes to add the cross reference to ensure that those requirements are not overlooked. This is not a substantive change.

Second, FEMA proposes to reorganize the general eligibility requirements in proposed paragraph (b)(2)(i) into a checklist format. Although the presentation has changed, the proposed text contains no new substantive requirements. These requirements are all contained in current 44 CFR 206.117(b)(2)(i) and (b)(2)(ii).

Third, although they are not new, FEMA proposes to clarify these existing requirements. Most notably, the current requirement that the damage must be ''disaster-related'' has been broken into two parts. As proposed, the component must have been functional immediately before the event, and the component must have been damaged and made not functional by the event. FEMA has historically used these two criteria to determine if damages are ''disaster-related.'' These two criteria break down the existing requirement, and make it easier to understand what FEMA means by the term ''disaster-related damages.'' FEMA cannot determine that a component that did not work before the event is not functional as a result of the event.

Further, the disaster must have actually caused damage to the component. If the damage was caused by an unrelated event, it is not eligible. FEMA has proposed language in paragraphs (b)(2)(iii) through (v) further clarifying the extent of available assistance. Those paragraphs are discussed later in this preamble.

The language in proposed paragraph (b)(2)(ii) restates the existing language in 44 CFR 206.117(c)(1). The substance of proposed paragraphs (b)(2)(ii)(A), (B), and (C) is unchanged. In new paragraph (D), FEMA proposes to remove the word ''plumbing'' because it is covered by the terms ''water'' and ''sewage,'' which remain. In paragraph (E), FEMA proposes to remove the word ''doors'' because they are included in proposed paragraph (B). Proposed paragraphs (F), (G), and (H) remain substantively unchanged except that FEMA merged the language in current paragraph (b)(2)(iii), setting out the type of hazard mitigation measures that are eligible, into proposed paragraph (H). FEMA intends no substantive change in application of the regulation as a result of these changes.

In proposed paragraph (b)(2)(iii), FEMA would clarify that not only the type of repair, but also the eligibility of the component itself, will vary depending on the nature of the disaster. This aligns with the existing eligibility requirement that the component must have been damaged by the event. The nature of an event will indicate whether the component would likely have been damaged by it. As an example, drywall on the second floor is unlikely to have been damaged from a three-foot flood.

Also in proposed paragraph (b)(2)(iii), FEMA would add new language noting that repair will be provided only to the extent that it makes the component functional. FEMA does not provide repairs or replacement to further improve a component beyond making it functional. IHP is not a loss indemnification program and does not ensure that applicants are returned to their pre-disaster living conditions. As an example, if only the condenser is damaged on a heating and air conditioning system, FEMA would provide assistance to repair the condenser, not replace the entire system, even if the system is near the end of its service life. Finally, in proposed paragraph (b)(2)(iii) FEMA restates the limitations in current paragraph (b)(2)(ii) that replacement assistance will only be provided when repair is not feasible, and current paragraph (c)(1) that repairs are limited to restoring the residence to a safe and sanitary living or functioning condition.

Proposed paragraph (b)(2)(iv) is new. It is intended to clarify the requirement in proposed paragraph (b)(2)(i)(B) that the component was functional immediately before the event. Components need not be fully functional before the event, nor is it disqualifying if the component posed a risk before the event. The key is that it must have had some functionality before the event, and incurred a change in functionality (must become unfunctional) as a result of the event.

Proposed paragraph (b)(2)(v) revises the content of current paragraph (b)(2)(iv) to remove the housing repair subcap. This change would conform the regulation to statutory changes in section 408(c)(2) of the Stafford Act. *See* 42 U.S.C. 5174(c) and section 686 of Public Law 109–295. FEMA stopped applying the subcaps when the Stafford Act was amended, therefore, the removal of this cap from the regulatory text will not have a substantive impact on the public. In the proposed rule, FEMA clearly states that individuals and households may use the entire amount of assistance available under the IHP for repair, or if FEMA determines that repair is infeasible, for replacement.

Proposed paragraph (b)(2)(vi) remains unchanged from the text of the current paragraph (b)(2)(v).

The language of proposed (b)(2)(vii) is new, but the substance is not. Applicants for housing repair assistance currently have the opportunity to appeal FEMA's eligibility determinations pursuant to 44 CFR 206.115. FEMA proposes to add an explicit cross reference to ensure that they are aware of the opportunity.

Further, FEMA's initial determination is based on an on-scene inspection performed by a FEMA inspector. If the applicant disagrees with the inspection and has information that would contradict the inspector's report, on appeal it is the applicant's responsibility to provide the documentation so that FEMA may appropriately evaluate eligibility. Depending on the reason for the denial or the substance of the applicant's dispute, an applicant may need to provide proof of occupancy, ownership, income, loss, and/or information concerning their housing situation prior to the disaster. In case it is later needed to support the claim, the applicant should keep, for 3 years, all receipts and records for any housing expenses incurred as a result of the disaster. See ''*Help After a Disaster: Applicant's Guide to the Individuals & Households Program''* at *http://www.fema.gov/assistance/process/guide.shtm.* This includes receipts for repair supplies and labor. To ensure that applicants are aware of their burden of proof on appeal, FEMA proposes to specifically highlight the documentation needed for an appeal. These are not new requirements, because generally, for applicants to successfully challenge a FEMA determination, they must show proof as to why they believe the determination was incorrect.

44 CFR 206.117—Paragraph (b)(3) Housing Replacement

In this paragraph, FEMA proposes five changes. First, we propose to remove the housing replacement subcap to conform with statutory changes to section 408(c)(2) of the Stafford Act. *See* 42 U.S.C. 5174(c) and section 686 of Public Law 109–295. FEMA is no longer required to cap the amount of available IHP assistance applied to housing replacement. In the proposed rule, FEMA clearly states that individuals and households may use the entire amount of assistance available under the IHP for this purpose.

Second, we propose to remove the eligibility requirement that the disaster-related damage meet or exceed $10,000 (as adjusted annually to reflect changes in the CPI). FEMA proposes to remove the $10,000 subcap, but maintain the underlying intent that replacement assistance only be provided where repair assistance is insufficient. To do so, FEMA proposes to revise paragraph (b)(3) to allow for replacement assistance if repair to an owner-occupied primary residence damaged by the declared event is not feasible, will not ensure the safety or health of the occupant, or will not make the residence functional.

Third, in response to a comment on the interim rule, FEMA proposes to reassign the authority to approve replacement assistance awards. FEMA proposes to change this authority from the FEMA ''Associate Administrator'' to the FEMA ''Regional Administrator or his or her designee.'' This change is intended to speed the processing of housing replacement assistance.

Fourth, just as with repair assistance, applicants must meet the eligibility requirements of 44 CFR 206.113 to be considered for replacement assistance. The residence must also have been functional immediately before the declared event, must have been damaged by the event, and the damage must not have been covered by insurance. These are the current requirements for replacement assistance; however, as with repair assistance, the requirements are not currently set out in checklist form in the regulations. Further, FEMA finds that it may be confusing to applicants that the basis for the amount of replacement assistance is in current paragraph (c), while the other eligibility requirements are contained in paragraph (b)(3). To address this, FEMA proposes to list the eligibility requirements in checklist form, mirroring those elements for repair assistance. FEMA also proposes to move the current text in paragraph (c)(2) to new paragraph (b)(3)(iii) without substantive change.

Finally, FEMA proposes to add a new paragraph (b)(3)(iv). As with repair assistance, FEMA finds it may be beneficial to provide a cross reference to the appeal regulations at 44 CFR 206.115, as well as, clarify that the applicant must also provide proof that the residence is eligible for replacement assistance. These are not new requirements, but merely list the necessary elements of an appeal.

44 CFR 206.117—Paragraph (b)(4) Permanent and Semi-Permanent Housing Construction

As with current paragraph (b)(3), FEMA proposes to consolidate the requirements for housing construction assistance by stating the eligibility requirements in checklist format and re-designating the current text of paragraph (b)(4) as paragraph (b)(4)(i), and moving the current text in paragraph (c)(3) to new paragraph (b)(4)(ii) without substantive change.

Also, section 685 of PKEMRA amended section 408(c)(4) of the Stafford Act by inserting ''or semi-permanent'' after ''permanent'' and by striking the word ''remote.'' These changes allow FEMA to provide not only permanent housing construction assistance, but also to construct semi-permanent housing. Further, this type of assistance is no longer limited to remote locations, but can be provided in those exceptional cases where alternative housing resources are not available and the other types of housing assistance provided by FEMA are unavailable, infeasible, or not cost effective. FEMA proposes to revise its housing construction regulations in new paragraph (b)(4)(i) to conform with these statutory changes. FEMA expects to provide this type of assistance in very rare circumstances. Alternative housing resources and the other types of housing assistance should sufficiently address a community's housing needs in most circumstances.

Finally, FEMA proposes to add a new paragraph (b)(4)(iii). As with repair and replacement assistance, FEMA finds it may be beneficial to provide a cross reference to the appeal regulations at 44 CFR 206.115, as well as clarify that the applicant must also provide proof that the residence is eligible for construction assistance. These are not new requirements, but merely list the necessary elements of an appeal.

44 CFR 206.117—Paragraph (c) Eligible Costs

As noted above, FEMA proposes to distribute the substance of current paragraph (c) throughout proposed paragraph (b). Therefore, FEMA proposes to remove paragraph (c).

III. Response to Comments From the Interim Rule Related to Housing Repair Assistance

In response to the interim rule, FEMA received written comments from five States. This section addresses the portion of those comments regarding housing repair assistance.

Caps on Repair and Replacement Assistance

One State recommended modification of the $5,000 cap, expressing concern that the repair cap may not bring homes into compliance with local minimum standards. The commenter stated that where there are no local standards, the low cap may force individuals and households to return to unsafe conditions. FEMA agreed with the commenters regarding the caps, and sought a modification to the statute. *See* 67 FR 61447. Another commenter raised similar concerns regarding the $10,000 cap on replacement assistance.

On October 4, 2006, PKEMRA amended section 408(c)(2) of the Stafford Act, by removing the repair and replacement caps. *See* 42 U.S.C. 5174(c). This was a self-implementing change which went into effect immediately, and FEMA no longer applies the caps. FEMA proposes to revise current 44 CFR 206.117(b)(2)(iv) and (b)(3) to remove the repair and replacement caps.

Approval Authority for Replacement Assistance (44 CFR 206.117(b)(3))

One State noted that approval at the Associate Administrator level was a deterrent to timely and compassionate assistance. The commenter recommended that the Regional Administrator be given approval authority for replacement assistance.

In response to this comment, FEMA proposes to revise 44 CFR 206.117(b)(3) by replacing ''Associate Director'' with ''Regional Administrator or his or her designee.'' FEMA proposes this change because the Regional Administrator will have greater familiarity with the damage in his or her region, and with greater decentralization housing replacement applications may be processed faster.

IV. Individuals and Households Program Implementation Review Report

During the comment period on the interim rule, FEMA met with the staff of five States in which the IHP was first implemented. The State and FEMA recovery program staff that first implemented IHP worked six disasters:

DR–1439–TX which resulted from severe storms, tornados, and flooding in Texas; DR–1440–AK which resulted from an earthquake in Alaska; DR–1441–TN which resulted from severe storms, tornados, and flooding in Tennessee; DR–1442–AL which resulted from severe storms and tornados in Alabama; DR–1443–MS which resulted from severe storms and tornados in Mississippi; and DR–1444–OH which resulted from severe storms and tornados in Ohio. The participants in the meeting were asked to identify best practices and problems or issues that needed corrective action. The meeting resulted in the Individuals and Households Program Implementation Review Report (Report), a copy of which is available in the docket for this rulemaking on *www.regulations.gov.* The recommendations focused primarily on procedural or other aspects of IHP that were not affected by this rule. Two issues in that report affect this rulemaking. Those issues and their resolution are:

Issue: Revise the $5,000 and $10,000 statutory limits.

Status or Resolution: As discussed elsewhere in this preamble, PKEMRA amended section 408(c)(2) of the Stafford Act, 42 U.S.C. 5174(c), by removing the repair and replacement caps. As a result, FEMA proposes to revise the regulations to remove both the $5,000 repair cap and the $10,000 replacement cap.

Issue: Replacement—establish uniform policy and flexible procedures.

Status or Resolution: In this proposed rule, FEMA attempts to improve its housing replacement assistance program. FEMA's procedures allow for flexibility, yet protect against abuse. In this proposed rule, FEMA delegates the decision regarding replacement eligibility to the Regional Administrators, provides clarity and cross references to appeal rights, clarifies eligibility criteria, and expands the amount of assistance by removing the repair and replacement subcaps. By clarifying the requirements, and making the regulations easier to read, FEMA intends to create uniformity in application.

V. Records Management

The Regulation Identifier Number (RIN) listed in the September 30, 2002 interim rule and the correction to the interim rule was 3067–AD25. When FEMA became a component of the Department of Homeland Security (DHS) in 2003, FEMA's RINs were renumbered, and 3067–AD25 became 1660–AA18.

The Docket ID for 1660–AA18 is FEMA–2008–0005. All of 1660–AA18's public submissions, supporting and related documents, and rules are posted to Docket ID FEMA–2008–0005. The public comments that addressed housing repair assistance, the subject of this rulemaking, have also been posted to Docket ID FEMA–2010–0035.

VI. Regulatory Analysis

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

FEMA has prepared and reviewed this rule consistent with Executive Order 12866, Regulatory Planning and Review (58 FR 51735, Oct. 4, 1993) as supplemented by Executive Order 13563, *Improving Regulation and Regulatory Review (76 FR 3821, Jan. 18, 2011).* This proposed rule is not a significant regulatory action, and therefore has not been reviewed by the Office of Management and Budget (OMB).

This proposed rule is intended to provide clarification with respect to the eligibility for housing repair assistance, without adding new requirements, as well as implement changes to section 408 of the Stafford Act made by PKEMRA. *See* 42 U.S.C. 5174. This rule will not impose any additional burden on the public or change the total amount of assistance available to individuals and households since this rule merely codifies FEMA practice since 2006.

The proposed changes resulting from PKEMRA (a) revise the regulations to align with PKEMRA's removal of the housing repair and replacement subcaps; (b) remove the limitation that housing construction assistance be provided only in a ''remote'' area, if the location is not otherwise insular (outside the continental United States); and (c) incorporate FEMA's new authority to provide assistance for the construction of ''semi-permanent'' housing.

When the current regulations were written, FEMA was prohibited from providing more than $5,000 (adjusted annually to reflect changes in the CPI) for repair assistance, and more than $10,000 (adjusted annually to reflect changes in the CPI) for replacement assistance under the Disaster Mitigation Act of 2000. These subcaps prevented applicants from spending all of their available IHP assistance (in fiscal year 2012, this amount is $31,400 per declared event (76 FR 63940, Oct. 14, 2011)) on housing repair or replacement, leaving nothing for their other needs such as clothing, funeral, or medical costs. The change in PKEMRA was self implementing and immediately went into effect. FEMA is no longer required to apply subcaps and has not applied them since PKEMRA became law in 2006. This rule change is intended to revise the regulations to conform to the statutory change and FEMA's current practice. It would not change the eligibility criteria and would not reduce the total amount of assistance available to individuals and households. This proposed change would not have an economic impact because it merely codifies FEMA current practice.

This rule also proposes to remove the term ''remote'' from 44 CFR 206.117(b)(3) to implement new authority to provide housing construction assistance in areas within the continental United States where alternative housing resources are not available, infeasible, or not cost effective. Currently, FEMA's regulations limit this type of assistance to only locations that are insular or remote. This proposed rule change would implement PKEMRA by providing housing construction assistance to disaster survivors in areas where alternative housing resources are not feasible. This rule change provides more flexibility for FEMA to meet the housing needs for disaster survivors, although it is expected that FEMA will only rarely exercise this authority. This is because alternative housing resources, such as rental units, manufactured housing, recreational vehicles, other readily fabricated dwellings, or FEMA-provided temporary housing units, typically are available within the continental United States. FEMA has not yet provided any direct assistance for housing construction in areas other than those that are remote and insular. This proposed change is not expected to have a significant economic impact or to negatively affect the eligibility criteria for assistance. Any economic impact from this proposed rule change would be an increase in Federal grant funds provided to individuals and households to provide housing in those extremely rare cases where alternative housing resources are not available, infeasible, or not cost effective. There would be no increased burden imposed on the public from this proposed change. There is no economic impact to this proposed change because this proposed rule merely codifies FEMA current practice since 2006.

This rule also proposes to add ''semi-permanent'' to the types of housing that could be constructed. This type of housing would be that with a life expectancy of more than 5 years, but

less than 25 years. While FEMA already provides temporary and permanent housing, by implementing this new authority, FEMA would have greater flexibility to meet the needs of a particular community, where the construction of a type of housing other than a long-term permanent structure may be more appropriate. Although this rule change is likely to provide more flexibility for FEMA to meet the housing needs for disaster survivors, it is not expected that FEMA will regularly exercise this authority. This proposed rule change would implement PKEMRA by giving FEMA more options in providing housing assistance to disaster survivors. It would not reduce the number of individuals or households eligible for housing assistance and would not affect eligibility requirements. There is no economic impact to this proposed change because this proposed rule merely codifies FEMA current practice.

B. Paperwork Reduction Act of 1995

FEMA determined that this proposed rule will not create a new collection of information or create a revision to an existing collection of information under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520. All information submitted by applicants seeking IHP housing assistance, including information submitted on appeal, is included in Office of Management and Budget (OMB) approved collections.

The following collections related to IHP have been approved by OMB under the following titles and control numbers: ''Disaster Assistance Registration'', OMB control number 1660–0002, expiration date August 31, 2013 and ''Federal Assistance to Individuals and Households Program (IHP)'', OMB control number 1660–0061, expiration date October 31, 2014. There would be no additional paperwork burden as a result of the changes proposed in this rule.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FEMA must consider the impact of this proposed regulation on small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. This proposed rule clarifies the eligibility criteria for housing repair, replacement, and construction assistance to individuals and households. It will not have an economic impact on small entities because it merely codifies FEMA current practice since PKEMRA became law in 2006. FEMA certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities.

D. Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a, establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by Federal agencies. A system of records is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifier assigned to the individual. FEMA, in partnership with other Federal agencies, hosts a single application and resource center at *http://www.disasterassistance.gov* that allows the public to apply for disaster assistance, benefits, and other services within FEMA and other Federal agencies. This application and resource center contains personally identifiable information about IHP applicants seeking housing repair, replacement, or construction assistance. The application resource center is contained in a Privacy Act System of Records entitled ''Disaster Recovery Assistance Files'' number ''DHS/FEMA–008'' which published on September 24, 2009 in the **Federal Register** at 74 FR 48763. This proposed rule would not change the application materials received or result in a new collection of personally identifiable information about individuals.

E. National Environmental Policy Act

Under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.,* an agency must prepare an environmental assessment and environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement. Most activities under section 408 and prior section 411 of the Stafford Act pertaining to temporary housing and financial assistance are categorically excluded from NEPA review under 44 CFR 10.8(d)(2)(xix)(D) and (F). Before undertaking other activities that are not categorically excluded (*e.g.,* placement of manufactured temporary housing units on FEMA-constructed group sites; permanent or semi-permanent housing construction), FEMA follows the procedures set forth in 44 CFR part 10 to assure NEPA compliance.

F. Executive Order 13132, Federalism

Executive Order 13132, Federalism, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, 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. *See* Executive Order 13132, 64 FR 43255, Aug. 10, 1999. Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action. The disaster assistance addressed by this proposed rule is provided to individuals and families, and would not have federalism implications.

G. Executive Orders 11988 and 11990, Floodplain Management and Protection of Wetlands

Under Executive Order 11988, Floodplain Management, as amended, Federal agencies are required to ''provide leadership to reduce the risk of flood loss, to minimize the impact of floods on human safety, health and welfare, and to restore and preserve the natural and beneficial values served by floodplains.'' *See* Executive Order 11988, as amended, 42 FR 26951, May 25, 1977, 44 FR 43239, July 20, 1979. Under Executive Order 11990, Protection of Wetlands, Federal agencies are required to ''provide leadership and * * * take action to minimize the destruction, loss or degradation of wetlands, and to preserve and enhance the natural and beneficial values of wetlands in carrying out the agency's responsibilities.'' *See* Executive Order 11990, as amended, 42 FR 26961, May 25, 1977, 52 FR 34617, Sept. 14, 1987. The requirements of these Executive Orders apply in the context of the provision of Federal financial assistance relating to, among other things, construction and property improvement activities, as well as conducting Federal programs affecting land use. The changes proposed in this rule would not have an effect on land use, floodplain management or wetlands. When FEMA undertakes specific actions that may

have such effects (*e.g.,* placement of manufactured temporary housing units on FEMA-constructed group sites; permanent or semi-permanent housing construction), FEMA follows the procedures set forth in 44 CFR part 9 to assure compliance with these Executive Orders.

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

FEMA has analyzed this proposed rule under Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks, 62 FR 19883, Apr. 23, 1997. This rule is not an economically significant rule and would not create an environmental risk to health or safety that might disproportionately affect children.

I. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* pertains to any proposed rulemaking which implements any rule that includes a Federal mandate 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. The Act also applies to any regulatory requirements that might significantly or uniquely affect small governments. FEMA has determined that this proposed rule would not result in the expenditure by State, local and Tribal governments, in the aggregate, nor by the private sector, of $100,000,000 or more in any one year as a result of a Federal mandate, nor would it significantly or uniquely affect small governments.

J. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, FEMA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by the Tribal government, or FEMA consults with those governments. *See* Executive Order 13175, 65 FR 67249, Nov. 9, 2000. This proposed rule would not significantly or uniquely affect the communities of Indian Tribal governments, nor would this proposed rulemaking impose substantial direct compliance costs on those communities.

K. Executive Order 12898, Environmental Justice

Under Executive Order 12898, Environmental Justice, each Federal agency must conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in, denying persons the benefit of, or subjecting persons to discrimination because of their race, color, or national origin. *See* Executive Order 12898, 59 FR 7629, Feb. 16, 1994. FEMA has incorporated environmental justice into its policies and programs.

The proposed housing repair, replacement and construction assistance regulations intentionally contain provisions that ensure they would not have a disproportionately high and adverse human health effect on any segment of the population. This rulemaking clarifies the eligibility requirements for assistance, and in doing so, maintains focus on the functionality of the component being repaired or replaced, and does not consider income or home value. Section 408 of the Stafford Act requires that such assistance be granted only for damage caused by a disaster event. Non-disaster related damage is not eligible for assistance under the Stafford Act. To ensure that this limitation will not be improperly exclusive, this proposed rule would clarify that components being repaired or residences being replaced need not be in full working order before the event to qualify for assistance. Components or residences that were fully or partially functional immediately before the declared event, despite their need for maintenance, may be eligible for repair assistance if they ceased to function as a result of the disaster.

One commenter stated that the proposed rule did not overtly discriminate against disaster survivors based on race, color, or national origin, but that it did discriminate covertly against those who are financially challenged, and, to the extent that the financially challenged consist disproportionately of minority groups, one might conclude that an element of the IHP program lacks environmental justice. The commenter stated that the housing repair cap of $5,000 has a gross negative impact on low-income disaster survivors, and results in more low-income disaster survivors returning to unsafe, unsanitary, and/or non-functional homes. The commenter stressed that low-income individuals were less likely to qualify for SBA loans, and Other Needs Assistance does not assist with structural repairs. Consequently, low-income individuals might have no choice but to move back into an unsuitable environment. The commenter recommended the liberal use of replacement assistance to provide additional help for the financially challenged.

As discussed elsewhere in this preamble, the $5,000 subcap is no longer in effect, and individuals and households may use up to the full amount of IHP funds ($31,400 for fiscal year 2012) for repair and replacement assistance. *See* 76 FR 63940 (Oct. 14, 2011). This figure is adjusted annually to reflect changes in the Consumer Price Index (CPI).

No action that FEMA can anticipate under this proposed rule would have a disproportionately high and adverse human health effect on any segment of the population. In addition, the rulemaking would not impose substantial direct compliance costs on those communities.

L. Executive Order 12988, 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. *See* Executive Order 12988, 61 FR 4729, Feb. 7, 1996.

M. Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights

FEMA has reviewed this rule under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, as supplemented by Executive Order 13406, Protecting the Property Rights of the American People. *See* Executive Order 12630, 53 FR 8859, Mar. 18, 1988 and Executive Order 13406, 71 FR 36973, June 28, 2006. This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630.

List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs—housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs—housing and community development, Natural

resources, Penalties, and Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Federal Emergency Management Agency proposes to amend 44 CFR part 206 as follows:

PART 206—FEDERAL DISASTER ASSISTANCE

1. The authority citation for part 206 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; Homeland Security Act of 2002, 6 U.S.C. 101; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; and E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

2. Amend § 206.117 to remove paragraph (c) and to revise paragraphs (a), (b)(2), (b)(3), and (b)(4) to read as follows:

§ 206.117 Housing assistance.

(a) *Definitions.* The definitions in this paragraph apply to this section only.

Caused by the disaster means as a direct result of a peril identified in the **Federal Register** Notice of a Presidentially-declared major disaster or emergency, the component is no longer functional.

Real Property Component or *Component* means each individual part of a dwelling that makes it habitable, as enumerated in paragraph (b)(2)(ii) of this section.

Semi-Permanent Housing means housing designed and constructed with finishes, material, and systems selected for moderate (or better) energy efficiency, maintenance, and life cycle cost, and with a life expectancy of more than 5 years but less than 25 years.

(b) * * *

(2) *Repairs.* (i) FEMA may provide financial assistance for the repair of real property components in an owner's primary residence if:

(A) The eligibility criteria in § 206.113 are met;

(B) The component was functional immediately before the declared event;

(C) The component was damaged, and the damage was caused by the disaster;

(D) The damage to the component is not covered by insurance; and

(E) Repair of the component is necessary to ensure the safety or health of the occupant or to make the residence functional.

(ii) FEMA may provide financial assistance for the repair of:

(A) Structural components of the residence. This includes real property components, such as the foundation, exterior walls, and roof.

(B) Windows and doors.

(C) The Heating, Ventilation and Air Conditioning system.

(D) Utility systems. This includes electrical, gas, water and sewage systems.

(E) Interior components. This includes, but is not limited to, the structure's floors, walls, ceilings, and cabinetry.

(F) The structure's access and egress, including privately owned access roads and privately owned bridges.

(G) Blocking, leveling, and anchoring of a mobile home, and reconnecting or resetting mobile home sewer, water, electrical and fuel lines and tanks.

(H) Items or services determined to be eligible hazard mitigation measures that reduce the likelihood of future damage to the residence, utilities, or infrastructure.

(iii) The components that may be deemed eligible for repair assistance, and the type of repairs authorized, will vary depending upon the nature of the disaster. Repairs are limited to restoration of the dwelling to a safe and sanitary living or functioning condition. Repair assistance will only be provided to the extent that the work makes the component functional. FEMA may provide for the replacement of components if repair is not feasible. The repairs of components must be of average quality, size, and capacity, taking into consideration the needs of the occupant.

(iv) Components that were functional immediately before the declared event may be eligible for repair assistance if the damage to the component was caused by the disaster and the component is no longer functional.

(v) Eligible individuals or households may receive up to the maximum amount of assistance (*See* § 206.110(b)) to repair damages to their primary residence irrespective of other financial resources, except insurance proceeds.

(vi) The individual or household is responsible for obtaining all local permits or inspections that applicable State or local building codes may require.

(vii) If the applicant disputes a determination made by FEMA regarding eligibility for repair assistance, the applicant may appeal that determination pursuant to the procedures in § 206.115. In addition to the requirements in § 206.115, the applicant must provide proof that the component meets the requirements of paragraph (b)(2)(i) of this section, including that the component was functional before the declared event and proof that the declared event caused the component to stop functioning. If the applicant disputes the amount of repair assistance awarded, the applicant must also provide justification for the amount sought.

(3) *Housing Replacement.* (i) FEMA may provide financial assistance for the replacement of an owner's primary residence if:

(A) The eligibility criteria in § 206.113 are met;

(B) The residence was functional immediately before the disaster;

(C) The residence was destroyed, and the damage was caused by, the disaster;

(D) The damage to the residence is not covered by insurance;

(E) Repair is not feasible, will not ensure the safety or health of the occupant, or will not make the residence functional; and

(F) Replacement is necessary to ensure the safety or health of the occupant.

(ii) All replacement assistance awards must be approved by the Regional Administrator or his/her designee. If replacement assistance is granted, the applicant may either use the maximum amount of assistance (*See* § 206.110(b)) to replace the dwelling in its entirety, or may use the assistance toward the cost of acquiring a new permanent residence.

(iii) Housing replacement assistance will be based on the verified disaster-related level of damage to the dwelling, or the statutory maximum (*See* § 206.110(b)), whichever is less.

(iv) If the applicant disputes a determination made by FEMA regarding eligibility for replacement assistance, the applicant may appeal that determination pursuant to the procedures in § 206.115. In addition to the requirements in § 206.115, the applicant must provide proof that repair is not feasible, or will not ensure the safety or health of the occupant or make the residence functional. If the applicant disputes the amount of replacement assistance awarded, the applicant must also provide justification for the amount sought.

(4) *Permanent and semi-permanent housing construction.* (i) FEMA may provide financial or direct assistance to applicants for the purpose of constructing permanent and semi-permanent housing if:

(A) The eligibility criteria in § 206.113 are met;

(B) The residence was functional immediately before the declared event;

(C) The residence was damaged by the event;

(D) The damage to the residence is not covered by insurance;

(E) The residence was an owner-occupied primary residence; and

(F) The residence is located in an insular area outside the continental United States or in another location where alternative housing resources are not available and the types of financial or direct temporary housing assistance described in paragraphs (b)(1), (2), and (3) of this section are unavailable, infeasible, or not cost-effective.

(ii) Permanent and semi-permanent housing construction, in general, must be consistent with current minimal local building codes and standards where they exist, or minimal acceptable construction industry standards in the area, including reasonable hazard mitigation measures, and Federal environmental laws and regulations. Dwellings will be of average quality, size and capacity, taking into consideration the needs of the occupant.

(iii) If the applicant disputes a determination made by FEMA regarding eligibility for construction assistance, the applicant may appeal that determination pursuant to the procedures in § 206.115. In addition to the requirements in § 206.115, the applicant must provide proof that the property is either located in an insular area outside the continental United States, or in a location where alternative housing resources are not available. The applicant must also provide proof that the types of financial or direct temporary housing assistance described in paragraph (b)(1) of this section are unavailable, infeasible, or not cost effective. If the applicant disputes the amount of construction assistance awarded, the applicant must also provide justification for the amount sought.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18568 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1141

[Docket No. EP 715]

Rate Regulation Reforms

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Surface Transportation Board (Board) proposes to change some of its existing regulations and procedures concerning rate complaint proceedings. The Board previously created two simplified procedures to reduce the time, complexity, and expense of rate cases. The Board now proposes to modify its rules to remove the limitation on relief for one simplified approach, and to double the relief available under the other simplified approach. The Board also proposes technical changes to the full and simplified rate procedures, and to raise the interest rate that railroads must pay on reparations if they are found to have charged unreasonable rates. The overarching goal is to ensure that the Board's simplified and expedited processes for resolving rate disputes are more accessible.

DATES: Comments addressing the proposals discussed herein are due by October 23, 2012. Replies are due by December 7, 2012. Rebuttal submissions are due by January 7, 2013.

ADDRESSES: Comments on this proposal 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 715, 395 E Street SW., Washington, DC 20423–0001.

Copies of written comments will be available for viewing and self-copying at the Board's Public Docket Room, Room 131, and will be posted to the Board's Web site.

FOR FURTHER INFORMATION CONTACT: The Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board proposes to modify some of its existing regulations and procedures regarding rate complaint proceedings. The Board's proposal is in four parts. Part I proposes refinements to the Simplified Stand-Alone Cost test by removing the limit on relief and increasing the precision of the calculation of Road Property Investment. Part II proposes to raise the limit on relief for a case brought under the Three-Benchmark test from $1 million to $2 million. Part III proposes to limit the use of cross-over traffic in a Full Stand-Alone Cost rate complaint proceeding and to modify the revenue allocation methodology. Part IV proposes to change the interest rate carriers must pay shippers when the rate charged has been found unlawfully high, from the current T-bill rate to the U.S. Prime Rate, as published in *The Wall Street Journal*.

Additional information is contained in the Board's decision served on July 25, 2012. To obtain a copy of this decision, visit the Board's Web site at *http://www.stb.dot.gov*. Copies of the decision may also be purchased by contacting the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238.

The Regulatory Flexibility Act of 1980, 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. 5 U.S.C. §§ 601–604. In its notice of proposed rulemaking, the agency must either include an initial regulatory flexibility analysis, 5 U.S.C. § 603(a), or certify that the proposed rule would not have a ''significant economic impact on a substantial number of small entities,'' 5 U.S.C. § 605(b). 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, 480 (7th Cir. 2009). An agency has no obligation to conduct a small entity impact analysis of effects on entities that it does not regulate. *United Dist. Cos.* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996).

This proposal would not have a significant economic impact upon a substantial number of small entities, within the meaning of the Regulatory Flexibility Act. The proposal imposes no additional record keeping by small railroads or any reporting of additional information. Nor do these proposed rules circumscribe or mandate any conduct by small railroads that is not already required by statute: the establishment of reasonable transportation rates. Small railroads have always been subject to rate reasonableness complaints and their associated litigation costs. Small railroads have been subject to the simplified rate procedures since 1996, when those procedures were first created. Finally, as the Board has previously concluded, the majority of railroads involved in these rate proceedings are not small entities within the meaning of the Regulatory Flexibility Act. *See Simplified Standards,* slip op. at 33–34. In the 32 years since the passage of the Staggers

Act—when Congress limited the Board's rate reasonableness jurisdiction where a carrier has market dominance over the transportation at issue—virtually all rate challenges have involved large Class I carriers. Therefore, the Board certifies under 5 U.S.C. 605(b) that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1141

Administrative practice and procedure.

Decided: July 25, 2012.

By the Board, Chairman Elliott, Vice Chairman Mulvey, and Commissioner Begeman.

Raina S. White,

Clearance Clerk.

For the reasons set forth in the preamble, the Surface Transportation Board proposes to amend part 1141 of title 49, chapter X, of the Code of Federal Regulations as follows:

1. Revise part 1141 to read as follows:

PART 1141—PROCEDURES TO CALCULATE INTEREST RATES

Authority: 49 U.S.C. 721.

§ 1141.1 Procedures to calculate interest rates.

(a) For purposes of complying with a Board decision in an investigation or complaint proceeding, interest rates to be computed shall be the most recent U.S. Prime Rate as Published by The Wall Street Journal. The rate levels will be determined as follows:

(1) For investigation proceedings, the interest rate shall be the U.S. Prime Rate as published by The Wall Street Journal in effect on the date the statement is filed accounting for all amounts received under the new rates.

(2) For complaint proceedings, the interest rate shall be the U.S. Prime Rate as published by The Wall Street Journal in effect on the day when the unlawful charge is paid. The interest rate in complaint proceedings shall be updated whenever The Wall Street Journal publishes a change to its reported U.S. Prime Rate. Updating will continue until the required reparation payments are made.

(b) For investigation proceedings, the reparations period shall begin on the date the investigation is started. For complaint proceedings, the reparations period shall begin on the date the unlawful charge is paid.

(c) For both investigation and complaint proceedings, the annual percentage rate shall be the same as the annual nominal (or stated) rate. Thus, the nominal rate must be factored exponentially to the power representing the portion of the year covered by the interest rate. A simple multiplication of the nominal rate by the portion of the year covered by the interest rate would not be appropriate because it would result in an effective rate in excess of the nominal rate. Under this ''exponential'' approach, the total cumulative reparations payment (including interest) is calculated by multiplying the interest factor for each period by the principal amount for that period plus any accumulated interest from previous periods. The ''interest factor'' for each period is 1.0 plus the interest rate for that period to the power representing the portion of the year covered by the interest rate.

[FR Doc. 2012–18514 Filed 7–27–12; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 120409402–2402–01]

RIN 0648–BB06

Second Fishing Capacity Reduction Program for the Longline Catcher Processor Subsector of the Bering Sea and Aleutian Islands Non-Pollock Groundfish Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement a second fishing capacity reduction program (also commonly known as ''buyback'') and an industry fee system to repay a $2.7 million loan for a single latent permit within the Longline Catcher Processor Subsector of the Bering Sea and Aleutian Islands (BSAI) non-pollock groundfish fishery (Reduction Fishery). The purpose of this action is to permanently reduce the greatest amount of fishing capacity at the least cost. This should result in increased harvesting productivity for the permit holders remaining in the fishery. The loan for this program will be added to the previous program loan of $35,700,000 authorized by the FY 2005 Appropriations Act (the Appropriations Act). For purposes of this regulation, the terms license and permit are used interchangeably.

DATES: Comments must be submitted in writing on or before August 29, 2012.

ADDRESSES: You may submit comments, identified by [NOAA–NMFS–2012–0050] by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov;* to submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter [NOAA–NMFS–2012–0050] in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''submit a comment'' icon on the right of that line.
- *Mail:* Submit written comments to Paul Marx, Chief, Financial Services Division, NMFS, Attn: BSAI Non-Pollock Groundfish Buyback Rulemaking, 1315 East-West Highway, Silver Spring, MD 20910.
- *Fax:* 301–713–1306; Submit comment Attn: Paul Marx.

Instructions: Comments must be submitted by one of the above methods to ensure that they are duly received and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, will not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel; WordPerfect, or Adobe PDF file formats only.

Copies of the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) prepared for this action may be obtained from the mailing address above or by calling Michael A. Sturtevant (see **FOR FURTHER INFORMATION CONTACT**).

Send comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule to Michael A. Sturtevant at the address

specified above and also to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 (Attention: NOAA Desk Officer) or email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–7825.

FOR FURTHER INFORMATION CONTACT: Michael A. Sturtevant at (301) 427–8799, fax (301) 713–1306, or *michael.a.sturtevant@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Statutory and Regulatory Background

In 1996, in response to the finding that many U.S. fisheries have excess fishing capacity, Congress provided for fishing capacity reduction programs. The intent of a program is to decrease the number of harvesters in the fishery, increase the economic efficiency of harvesting, and facilitate the conservation and management of fishery resources in each fishery in which NMFS conducts a reduction program. Typically, permit holders are paid to voluntarily surrender their fishing permits including relevant fishing histories for that fishery, or surrender all their fishing permits and cancel their fishing vessels' fishing endorsements by permanently withdrawing the vessels from all fisheries. The cost of the program is paid either by the remaining harvesters through a loan or taxpayers through a direct appropriation from Congress. Section 312(b)–(e) (16 U.S.C. 1861a(b)–(e)) was added to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to authorize such programs. Congress also amended Title XI of the Merchant Marine Act, 1936 (Title XI), adding new sections 1111 and 1112 to finance capacity reduction costs. The Title XI provisions involving fishing capacity reduction loans have been codified at 46 U.S.C. 53735.

To implement capacity reduction programs, NMFS promulgated regulations published as subpart L to 50 CFR part 600 (50 CFR 600.1000 *et seq.*), which contain a framework rule for buyback programs generally. For each individual program, NMFS promulgates regulations at subpart M to 50 CFR part 600 to implement the specific terms of that particular buyback. To undertake this second round of capacity reduction for the BSAI Longline Catcher Processor Subsector, NMFS must publish these regulations.

Initial Reduction Program

The measures contained in this proposed rule to establish the capacity reduction program are authorized the by Appropriations Act. The Appropriations Act authorizes the establishment of fishing capacity reduction programs for catcher processor subsectors within the Alaska groundfish fisheries (i.e., the longline catcher processor subsector, the American Fisheries Act (AFA) trawl catcher processor subsector, the non-AFA trawl catcher processor subsector, and the pot catcher processor subsector) based on capacity reduction plans and contracts developed by industry and approved by NMFS. Additionally, Public Law 108–199 provided the initial $500,000 subsidy cost to fund a $50 million loan, and Public Law 108–447 provided an additional $250,000 subsidy cost to fund $25 million more (in addition to providing for the buyback program itself). Under the Authorization Act, each subsector was allocated a specific amount of the total loan authority.

In 2007, NMFS approved and implemented a $35.7 million fishing capacity reduction loan program for the Longline Catcher Processor Subsector, which represented the full amount authorized for that subsector. The initial program removed three fishing vessels and 12 fishing licenses and permits for a loan amount of $35 million. All long-line catcher processors harvesting non-pollock groundfish were required to pay and forward a fee to NMFS to repay the loan. The original fee assessment was $0.02 per pound caught with payment and collection beginning on October 24, 2007, which has since been reduced to $0.015.

None of the other subsectors have expressed an interest in implementing a capacity reduction program for their subsector. A provision in the Appropriations Act permits the Secretary of Commerce to make available any of the unused loan amounts, originally allocated for each subsector, for capacity reduction programs in any of the subsectors after January 1, 2009.

Program Summary

Members of the BSAI Longline Catcher Processor Subsector informed NMFS that they wished to access the remaining loan amounts to undertake a second buyback. To implement this next buyback, the Freezer Longline Conservation Cooperative (FLCC) on behalf of the Reduction Fishery was required by the Appropriations Act to draft and submit to NMFS a Reduction Plan. On August 27, 2010, the FLCC submitted a Reduction Plan to access $2.7 million of the remaining funds. A Reduction Agreement, Reduction Contract, and application of the statutes and regulations referred to above are the basis for the Reduction Plan. The FLCC's Reduction Plan involves just one permit.

The Reduction Agreement and the Reduction Contract are the two key components of the Reduction Plan and this proposed rule. Substantive provisions of the Reduction Agreement and the Reduction Contract would be codified at 50 CFR 600.1108.

Reduction Program—Overview

All permit holders in the Longline Subsector who wished to relinquish their fishing permits were welcome to participate in the Reduction Program. The Program was divided into four phases: (1) Enrollment; (2) offer selection; (3) plan submission; and (4) implementation, after approval by referendum. The first three phases have been completed. Thus, this rule concerns itself only with the implementation phase of the program.

Reduction Program: The Capacity Reduction Agreement

Reduction Agreement Terms and Definitions

Capitalized terms used in the Reduction Agreement are defined in Schedule A to the Reduction Agreement; other terms are defined within the text of the Reduction Agreement. Reduction Agreement terms that are essential to understanding the regulatory provisions are set forth in the proposed § 600.1108(b).

Reduction Agreement: Major Sections

There are three major sections of the Reduction Agreement: Qualification and Enrollment of Subsector Members; Selection of Offers to Remove Fishing Capacity by the Reduction Plan; and Submission of the Reduction Plan, including the repayment requirements. Identical provisions previously codified in 50 CFR 600.1105 will be incorporated into this section by reference. The proposed rule will also include a fee collection system similar to the one codified at § 600.1106.

Qualification and Enrollment

The FLCC received four offers from the Subsector Members. Each of the four offerors executed a Reduction Agreement and submitted specified supporting documents evidencing an applicant's status as a Subsector Member. The FLCC Auditor reviewed all documents for strict compliance with the regulatory provisions in § 600.1105.

Selection of Offers To Remove Fishing Capacity by the Reduction Plan

The selection process was consistent with the buyback previously codified at § 600.1105(d) except that the funding source for the loan comes from the residual funds outlined above. In accordance with the previously developed procedures, the FLCC completed the selection process to rank the offers. Following completion of the selection process, the FLCC accepted only one latent permit to be bought out for $2,700,000.

Plan Submission

After the Selection Process was completed, the FLCC developed the Reduction Plan. The Reduction Plan was submitted to NMFS for its approval on behalf of the Secretary of Commerce. As required by the Appropriations Act, the FLCC has notified the North Pacific Fishery Management Council. Only one License Limitation Program (LLP) license and its fishing history are being submitted for removal from the Reduction Fishery. This latent LLP license is not associated with a vessel. Therefore, no vessel is being removed from the fishery under this Reduction Program. Fees to repay the loan will be collected as set forth in the proposed § 600.1108.

Approval of the Reduction Plan

The criteria for NMFS, on behalf of the Secretary, to approve any Reduction Plan are specified in § 600.1108(k). Among other things, the Assistant Administrator of NMFS must find that the Reduction Plan is consistent with the Appropriations and the Magnuson-Stevens Acts, and that it will result in the maximum sustained reduction in fishing capacity at the least cost and in the minimum amount of time.

The Reduction Plan includes the LLP license selected through the offer process as the asset to be purchased in the Reduction Program. The Reduction Plan also includes the FLCC's supporting documents and rationale for establishing that the current offer represents the expenditure of the least money for the greatest capacity reduction. Acceptance of the offer is at the sole discretion of NMFS.

The FLCC may be required to revise and resubmit the Reduction Plan to conform to the provisions of the final rule after the final rule (resulting from this proposed rule) is published.

The Referendum

NMFS will conduct a referendum to determine the industry's willingness to repay a fishing capacity reduction loan to purchase the license and fishing rights identified in the Reduction Plan. A successful referendum by a majority of all members of the Reduction Fishery would bind all parties and complete the reduction process.

The current Fishing Capacity Reduction Framework regulatory provisions at § 600.1010 stipulate the procedural and other requirements by which NMFS shall conduct referenda on fishing capacity reduction programs. The proposed § 600.1108(l) makes those framework referendum requirements applicable to this Reduction Program. Only after approval of the Reduction Program via a referendum will the Reduction Program be implemented.

Loan Repayment

Upon completion of a successful referendum to approve a fishing capacity reduction loan, the repayment plan, amortized over a 30-year term, will be implemented. Once the Reduction Program is implemented, repayment of the loan by monthly collection of fees from the remaining Subsector Members operating in the Reduction Fishery will be initiated.

In accordance with § 600.1013, the fees for each individual program should not exceed 5 percent of the average ex-vessel production value of the Reduction Fishery. Thus, the total possible fee from two programs (this proposed rule and the rule codified under § 600.1105) will not exceed 10 percent of the average ex-vessel pacific cod revenues for one year. In the event that the total principal and interest due for this program exceeds this level, an additional fee for the season will be assessed. This temporary fee assessment will be $0.01 per pound round weight for pollock, arrowtooth flounder, Greenland turbot, skate, yellowfin sole and rock sole.

The fee will be calculated on an annual basis as: the principal and interest payment amount necessary to amortize the loan over a 30-year term, divided by the Reduction Fishery portion of the BSAI Pacific cod initial total allowable catch (ITAC) allocation in metric tons (converted to pounds). NMFS estimates that the actual fees for this program will be $0.001 per pound, based upon the estimated fishery revenue from 2010 amortized over a 30-year loan. This program, coupled with the previously codified program in § 600.1105, will bring total fish catch fees to approximately $0.016 per pound.

For more specific information on submission of the Reduction Plan, including fees to repay the Reduction Loan, see § 600.1108(e) of this proposed rule. For specific information on the fee payment and collection system, see provision (m) of this proposed rule.

The Reduction Program: Other Matters Relating to the Reduction Agreement and Reduction Plan Review/Disputes

The Reduction Agreement provided for an expedited process to review any decision by the Auditor and for settlement of disputes utilizing an expedited review process by pre-selected legal counsel and, if necessary, binding arbitration. However, this provision was not activated as no disputes occurred during the selection process of this proposed buyback.

Other Provisions of the Reduction Agreement

Proposed regulatory provisions mirroring the Reduction Agreement's provisions for Specific Performance, Miscellaneous, Amendment, and Warranties are specified at § 600.1108(g), (h), (i), and (j), respectively.

The Fee Payment and Collection System

The payment and collection system will remain the same for the loan the subsector previously approved in 2007. Under this proposed rule, provision § 600.1108(m) outlines the requirements for repayment of this loan. This provision mirrors the fee system codified in § 600.1106 for the 2007 loan, except in total amount. The amount of the loan in this proposed rule is $2,700,000.

The Contract

An appendix to the proposed § 600.1108 sets forth the Contract component of the Reduction Program for the Longline Subsector. The appendix, or Contract, was previously codified as an appendix to the regulatory text of § 600.1105. This proposed rule will reference the appendix without reprinting it.

In addition to public comment about the proposed rule's substance, NMFS also seeks public comment on any ambiguity or unnecessary complexity arising from the language used in this proposed rule.

Classification

The Assistant Administrator for Fisheries, NMFS, determined that this proposed rule is consistent with the Appropriations and the Magnuson-Stevens Acts, and other applicable law, subject to further consideration after public comment.

In compliance with the National Environmental Policy Act, NMFS prepared an environmental assessment for this proposed rule. The assessment

discusses the impact of this proposed rule on the natural and human environment and integrates a Regulatory Impact Review (RIR) and an Initial Regulatory Flexibility Analysis (IRFA). NMFS will send the assessment, the review, and the analysis to anyone who requests a copy (see **ADDRESSES**).

NMFS prepared an IRFA, as required by section 603 of the Regulatory Flexibility Act (RFA), to describe the economic impacts that this proposed rule, if adopted, would have on small entities. NMFS intends the analysis to aid us in considering regulatory alternatives that could minimize the economic impact on affected small entities. The proposed rule does not duplicate or conflict with other Federal regulations.

Summary of IRFA

The Small Business Administration (SBA) has defined small entities as all fish harvesting businesses that are independently owned and operated, are not dominant in their field of operation, and have annual receipts of $4 million or less. In addition, processors with 500 or fewer employees for related industries involved in canned or cured fish and seafood, or preparing fresh fish and seafood, are also considered small entities. Small entities within the scope of this proposed rule include individual U.S. vessel owners and fish dealers. There are no disproportionate impacts between large and small entities.

Description of the Number of Small Entities

The IRFA uses the most recent year of data available to conduct the analysis (2009–2010). The vessel owners that might be considered large entities were either affiliated with owners of multiple vessels or were catcher processors. In the Reduction Fishery, 17 of the 36 vessel owners meet the threshold for small entities based on gross revenue. However, these vessels are not considered small entities for purposes of the RFA because of their affiliations with the larger fishing entities through the FLCC. All vessels in the Longline Subsector would benefit from a permit buyback because there will be less potential competition for the harvest. Because the proposed action would not result in changes to allocation percentages and participation is voluntary, net effects are expected to be minimal relative to the status quo.

Implementation of the buyback program will not change the overall reporting structure and recordkeeping requirements of the vessels in the BSAI Pacific cod fisheries. However, this program will impose collection of information requirements totaling 16 hours 10 minutes.

The proposed rule's impact would be positive for both the selected Offeror and for the post-reduction catcher processors whose landing fees repay the reduction loan because the Offeror and a majority of the remaining catcher processors will have voluntarily assumed the impact:

1. The Offeror voluntarily made an offer of $2,700,000. Presumably, no Offeror would volunteer to make an offer with an amount that is inconsistent with the Offeror's interest; and

2. Reduction loan repayment landing fees would be instituted, and NMFS will complete the Reduction Program, only if a majority of all Subsector Members vote in favor of the Reduction Plan in a referendum. Presumably, Subsector Members will not vote in favor of the Reduction Plan unless they conclude that the Reduction Program's prospective capacity reduction will be sufficient to enable them to increase their revenues enough to justify the fee.

Those participants who remain in the fishery after the buyback will incur additional fees of up to 5 percent of the ex-vessel production value of post-reduction landings. However, the additional costs would likely be mitigated by increased harvest opportunities for those remaining in the fishery.

NMFS believes that this proposed rule would not affect authorized BSAI Pacific cod ITAC or other non-pollock groundfish harvest levels nor harvesting practices.

NMFS rejected the no action alternative considered in the EA because NMFS would not be in compliance with the mandate of section 219 of the Appropriations Act to establish a buyback program. In addition, the Longline Catcher Processor Subsector of the non-pollock groundfish fishery would remain overcapitalized. Although too many vessels compete to catch the current subsector's total allowable catch (TAC) allocation, fishermen remain in the fishery because they have no other means to recover their significant capital investment. Overcapitalization reduces the potential net value that could be derived from the non-pollock groundfish resource by dissipating rents, driving variable operating costs up, and imposing economic externalities. At the same time, excess capacity and effort diminish the effectiveness of current management measures (e.g. landing limits and seasons, bycatch reduction measures). Overcapitalization has diminished the economic viability of members of the fleet and increased the economic and social burden on fishery-dependent communities.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

This proposed rule contains information collection requirements subject to the Paperwork Reduction Act (PRA). The Office of Management and Budget (OMB) previously approved this information collection under OMB Control Number 0648–0376 with requirements for 878 respondents with a total response time of 38,653 hours.

NMFS estimates that Sector Members would require an average of four hours to vote in a referendum. Persons affected by this proposed rule would also be subject to other collection-of-information requirements referred to in the proposed rule and also approved under OMB Control Number 0648–0376. These requirements and their associated response times are: completing and filing a fish ticket (10 minutes), submitting monthly fish buyer reports (2 hours), submitting annual fish buyer reports (4 hours), and tendering fish buyer/fish seller reports when a person fails either to pay or to collect the loan repayment fee (2 hours).

These response estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; 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, including through the use of automated collection techniques or other forms of information technology. Interested persons may send comments regarding this burden estimate or any other aspect of this data collection requirement, including suggestions for reducing the burden, to both NMFS and OMB (see **ADDRESSES**).

This action would not result in any adverse effects on endangered species or marine mammals.

List of Subjects in 50 CFR Part 600

Fisheries, Fishing capacity reduction, Fishing permits, Fishing vessels, Intergovernmental relations, Loan programs—business, reporting and recordkeeping requirements.

Dated: July 24, 2012.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 600 to read as follows:

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

Subpart M—Specific Fishery or Program Fishing Capacity Reduction Regulations

1. The authority citation for 50 CFR part 600, subpart M, is revised to read as follows:

Authority: 5 U.S.C. 561, 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 1861a(b) through (e), 46 App. U.S.C. 53735, section 144(d) of Division B of Pub. L. 106–554, section 2201 of Pub. L. 107–20, and section 205 of Pub. L. 107–117, Pub. L. 107–206, Pub. L. 108–7, Pub. L. 108–199, and Pub. L. 108–447.

2. Section 600.1108 is added to subpart M to read as follows:

§ 600.1108 Longline catcher processor subsector of the Bering Sea and Aleutian Islands (BSAI) non-pollock groundfish fishery program.

(a) *Purpose.* This section implements the capacity reduction program that Title II, section 219(e) of Public Law 108–447 established for the longline catcher processor subsector of the Bering Sea and Aleutian Islands (BSAI) non-pollock groundfish fishery.

(b) *Definitions.* Unless otherwise defined in this section, the terms defined in § 600.1000 of subpart L and § 600.1105 of subpart M expressly apply to this section. The following terms have the following meanings for the purpose of this section:

Reduction fishery means the Hook & Line, Catcher Processor (Longline Subsector); sometimes referred to as the AH&LCP Subsector) portion of the BSAI Pacific cod ITAC (in metric tons) set by the North Pacific Fishery Management Council (NPFMC) in December of each year multiplied by 2,205 (i.e., the rounded number of pounds in a metric ton)or the Longline Subsector of the BSAI non-pollock groundfish fishery that § 679.2 of this chapter defined as groundfish area/species endorsement.

(c) *Capacity Reduction Program.* As a result of the completion of the Selection Process, written notification from the FLCC to NMFS identifying the selected offeror, and submission of the reduction plan, the capacity reduction program is implemented as follows:

(1) *Loan repayment*—(i) *Term.* As authorized by section 219(B)(2) of the Appropriations Act, the capacity reduction loan (the Reduction Loan) shall be amortized over a thirty (30) year term. The Reduction Loan's original principal amount may not exceed the amount approved by the subsector. The subsector has currently approved a loan of two million seven hundred thousand dollars ($2,700,000). Subsector Members acknowledge that in the event payments made under the Reduction Plan are insufficient to repay the actual loan, the term of repayment shall be extended by NMFS until the loan is paid in full. Repayment calculations and records will be kept separately for each program.

(ii) *Interest.* The Reduction Loan's interest rate will be the U.S. Treasury's cost of borrowing equivalent maturity funds plus 2 percent. NMFS will determine the Reduction Loan's initial interest rate when NMFS borrows from the U.S. Treasury the funds with which to disburse reduction payments. The initial interest rate will change to a final interest rate at the end of the Federal fiscal year in which NMFS borrows the funds from the U.S. Treasury. The final interest rate will be 2 percent plus a weighted average, throughout that fiscal year, of the U.S. Treasury's cost of borrowing equivalent maturity funds. The final interest rate will be fixed, and will not vary over the remainder of the reduction loan's 30-year term. The Reduction loan will be subject to a level debt amortization. There is no prepayment penalty.

(iii) *Fees.* The Reduction Loan shall be repaid by fees collected from the Longline Subsector. The fee amount will be based upon: The principal and interest due over the next twelve months divided by the product of the Longline Subsector. In the event that the Longline Subsector portion for the ensuing year is not available, the Longline Subsector portion forecast from the preceding year will be used to calculate the fee.

(A) The fee will be expressed in cents per pound rounded up to the next one-tenth of a cent. For example: If the principal and interest due equal $2,900,000 and the Longline Subsector portion equals 100,000 metric tons, then the fee per round weight pound of Pacific cod will equal 1.4 cents per pound. [2,900,000/(100,000 × 2,205) = .01315]. The fee will be assessed and collected on Pacific cod to the extent possible and if not, will be assessed and collected as provided for in paragraph (c)(3)(iii)(B) of this section.

(B) Fees must be assessed and collected on Pacific cod used for bait or discarded. Although the fee could be up to 5 percent of the ex-vessel production value of all post-reduction Longline Subsector landings, the fee will be less than 5 percent if NMFS projects that a lesser rate can amortize the fishery's reduction loan over the reduction loan's 30-year term. In the event that the total principal and interest due exceeds 5 percent of the ex-vessel Pacific cod revenues, a standardized additional fee will be assessed. The additional fee shall be one cent per pound round weight, which is calculated based on the latest available revenue records and NMFS conversion factors for pollock, arrowtooth flounder, Greenland turbot, skate, yellowfin sole and rock sole.

(C) To verify that the fees collected do not exceed 5 percent of the fishery revenues, the annual total of principal and interest due will be compared to the latest available annual Longline Subsector revenues. In the event that any of the components necessary to calculate the next year's fee are not available, or for any other reason NMFS believes the calculation must be postponed, the fee will remain at the previous year's amount until such a time that new calculations are made and communicated to the post-reduction fishery participants.

(D) It is possible that the fishery may not open during some years and no Longline Subsector portion of the ITAC is granted. Consequently, the fishery will not produce fee revenue with which to service the reduction loan during those years. However, interest will continue to accrue on the principal balance. When this happens, if the fee rate is not already at the maximum 5 percent, NMFS will increase the fishery's fee rate to the maximum 5 percent of the revenues for Pacific cod and the species mentioned in paragraph (d)(2)(iii)(B) of this section, apply all subsequent fee revenue first to the payment of accrued interest, and continue the maximum fee rates until all principal and interest payments become current. Once all principal and interest payments are current, NMFS will make a determination about adjusting the fee rate.

(iv) *Reduction loan.* NMFS has promulgated framework regulations generally applicable to all fishing capacity reduction programs in subpart L of this part. The reduction loan shall be subject to the provisions of § 600.1012, except that: the subsector members' obligation to repay the reduction loan shall be discharged by the owner of the Longline Subsector license regardless of which vessel catches fish under this license and regardless of who processes the fish in

the reduction fishery in accordance with § 600.1013. Longline Subsector license owners in the reduction fishery shall be obligated to collect the fee in accordance with § 600.1013.

(v) *Collection.* The LLP License holders of vessels harvesting in the post-capacity reduction plan Longline Subsector shall be responsible for self-collecting the repayment fees owed by the LLP License holder. Fees shall be submitted to NMFS monthly and shall be due no later than fifteen (15) calendar days following the end of each calendar month.

(vi) *Recordkeeping and reporting.* The holder of the LLP Licenses on which vessels harvesting in the post-capacity reduction plan Longline Subsector is designated shall be responsible for compliance with the applicable recordkeeping and reporting requirements.

(2) *Agreement with Secretary.* The Selected Offeror shall complete and deliver to the FLCC for inclusion in the Reduction Plan submitted to NMFS, designee for the Secretary, a completed and fully executed Reduction Contract. The LLP License set forth on the Selected Offer shall be included as Reduction Fishing Interests in such Reduction Contract.

(d) *Decisions of the Auditor and the FLCC.* Time was of the essence in developing and implementing a Reduction Plan and, accordingly, the Offeror is limited to, and bound by, the decisions of the Auditor and the FLCC.

(1) The Auditor's examination of submitted applications, Offers, Prequalification Offers and Rankings was solely ministerial in nature. That is, the Auditor verified whether the documents submitted by Subsector Members were, on their face, consistent with each other and the Database, in compliance with the requirements set forth in the Reduction Agreement, and signed by an Authorized Party. The Auditor presumed the validity of all signatures on documents submitted. The Auditor made no substantive decisions as to compliance (e.g., whether an interim LLP License satisfies the requirements of the Act, or whether a discrepancy in the name appearing on LLP Licenses and other documents was material).

(2) [Reserved]

(e) *Specific Performance.* The parties to the Reduction Agreement have agreed that the opportunity to develop and submit a capacity reduction program for the Longline Subsector under the terms of the Appropriations Act is both unique and finite and that failure of the Selected Offeror to perform the obligations provided by the Reduction Agreement will result in irreparable damage to the FLCC and the Subsector Members. Accordingly, the parties to the Reduction Agreement expressly acknowledge that money damages are an inadequate means of redress and agree that upon the failure of the Selected Offeror to fulfill their obligations under the Reduction Agreement that specific performance of those obligations may be obtained by suit in equity brought by the FLCC in any court of competent jurisdiction without obligation to arbitrate such action.

(f) *Miscellaneous*—(1) *Termination.* The Reduction Agreement may be terminated at any time prior to approval of the Reduction Plan by NMFS, on behalf of the Secretary, by written notice from 50 percent of Subsector Members.

(2) *Choice of law/venue.* The Reduction Agreement shall be construed and enforced in accordance with the laws of the State of Washington without regard to its choice of law provisions. The parties submit to the exclusive personal jurisdiction of the United States District Court located in Seattle, Washington, with respect to any litigation arising out of or relating to the Reduction Agreement or out of the performance of services hereunder.

(3) *Incorporation.* All executed counterparts of the Reduction Agreement, Application Forms and Offers constitute the agreement between the parties with respect to the subject matter of the Reduction Agreement and are incorporated into the Reduction Agreement as if fully written.

(4) *Counterparts.* The Reduction Agreement may be executed in multiple counterparts and will be effective as to signatories on the Effective Date. The Reduction Agreement may be executed in duplicate originals, each of which shall be deemed to be an original instrument. All such counterparts and duplicate originals together shall constitute the same agreement, whether or not all parties execute each counterpart.

(i) The facsimile signature of any party to the Reduction Agreement shall constitute the duly authorized, irrevocable execution and delivery of the Reduction Agreement as fully as if the Reduction Agreement contained the original ink signatures of the party or parties supplying a facsimile signature.

(ii) [Reserved]

(g) *Amendment.* All Subsector Members acknowledge that the Reduction Agreement, the Reduction Contract, and the Reduction Plan may be subject to amendment to conform to the requirements for approval of the Reduction Plan by NMFS on behalf of the Secretary. The Auditor shall distribute to each Subsector Member in electronic format the amended form of the Reduction Agreement, the Reduction Contract, and the Reduction Plan, which amended documents in the form distributed by the Auditor and identified by the Auditor by date and version, the version of each such document then in effect at the time of any dispute arising or action taken shall be deemed binding upon the parties with respect to such dispute and/or action.

(h) *Warranties.* The Offeror must expressly warrant and represent in the Reduction Agreement that:

(1) The Offeror has had an opportunity to consult with an attorney or other advisors with respect to the Reduction Agreement, the Reduction Contract, and the Act and the ramifications of the ratification of the Reduction Plan contemplated therein;

(2) The Offeror has full understanding and appreciation of the ramifications of executing and delivering the Reduction Agreement and, free from coercion of any kind by the FLCC or any of its members, officers, agents and/or employees, executes and delivers the Reduction Agreement as the free and voluntary act of the Offeror;

(3) The execution and delivery of the Reduction Agreement, does not and will not conflict with any provisions of the governing documents of the Offeror;

(4) The person executing the Reduction Agreement has been duly authorized by the Offeror to execute and deliver the Reduction Agreement and to undertake and perform the actions contemplated herein; and

(5) The Offeror has taken all actions necessary for the Reduction Agreement to constitute a valid and binding obligation, enforceable in accordance with its terms.

(i) *Approval of the Reduction Plan.* Acceptance of the Offer is at the sole discretion of NMFS on behalf of the Secretary of Commerce. To be approved by NMFS, on behalf of the Secretary, any Reduction Plan developed and submitted in accordance with this section and Subpart M to this part must be found by the Assistant Administrator of NMFS, to:

(1) Be consistent with the requirements of section 219(e) of the FY 2005 Appropriations Act (Pub. L. 108–447);

(2) Be consistent with the requirements of section 312(b) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1861(a)) except for the requirement that a Council or Governor of a State request such a program (as set

out in section 312(b)(1)) and for the requirements of section 312(b)(4);

(3) Contain provisions for a fee system that provides for full and timely repayment of the capacity reduction loan by the Longline Subsector and that it provide for the assessment of such fees;

(4) Not require a bidding or auction process;

(5) Result in the maximum sustained reduction in fishing capacity at the least cost and in the minimum amount of time; and

(6) Permit vessels in the Longline Subsector to be upgraded to achieve efficiencies in fishing operations provided that such upgrades do not result in the vessel exceeding the applicable length, tonnage, or horsepower limitations set out in Federal law or regulation.

(j) *Referendum.* The following provisions apply to the Reduction Plan of this section to the extent that they do not conflict with subpart L including §§ 600.1009, 600.1010, 600.1013, and 600.1014 or 16 U.S.C. 1861a; except where the referendum is successful if a majority of all permit holders within the fishery vote in favor of the Reduction Program is accordance with 18 U.S.C. 1861a(d)(1)(B).

(k) *Fee payment and collection system.* Upon successful completion of the Referendum discussed above as authorized by Public Law 108–447 and in accordance with 16 U.S.C. 1861a and § 600.1012 this fee collection system establishes:

(1) The subsector members' obligation to repay the reduction loan, and

(2) The loan's principal amount, interest rate, and repayment term; and

(3) In accordance with §§ 600.1013 through 600.1016, implements an industry fee system for the reduction fishery.

(l) *Reduction loan amount.* The reduction loan's original principal amount is $2,700,000.

(m) *Interest accrual from inception.* Interest begins accruing on the reduction loan from the date which NMFS disburses such loan.

(n) *Interest rate.* The reduction loan's interest rate shall be the applicable rate which the U.S. Treasury determines at the end of fiscal year in which loan is disbursed plus 2 percent.

(o) *Repayment terms.* For the purpose of determining fee rates, the reduction loan's repayment term is 30 years from the date NMFS disburses the loan. However, fee collections shall continue indefinitely until the loan is fully repaid.

(p) *Reduction loan repayment.* The subsector members shall repay the reduction loan in accordance with § 600.1012. Both fish buyers and fish sellers are considered subsector members for purposes of fee collection, deposit, disbursement, and accounting in accordance with § 600.1013.

(1) Subsector members in the reduction fishery shall collect and pay the fee amount in accordance with § 600.1105;

(2) Subsector members in the reduction fishery shall deposit and disburse, as well as keep records for and submit reports about, the applicable fees in accordance with § 600.1014, except the requirements under paragraphs (c) and (e) of this section. All collected fee revenue a fish buyer collects to repay the loan identified in paragraph (c) of this section shall be made to NMFS no later than fifteen (15) calendar days following the end of each calendar month. The annual reports identified in paragraph (e) of this section shall be submitted to NMFS by February 1 of each calendar year.

(3) The reduction loan is, in all other respects, subject to the provisions of §§ 600.1012 through 600.1017.

(q) *Enforcement for failure to pay fees.* The provisions and requirements of § 600.1016 (Enforcement) shall also apply to fish sellers and fish buyers subject to this fishery.

[FR Doc. 2012–18398 Filed 7–27–12; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 77, No. 146
Monday, July 30, 2012

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

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Idaho Panhandle Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 112–141) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 110–343) the Idaho Panhandle Resource Advisory Committee will meet Friday, August 24, 2012, at 9:00 a.m. in Coeur d'Alene, Idaho for a business meeting. The business meeting is open to the public.

DATES: August 24, 2012.

ADDRESSES: The meeting location is the Idaho Panhandle National Forests' Supervisor's Office, located at 3815 Schreiber Way, Coeur d'Alene, Idaho 83815.

FOR FURTHER INFORMATION CONTACT: Mary Farnsworth, Forest Supervisor and Designated Federal Official, at (208) 765–7369.

SUPPLEMENTARY INFORMATION: The meeting agenda will focus on reviewing proposals for forest projects and recommending funding during the monitoring meeting. The public forum begins at 9:00 a.m.

Dated: July 24, 2012.

Christine Dawe,

Deputy Forest Supervisor.

[FR Doc. 2012–18458 Filed 7–27–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Siskiyou County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Sisikiyou County Resource Advisory Commitee will meet in Yreka, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is for the committee to hear project status, review project proposals and to vote and make recommendations. The meeting is open to the public. Opportunity for public comment will be provided.

DATES: The meeting will be held Monday, August 20, 2012 4:00 p.m.

ADDRESSES: The meeting will be held at The Klamath National Forest Supervisor's Office, main conference room, at 1711 South Main Street in Yreka, CA.

Written comments may be submitted as described under Supplementary Information. 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 the Klamath National Forest Supervisor's Office. Please call ahead to (530) 841–4484 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Kerry Greene, Community Development and Outreach Specialist, phone: (530) 841–4484 or email: *kggreene@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday. Please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accomodation for access to the facility or procedings by contacting the person listed For Further Information.

SUPPLEMENTARY INFORMATION: The following business will be conducted: project updates and financial status, and review of project proposals currently under consideration by the RAC. New project proposals are now being accepted. A meeting agenda and copies of submitted proposals can be accessesd at: *https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf/RAC/Siskiyou+County-CA.*

Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in advance to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to Klamath National Forest 1711 S. Main Street Yreka, CA 96097, or by email to *kggreene@fs.fed.us,* or via facsimile to (530) 841–4571.

A summary of the meeting will be posted at: *https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf/RAC/Siskiyou+County-CA* within 21 days of the meeting.

Dated: *July 24, 2012.*

Dan Blessing.

Acting Forest Supervisor.

[FR Doc. 2012–18472 Filed 7–27–12; 8:45 am]

BILLING CODE 3410–11–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Tennessee Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Tennessee Advisory Committee (Committee) to the Commission will hold two meetings on Thursday, August 16, 2012, at the Nashville Public Library, 615 Church Street Nashville, Tennessee 37219. The first meeting is scheduled to begin at 2:00 p.m. and adjourn at approximately 2:45 p.m.; the purpose of the meeting is for Committee members to receive a briefing on voting rights in Tennessee for ex-felons. The second meeting is scheduled to begin at approximately 2:45 p.m. and adjourn at approximately 3:30 p.m.; the purpose of the meeting is for the Committee to plan its project on voting rights for ex-felons.

Members of the public are entitled to submit written comments. The comments must be received in the Southern Regional Office of the Commission by September 15, 2012. The address is Southern Regional Office, U.S. Commission on Civil Rights, 61 Forsyth Street Suite 16T126, Atlanta, GA 30303. Persons wishing to email their comments or who desire additional information should contact Peter Minarik, Regional Director, Southern Regional Office, at (404) 562–7000, (or for hearing impaired TDD 800–877–8339), or by email *erodriguez@usccr.gov.* Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Southern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Southern Regional Office at the above email or street address. The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, July 24, 2012.

Peter Minarik,

Acting Chief,Regional Programs Coordination Unit.

[FR Doc. 2012–18392 Filed 7–27–12; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: October School Enrollment Supplement to the Current Population Survey.

OMB Control Number: 0607–0464.

Form Number(s): None.

Type of Request: Extension of a currently approved collection.

Burden Hours: 2,950.

Number of Respondents: 59,000.

Average Hours per Response: 3 minutes.

Needs and Uses: The purpose of this request for review is to obtain continued clearance for the supplemental inquiry concerning school enrollment to be conducted in conjunction with the October Current Population Survey (CPS). The School Enrollment Supplement is jointly sponsored by the U.S. Census Bureau, the Bureau of Labor Statistics (BLS), and the National Center for Education Statistics (NCES). A number of questions in this supplement may appear in the American Community Survey (ACS) and in other demographic surveys. However, this supplement's comprehensive set of questions does not duplicate any other single information collection, and ensures the historical continuity of a data series that spans over 5 decades.

This data series provides basic information on enrollment status of various segments of the population necessary as background for policy formulation and implementation. The CPS October supplement is the only annual source of data on public/private elementary and secondary school enrollment and characteristics of private school students and their families, which are used for tracking historical trends and for policy planning and support. The basic school enrollment questions have been collected annually in the CPS for 50 years. Consequently, this supplement is the only source of historical data—at the national level—on the age distribution and family characteristics of college students, and on the demographic characteristics of preprimary school enrollment. As part of the federal government's efforts to collect data and provide timely information to local governments for policymaking decisions, this supplement provides national trends in enrollment and progress in school. Discontinuance of these data would mean not complying with the federal government's obligation to provide data to decision makers on current educational issues and would disrupt a data series that has been in existence for 50 years.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 182, and Title 29 U.S.C., Sections 1–9.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or email (*bharrisk@omb.eop.gov*).

Dated: July 25, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–18451 Filed 7–27–12; 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: U.S. Census Bureau.

Title: Generic Clearance for 2020 Census Field Tests to Research the Use of Automation in Field Data Collection Activities.

OMB Control Number: None.

Form Number(s): Unknown at this time.

Type of Request: New collection.

Burden Hours: 2,167.

Number of Respondents: 13,000.

Average Hours per Response: 10 minutes.

Needs and Uses: The U.S. Census Bureau is committed to conducting a 2020 Census that costs less while maintaining high quality results. Field data collection activities are a significant cost driver in the decennial census. Field data collection activities include creating and updating address lists, updating maps, enumerating households and persons, collecting data on vacant housing units, and conducting quality control operations. In previous censuses, these activities required the use of a large temporary field staff with limited training using manual or paper forms and systems.

Advances in technology may create new opportunities to perform field data collection tasks in an automated environment. The Census Bureau plans to research and learn the use of new technologies to test their capabilities in performing data collection activities. As part of the learning process, the Census Bureau plans to conduct operations using new technologies. This research

and learning are integral to the Strategic Plan for the 2020 Census.

Designing and testing innovations are part of the planning of every recent decennial census. To carry out these tests, the Census Bureau plans to conduct field activities by programming and using mobile computing devices, such as smart phones and tablets, and using multiple software operating systems. The tests will inform census planners and stakeholders on their ability to program applications on different devices. In addition, the tests will measure the accuracy, productivity, and user experience with different combinations of mobile device and applications. Tests may also provide data on the feasibility to program applications on privately owned devices. In previous censuses, the Census Bureau has purchased equipment that it issues to the temporary field staff. After the census, this equipment was disposed as excess property.

The Census Bureau plans to conduct these tests in small geographic areas involving a small number of housing units and persons over the next three years. The specific areas have not yet been determined. We will follow the protocol of past generic clearances: 14 to 30 days before the scheduled start date of each field test, we will provide OMB with a detailed background on the activity, estimates of respondent burden, and samples of pertinent forms and/or questions. We will provide OMB annually a report documenting the activities performed under this clearance at the end of each year.

The following sections describe the categories of activities to be included under the clearance. The Census Bureau has conducted these activities (or similar ones) previously and the individual respondent burden remains relatively unchanged from one time to another.

Address Listing and Mapping Tasks

The Census Bureau maintains a Master Address File (MAF) of housing units and other living quarters. Census links each MAF location to the Census Bureau mapping system called the Topologically Integrated Geographic Encoding and Referencing (TIGER) database. The MAF needs updating to account for new housing units and other living quarters. The TIGER database needs updating to account for feature changes such as new streets and street names.

The Census Bureau will update map features and address lists on mobile computing devices. During the test, it may be necessary to ask residents or other knowledgeable persons in a test area for street name and address numbers. The Census Bureau will record responses into extracts of the mapping and MAF databases that have been loaded onto the mobile computing device. The primary purpose of this activity during the test is to evaluate the performance of these tasks on a mobile computing device in a field environment. The data collected may be stored on the mobile computing device and/or other data storage system. Address data are protected information under U.S. Code Title 13, and the test will comply with the Census Bureau privacy and security requirements for collecting, transmitting, storing, and using information obtained during the test.

Enumeration Functions

During personal interviews, the decennial census asks a series of questions of a household respondent and records the answers. The enumeration functions research will focus on using various applications and mobile computing devices to enumerate households and persons. The research and evaluation may include: Developing an automated enumeration questionnaire; usability issues; conducting interviews; scheduling return visits; recording contact outcomes; recording the status of a housing unit (such as occupied or vacant); adding addresses; making work assignments; measuring production; having the ability to toggle to a Spanish instrument; enumerator routing; and transmitting data. To test enumeration functions, the Census Bureau may conduct the enumeration directly with a household member or knowledgeable respondent. The Census Bureau will provide the actual questions asked to Office of Management and Budget following established protocol.

During these tests, the Census Bureau could develop other applications on the mobile computing devices to collect information. These applications could include: allowing respondents to enter their information directly into the device; perform voice recognition commands and recordings; and to input data during a phone call.

Quality Control Functions

The quality control (QC) functions research is intended to test quality control functions and applications on different mobile computing devices for both listing and enumeration. The purposes of testing these functions are to develop requirements for the QC portion of the listing and enumeration applications in 2020. The scope of the tests may include revisiting areas and households to verify information collected in previous operations; correcting and adding map features, addresses, and households; and applying pass/fail requirements. The tests may include collecting GPS coordinates of addresses to identify and reduce incorrect geographic identifiers of addresses.

All activities described directly support the Census Bureau's efforts to maintain or improve quality while controlling costs in the 2020 Census. The information collected from households during these tests is to research new technologies to plan the 2020 Census. Information from respondents will not be used in any data products produced by the Census Bureau such as statistical measures or indicators. Responses may be used in future research studies that build upon the results of these early tests. The Census Bureau may use address and mapping information collected during these tests to update its MAF and mapping databases.

Affected Public: Individuals or households.

Frequency: One time.

Respondent's Obligation: Mandatory.

Legal Authority: U.S. Code Title 13, Sections 141 and 193.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or email (*bharrisk@omb.eop.gov*).

Dated: July 25, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–18452 Filed 7–27–12; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Applications To Serve as Accountability Agents in the Asia Pacific Economic Cooperation (APEC) Cross Border Privacy Rules (CBPR) System

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of Opportunity for Organizations to Submit Applications to Serve as Accountability Agents in the Asia Pacific Economic Cooperation (APEC) Cross Border Privacy Rules (CBPR) System.

SUMMARY: The International Trade Administration's Office of Technology and Electronic Commerce (OTEC) invites interested organizations to submit applications for recognition by APEC to act as an Accountability Agent for U.S.-based companies that are subject to Federal Trade Commission jurisdiction as part of APEC's Cross Border Privacy Rules system.

DATES: Applications may be submitted beginning in July 2012. There is no closing date for submitting applications.

ADDRESSES: All questions concerning this notice should be sent to the attention of Joshua Harris at one of the following addresses. See **SUPPLEMENTARY INFORMATION** for additional instructions on submitting applications.Joshua Harris: 1401 Constitution Ave. NW., Room 4324, Washington, DC 20230.*joshua.harris@trade.gov*.

FOR FURTHER INFORMATION CONTACT: Joshua Harris, Office of Technology and Electronic Commerce, International Trade Administration, U.S. Department of Commerce, by telephone at (202) 482–0142 (this is not a toll-free number) or by email at *joshua.harris@trade.gov*.

SUPPLEMENTARY INFORMATION: In 2004, Leaders of the 21 APEC economies endorsed the ''APEC Privacy Framework'' (Framework). The goal of the Framework is to facilitate the flow of information between the 21 economies in APEC by promoting a common set of privacy principles that will enhance electronic commerce, facilitate trade and economic growth, and strengthen consumer privacy protections. In order to implement this Framework, member economies developed a voluntary system of Cross Border Privacy Rules (CBPR), which was completed in September 2011 and endorsed by APEC Leaders in November 2011 (the Leaders' Declaration is available at *http://www.apec.org/Meeting-Papers/Leaders-Declarations/2011/2011_aelm.aspx)*. The Leaders' Declaration instructs APEC member economies to implement the APEC Cross Border Privacy Rules System to reduce barriers to information flows, enhance consumer privacy, and promote interoperability across regional data privacy regimes. In July 2012, the United States formally commenced participation in the CBPR system.

The 21 APEC economies include Australia, Brunei Darussalam, Canada, Chile, the People's Republic of China, Hong Kong, Indonesia, Japan, the Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, the United States, and Vietnam.

The CBPR system requires organizations to develop their own internal business rules on cross-border privacy procedures, which must be assessed as compliant with the minimum requirements of the APEC system by an independent public or private sector body, called an Accountability Agent. Under the CBPR system, an ''Accountability Agent'' is a third-party organization that provides verification services related to the data privacy policies and practices for those businesses seeking CBPR certification. Only APEC-recognized Accountability Agents may perform CBPR certifications. A recognized Accountability Agent would only be able to certify as CBPR compliant those organizations that are subject to the enforcement authority of the Cross-border Privacy Enforcement Arrangement (CPEA)—participating privacy enforcement authorities within the economies in which it has been approved to operate. The CPEA creates a framework for regional cooperation in the enforcement of privacy laws. In the case of the United States, organizations interested in serving as an Accountability Agent for U.S.-based companies must be subject to the enforcement authority of the Federal Trade Commission, the U.S. privacy enforcement authority for the CBPR system. APEC recognition is granted by a consensus determination by APEC member economies that an applicant Accountability Agent meets the established recognition criteria.

APEC's ''Accountability Agent APEC Recognition Application'', a 61 page document which details the application process as well as the recognition criteria, is available at: *www.export.gov/infotech*.

Interested organizations must notify the Department of Commerce of their intent to seek APEC recognition and submit a completed application for initial review to the Office of Technology and Electronic Commerce by email at *joshua.harris@trade.gov*. Only complete application packages will be forwarded on to APEC for consideration of recognition.

Dated: July 25, 2012.

Robin Layton,

Director, Office of Technology and Electronic Commerce, U.S. Department of Commerce.

[FR Doc. 2012–18515 Filed 7–27–12; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1843]

Reorganization of Foreign-Trade Zone 183 Under Alternative Site Framework; Austin, TX

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (74 FR 1170–1173, January 12, 2009; correction 74 FR 3987, January 22, 2009; 75 FR 71069–71070, November 22, 2010) as an option for the establishment or reorganization of general-purpose zones;

Whereas, the Foreign-Trade Zone of Central Texas, Inc., grantee of Foreign-Trade Zone 183, submitted an application to the Board (FTZ Docket 8–2012, filed February 09, 2012) for authority to reorganize under the ASF with a service area of Bastrop, Caldwell, Hays, Travis and Williamson Counties, Texas, within and adjacent to the Austin Customs and Border Protection port of entry, and FTZ 183's existing Sites 1 through 24 would be categorized as magnet sites;

Whereas, notice inviting public comment was given in the **Federal Register** (77 FR 8806, February 15, 2012) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 183 under the alternative site framework is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard

2,000-acre activation limit for the overall general-purpose zone project, and to a five-year ASF sunset provision for magnet sites that would terminate authority for Sites 1 through 24 if not activated by July 31, 2017.

Signed at Washington, DC, this 23rd day of July 2012.

Paul Piquado,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2012–18586 Filed 7–27–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC107

Takes of Marine Mammals Incidental to Specified Activities; Piling and Fill Removal in Woodard Bay Natural Resources Conservation Area, Washington

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received an application from the Washington State Department of Natural Resources (DNR) for an incidental harassment authorization (IHA) to take marine mammals, by harassment, incidental to restoration activities within the Woodard Bay Natural Resources Conservation Area (NRCA). Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to the DNR to incidentally take harbor seals, by Level B harassment only, during the specified activity.

DATES: Comments and information must be received no later than August 29, 2012.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.Laws@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

An electronic copy of the application, a list of the references used in this document, and other supplemental documents 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.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Ben Laws, 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 published in the **Federal Register** to provide public notice and initiate a 30-day comment period.

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.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by Level B harassment as defined below. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization. If authorized, the IHA would be effective for one year from date of issuance.

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 May 18, 2012, we received an application from the DNR for an IHA for the taking, by Level B harassment only, of small numbers of harbor seals (*Phoca vitulina*) incidental to activities conducted in association with an ongoing habitat restoration project within the Woodard Bay NRCA, Washington. DNR was first issued an IHA that was valid from November 1, 2010, through February 28, 2011 (75 FR 67951), and was subsequently issued a second IHA that was valid from November 1, 2011, through February 28, 2012 (76 FR 67419). Restoration activity planned for 2012–13, depending upon final funding, includes removal of fill and associated materials in Woodard Bay and Chapman Bay and removal of creosote pilings and structure in Chapman Bay. Pilings would be removed by vibratory hammer extraction methods or by direct pull with cables. The superstructure materials would be removed by excavator and/or cables suspended from a barge-mounted crane. The proposed activities would occur only between November 1 through March 15 (2012–13), and could require a maximum total of approximately 70 days.

Description of the Specified Activity

The Woodard Bay NRCA, located within Henderson Inlet in southern Puget Sound, was designated by the Washington State Legislature in 1987 to

protect a large, intact complex of nearshore habitats and related biological communities, and to provide opportunities for low-impact public use and environmental education for the people of Washington. The site includes the former Weyerhaeuser South Bay Log Dump, which operated from the 1920s until the 1980s. The remnant structures from the log dump, including several hundred creosoted timber pilings and a trestle and pier and associated fill, continue to negatively impact nearshore ecosystems protected by the conservation area. Therefore, the DNR has begun restoration activities in the NRCA to remove these dilapidated structures in order to enhance ecological structure and function as well as low-impact public use.

However, certain remnant log booms are not planned for removal—and, in fact, have been maintained—due to their function as habitat for harbor seals. These few remnant log boom structures have been utilized as haul-out habitat for resting, pupping and molting for more than 30 years, and play an important role in supporting a healthy population of harbor seals. Seals concentrate and primarily haul out at only two locations within the NRCA (see figures in DNR's application and Monitoring Report).

These two different haul-out sites within NRCA are referred to as the north and south sites. The north site, located adjacent to the northern tip of the Chapman Bay Pier, is composed of several rows of log booms fastened to creosoted pilings. The south site, located east of the Chapman Bay Pier in the main operational area of the log dump, is composed of six log boom rows and one floating platform attached to creosoted pilings. The booms are utilized year-round by harbor seals of all ages and are ideal for harbor seal pupping due to easy access to water escape routes and the low platform for pups to get in and out of the water (Calambokidis *et al.,* 1991; Lambourn *et al.,* 2007). In recent years, the log boom haul-out area has decreased significantly because logs have decayed, sunk, or floated away (Lambourn *et al.,* 2007), and attempts have been made to re-establish some of the lost haul-out area. These booms are situated in the vicinity of the piles and structure planned for removal. The DNR anticipates harbor seals may flush into the water upon crew arrival and onset of fill removal and pile and structure removal activities; hence, harbor seals may be behaviorally harassed during these activities. The DNR is thus requesting an IHA to take harbor seals, by Level B harassment only, incidental to the specified restoration activities. The proposed activities may result in behavioral disturbance of seals due to noise or visual stimuli from the vibratory hammer, work vessels, heavy equipment onshore, or work crews.

Proposed restoration activities requested under the IHA are funding dependent. They include all or part of the following:

1. Fill Removal

- Remove 13,000 yd^3 of fill from Woodard Bay
- Remove 325 yd^3 of fill from Chapman Bay
- Remove associated creosoted timber, pilings, metal scraps and concrete abutment

2. Piling and Structure Removal

- Remove 10,000 ft^2 of pier superstructure and 470 pilings from Chapman Bay Pier
- Remove 30 anchor piles from Chapman Bay

Fill removal from Woodard and Chapman Bays would be accomplished from the uplands by heavy equipment and haul trucks. The creosoted pilings in the fill would be removed from the uplands by a crane-mounted vibratory hammer. This portion of the project is estimated to take approximately 12–14 weeks to complete. The majority of fill removal work is located in Woodard Bay, which is separated from the harbor seal haul-out areas (located in Chapman Bay) by land. This work would likely result in less disturbance of harbor seals than would the work located in Chapman Bay. In addition, the material to be removed would be hauled offsite by the contractor via Whitham Road, which is the main road into the NRCA and which leads away from the haul-out area (see Figure 4 of DNR's application). Fill removal would largely occur above the Ordinary High Water Mark. Fill removal activities may occur between November 1 and March 15. Chapman Bay fill removal is roughly 250 m from the south haul-out and 975 m from the north haul-out.

Piling and structure removal work would be accomplished by barge and skiffs. The pilings would be removed by vibratory hammer or by direct pull with cables; both methods are suspended from a barge-mounted crane. The vibratory hammer is a large steel device lowered on top of the pile, which then grips and vibrates the pile until it is loosened from the sediment. The pile is then pulled up by the hammer and placed on a barge. For direct pull, a cable is set around the piling to grip and lift the pile from the sediment. The superstructure materials would be removed by excavator and/or cables suspended from a barge-mounted crane.

Approximately 500 12- to 24-in diameter pilings, along with associated pier superstructure, would be removed near but not directly adjacent to haul-outs. After vibration, a choker is used to lift the pile out of the water where it is placed on the barge for transport to an approved disposal site. Pilings that cannot be removed by hammer or cable, or that break during extraction, would be recorded via GPS for divers to relocate at the final phase of project activities. The divers would then cut the pilings at or below the mudline using underwater chainsaws. Operations would begin on the pilings and structures that are furthest from the seal haul-out so that there is an opportunity for the seals to adjust to the presence of the contractors and their equipment. Vibratory extraction operations may occur between November 1 and January 15 and are expected to occur for approximately 20 days over the course of this work window. Other work days would be spent removing pier superstructure, which does not involve vibratory extraction, but has the potential to result in behavioral harassment due to the proximity to working crew. The portion of the Chapman Bay Pier that would be removed is approximately 100 m from the south haul-out area and 250 m from the north haul out.

Description of Marine Mammals in the Area of the Specified Activity

Harbor seals are the only marine mammal regularly found within the action area. Two Steller sea lions (*Eumetopias jubatus*) were observed, at a distance, swimming in Henderson Inlet during site restoration activities in 2010. There have been very few sightings of Steller sea lions in Henderson Inlet, and none were observed during subsequent restoration activities in 2011. They do not breed in Puget Sound, do not regularly use the action area, and, as such, are not likely to be affected by restoration activities. Steller sea lions are not considered further in this document.

Species Description—Harbor seals, which are members of the Phocid family (true seals), inhabit coastal and estuarine waters and shoreline areas from Baja California, Mexico to western Alaska. For management purposes, differences in mean pupping date (i.e., birthing) (Temte, 1986), movement patterns (Jeffries, 1985; Brown, 1988), pollutant loads (Calambokidis *et al.,* 1985) and fishery interactions have led to the recognition of three separate harbor seal stocks along the west coast

of the continental U.S. (Boveng, 1988). The three distinct stocks are: (1) inland waters of Washington (including Hood Canal, Puget Sound, and the Strait of Juan de Fuca out to Cape Flattery), (2) outer coast of Oregon and Washington, and (3) California (Carretta *et al.,* 2007). The inland waters of Washington stock is the only stock that may occur within the project area.

The average weight for adult seals is about 180 lb (82 kg) and males are slightly larger than females. Male harbor seals weigh up to 245 lb (111 kg) and measure approximately 5 ft (1.5 m) in length. The basic color of harbor seals' coat is gray and mottled but highly variable, from dark with light color rings or spots to light with dark markings (NMFS, 2008).

Population Abundance—Estimated population numbers for the inland waters of Washington, including the Hood Canal, Puget Sound, and the Strait of Juan de Fuca out to Cape Flattery, have been most recently estimated at 14,612 individuals (Carretta *et al.,* 2007). However, because the most recent abundance estimate is greater than 8 years old, there is no current estimate of abundance. Between 1983 and 1996, the annual rate of increase for this stock was 6 percent (Jeffries *et al.,* 1997). Based on this information and trends of other harbor seal stocks, the current abundance estimate is likely an underestimate. Based on the analyses of Jeffries *et al.* (2003) and Brown *et al.* (2005), both the Washington and Oregon coastal harbor seal stock have reached carrying capacity and are no longer increasing. Harbor seals are not listed as depleted nor considered strategic under the MMPA or as endangered or threatened under the Endangered Species Act (ESA). The stock is within its Optimum Sustainable Population level (Jeffries *et al.,* 2003). Harbor seals are considered the most abundant resident pinniped species in Puget Sound (Lance and Jeffries, 2009).

The harbor seal population within the NRCA is considered one of the healthier ones in southern Puget Sound. Seal numbers have been monitored at the site since 1977, when there were less than 50 seals. In 1996, the highest count year, there were 600 seals. The average maximum annual count between 1977 and 2008 was 315 seals (Buettner *et al.,* 2008). Annual seal counts end by October and numbers of individuals decline throughout the winter. From 2006 to 2009, October counts averaged 171 and ranged between 79 and 275 (Lambourn, 2010).

Distribution—Harbor seals are coastal species, rarely found more than 12 mi (20 km) from shore, and frequently occupy bays, estuaries, and inlets (Baird, 2001). Individual seals have been observed several miles upstream in coastal rivers. Ideal harbor seal habitat includes haul-out sites, shelter during the breeding periods, and sufficient food (Bjørge, 2002). Haul-out areas can include intertidal and subtidal rock outcrops, sandbars, sandy beaches, peat banks in salt marshes, and man-made structures such as log booms, docks, and recreational floats (Wilson, 1978; Prescott 1982; Schneider and Payne, 1983; Gilber and Guldager, 1998; Jeffries *et al.,* 2000). Human disturbance can affect haul-out choice (Harris *et al.,* 2003).

Behavior and Ecology—Harbor seals are typically seen in small groups resting on tidal reefs, boulders, mudflats, man-made structures, and sandbars. Harbor seals are opportunistic feeders that adjust their patterns to take advantage of locally and seasonally abundant prey (Payne and Selzer, 1989; Baird, 2001; Bjørge, 2002). The harbor seal diet consists of fish and invertebrates (Bigg, 1981; Roffe and Mate, 1984; Orr *et al.,* 2004). Although harbor seals in the Pacific Northwest are common in inshore and estuarine waters, they primarily feed at sea (Orr *et al.,* 2004) during high tide. Researchers have found that they complete both shallow and deep dives during hunting depending on the availability of prey (Tollit *et al.,* 1997). Their diet in Puget Sound consists of common prey resources such as hake, herring and adult and out-migrating juvenile salmonids.

Harbor seals mate at sea and females give birth during the spring and summer, although the pupping season varies by latitude. In coastal and inland regions of Washington, pups are born from April through January. Pups are generally born earlier in the coastal areas and later in inland waters (Calambokidis and Jeffries, 1991; Jeffries *et al.,* 2000). Suckling harbor seal pups spend as much as forty percent of their time in the water (Bowen *et al.,* 1999).

The remnant log booms at the Woodard Bay NRCA support a year-round population of harbor seals, which use the boom structures for haul-out habitat to rest, pup, and molt in two primary locations; to the east and to the north of the Chapman Bay Pier (see Figure 4 in DNR's application). Haul-out behavior is shown to be affected by time of day and tide cycle, as well as factors related to seasonal weather patterns such as air temperature, wind speed, cloud cover, and sea conditions (Buettner *et al.,* 2008). Annually, use of the log booms peaks from July, when females haul out to give birth to their pups, through October, during the late pupping season and molt (WA DNR, 2002).

Acoustics—In air, harbor seal males produce a variety of low-frequency (less than 4 kHz) vocalizations, including snorts, grunts, and growls. Male harbor seals produce communication sounds in the frequency range of 100–1,000 Hz (Richardson *et al.,* 1995). Pups make individually unique calls for mother recognition that contain multiple harmonics with main energy below 0.35 kHz (Bigg, 1981; Thomson and Richardson, 1995). Harbor seals hear nearly as well in air as underwater and had lower thresholds than California sea lions (*Zalophus californianus*) (Kastak and Schusterman, 1998). Kastak and Schusterman (1998) reported airborne low frequency (100 Hz) sound detection thresholds at 65.4 dB re: 20 μPa for harbor seals. In air, they hear frequencies from 0.25–30 kHz and are most sensitive from 6–16 kHz (Richardson, 1995; Terhune and Turnbull, 1995; Wolski *et al.,* 2003).

Adult males also produce underwater sounds during the breeding season that typically range from 0.25–4 kHz (duration range: 0.1 s to multiple seconds; Hanggi and Schusterman, 1994). Hanggi and Schusterman (1994) found that there is individual variation in the dominant frequency range of sounds between different males, and Van Parijs *et al.* (2003) reported oceanic, regional, population, and site-specific variation that could be vocal dialects. In water, they hear frequencies from 1–75 kHz (Southall *et al.,* 2007) and can detect sound levels as weak as 60–85 dB re: 1 μPa within that band. They are most sensitive at frequencies below 50 kHz; above 60 kHz sensitivity rapidly decreases.

Potential Effects on Marine Mammals

Potential effects of DNR's proposed activities are likely to be limited to behavioral disturbance resulting from visual stimuli of seals at the two described log boom haul-outs. Other potential disturbance could result from the introduction of sound into the environment as a result of pile removal activities; however, this is unlikely to cause an appreciably greater amount of harassment in either numbers or degree, in part because it is anticipated that most seals would be disturbed initially by physical presence of crews, vessels, or heavy equipment or by sound from vessels.

There is a general paucity of data on sound levels produced by vibratory extraction of timber piles; however, it is reasonable to assume that extraction would not result in higher sound

pressure levels (SPLs) than vibratory installation of piles. As such, we assume that source levels from the proposed activity would not be as high as average source levels for vibratory installation of 12- to 24-in steel piles (155–165 dB; Caltrans, 2009). Our general in-water harassment thresholds for pinnipeds exposed to continuous noise, such as that produced by vibratory pile extraction, are 190 dB root mean square (rms) re: 1 µPa as the potential onset of Level A (injurious) harassment and 120 dB RMS re: 1 µPa as the potential onset of Level B (behavioral) harassment. These levels are considered precautionary and we are currently revising these thresholds to better reflect the most recent scientific data.

Vibratory extraction would not result in sound levels near 190 dB; therefore, injury would not occur. However, underwater noise from vibratory extraction would likely exceed 120 dB in the vicinity of the haul-outs and may induce responses in-water such as avoidance or other alteration of behavior at time of exposure. However, seals flushing from haul-outs in response to small vessel activity and the presence of work crews would already be considered as 'harassed'. We only consider a single incidence of harassment per individual in any given 24-hour period; therefore, additional incidents that may occur to the same individual from different stimuli are not considered additional takes.

The airborne sound disturbance criteria for Level A harassment is 90 dB RMS re: 20 µPa for harbor seals. Based on information on airborne source levels measured for pile driving with vibratory hammer, removal of wood piles is unlikely to exceed 90 dB (WA DNR, 2011); further, the vibratory hammer would be outfitted with a muffling device ensuring that airborne SPLs are no higher than 80 dB. Potential effects of the action on harbor seals are detailed in the following text.

Behavioral Disturbance

Disturbance can result in a variety of effects, such as subtle or dramatic changes in behavior or displacement. Behavioral reactions of marine mammals are difficult to predict because they are dependent on numerous factors, including species, maturity, experience, activity, reproductive state, time of day, and weather. If a marine mammal does react to a stimulus by changing its behavior or moving a small distance, the impacts of that change may not be important to the individual, the stock, or the species as a whole. However, if marine mammals are displaced from an important feeding or breeding area for a prolonged period, impacts on the animals could be important. In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing stimuli than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans.

Because the few available studies show wide variation in response to stimuli, pinniped responses are difficult to quantify. The literature shows that a range of effects are possible, including no obvious visible response, or behavioral responses that may include annoyance and increased alertness, visual orientation towards the stimulus, investigation of the stimulus, change in movement pattern or direction, habituation, alteration of feeding and social interaction, or temporary or permanent avoidance of the affected area. Minor behavioral responses do not necessarily cause long-term effects to the individuals involved. Severe responses include panic, immediate movement away from the stimulus, and stampeding, which could potentially lead to injury or mortality (Southall *et al.,* 2007).

In their comprehensive review of available literature, Southall *et al.* (2007) reported that the limited data suggest exposures between approximately 90 and 140 dB generally do not appear to induce strong behavioral responses in pinnipeds, while higher levels of pulsed sound, ranging between 150 and 180 dB, will prompt avoidance of an area. For airborne sound Southall *et al.* (2007) note there is extremely limited data suggesting very minor, if any, observable behavioral responses by pinnipeds exposed to airborne pulses of 60 to 80 dB.

Southall *et al.* (2007) noted that quantitative studies on behavioral reactions of pinnipeds to sound are rare, but described the following:

- Harris *et al.* (2001) observed the response of ringed (*Pusa hispida*), bearded (*Erignathus barbatus*), and spotted seals (*Phoca largha*) to underwater operation of a single air gun and an eleven-gun array. Received exposure levels were 160 to 200 dB. In some instances, seals exhibited no response to sound.
- Blackwell *et al.* (2004) observed ringed seals during impact installation of steel pipe pile. Received underwater SPLs were measured at 151 dB at 63 m. The seals exhibited either no response or only brief orientation response (defined as ''investigation or visual orientation'').
- In addition, Blackwell *et al.* (2004) studied the response of ringed seals within 500 m of impact driving of steel pipe pile to airborne sound. Received levels of airborne sound were measured at 93 dB at a distance of 63 m. Seals had either no response or limited response to pile driving. Reactions were described as ''indifferent'' or ''curious.''
- Miller *et al.* (2005) observed responses of ringed and bearded seals to a seismic air gun array. Received underwater sound levels were estimated at 160 to 200 dB. There were fewer seals present close to the sound source during air gun operations in the first year, but in the second year the seals showed no avoidance. In some instances, seals were present in very close range of the sound. The authors concluded that there was ''no observable behavioral response'' to seismic air gun operations.

Jacobs and Terhune (2002) observed harbor seal reactions to acoustic harassment devices (AHDs) with source level of 172 dB deployed around aquaculture sites. Seals were generally unresponsive to sounds from the AHDs. During two specific events, individuals came within 141 and 144 ft (43 and 44 m) of active AHDs and failed to demonstrate any measurable behavioral response; estimated received levels based on the measures given were approximately 120 to 130 dB.

Kastelein *et al.* (2006) exposed nine captive harbor seals in an approximately 82 × 98 ft (25 × 30 m) enclosure to non-pulse sounds used in underwater data communication systems (similar to acoustic modems). Test signals were frequency modulated tones, sweeps, and bands of sound with fundamental frequencies between 8 and 16 kHz; 128 to 130 ±3 dB source levels; 1- to 2-s duration (60–80 percent duty cycle); or 100 percent duty cycle. They recorded seal positions and the mean number of individual surfacing behaviors during control periods (no exposure), before exposure, and in 15-min experimental sessions (n = 7 exposures for each sound type). Seals generally swam away from each source at received levels of approximately 107 dB, avoiding it by approximately 16 ft (5 m), although they did not haul out of the water or change surfacing behavior. Seal reactions did not appear to wane over repeated exposure (i.e., there was no obvious habituation), and the colony of seals generally returned to baseline conditions following exposure. The seals were not reinforced with food for remaining in the sound field.

Reactions of harbor seals to the simulated sound of a 2-megawatt wind power generator were measured by Koschinski *et al.* (2003). Harbor seals

surfaced significantly further away from the sound source when it was active and did not approach the sound source as closely. The device used in that study produced sounds in the frequency range of 30 to 800 Hz, with peak source levels of 128 dB at 1 m at the 80- and 160–Hz frequencies.

Vessel sounds do not seem to have strong effects on seals in the water, but the data are limited. When in the water, seals appear to be much less apprehensive about approaching vessels. Some would approach a vessel out of apparent curiosity, including noisy vessels such as those operating seismic airgun arrays (Moulton and Lawson, 2002). Gray seals (*Halichoerus grypus*) have been known to approach and follow fishing vessels in an effort to steal catch or the bait from traps. In contrast, seals hauled out on land often are quite responsive to nearby vessels. Terhune (1985) reported that northwest Atlantic harbor seals were extremely vigilant when hauled out and were wary of approaching (but less so passing) boats. Suryan and Harvey (1999) reported that Pacific harbor seals commonly left the shore when powerboat operators approached to observe the seals. Those seals detected a powerboat at a mean distance of 866 ft (264 m), and seals left the haul-out site when boats approached to within 472 ft (144 m).

Hearing Impairment and Other Physiological Effects

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very strong sounds. Hearing impairment is measured in two forms: Temporary threshold shift (TTS) and permanent threshold shift (PTS). PTS is considered injurious whereas TTS is not, as it is temporary and hearing is fully recoverable. Non-auditory physiological effects might also occur in marine mammals exposed to strong underwater sound. Possible types of non-auditory physiological effects or injuries that may occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. It is possible that some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds, particularly at higher frequencies. Neither auditory nor non-auditory physiological effects are anticipated to occur as a result of DNR activities.

PTS is presumed to be likely if the hearing threshold is reduced by more than 40 dB (i.e., 40 dB of TTS). Due to the low source levels produced by vibratory extraction, NMFS does not expect that marine mammals will be exposed to levels that could elicit PTS; therefore, it will not be discussed further. The following subsection discusses in somewhat more detail the possibilities of TTS.

TTS—TTS, reversible hearing loss caused by fatigue of hair cells and supporting structures in the inner ear, is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the sound ends.

We consider TTS to be a form of Level B harassment rather than injury, as it consists of fatigue to auditory structures rather than damage to them. Pinnipeds have demonstrated complete recovery from TTS after multiple exposures to intense sound, as described in the studies below (Kastak *et al.,* 1999, 2005). The 190-dB injury criterion is not considered to be the level above which TTS might occur. Rather, it is the received level above which, in the view of a panel of bioacoustics specialists convened before TTS measurements for marine mammals became available, one could not be certain that there would be no injurious effects, auditory or otherwise, to pinnipeds. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound.

Human non-impulsive sound exposure guidelines are based on exposures of equal energy (the same sound exposure level [SEL]; SEL is reported here in dB re: 1 $\mu Pa^2 - s$/re: 20 $\mu Pa^2 - s$ for in-water and in-air sound, respectively) producing equal amounts of hearing impairment regardless of how the sound energy is distributed in time (NIOSH, 1998). Until recently, previous marine mammal TTS studies have also generally supported this equal energy relationship (Southall *et al.,* 2007). Three newer studies, two by Mooney *et al.* (2009a,b) on a single bottlenose dolphin (*Tursiops truncatus*) exposed to either playbacks of U.S. Navy mid-frequency active sonar or octave-band sound (4–8 kHz) and one by Kastak *et al.* (2007) on a single California sea lion exposed to airborne octave-band sound (centered at 2.5 kHz), concluded that for all sound exposure situations, the equal energy relationship may not be the best indicator to predict TTS onset levels. Generally, with sound exposures of equal energy, quieter sounds (lower SPL) of longer duration were found to induce TTS onset more than louder sounds (higher SPL) of shorter duration. Given the available data, the received level of a single seismic pulse (with no frequency weighting) might need to be approximately 186 dB SEL in order to produce brief, mild TTS.

There are few known studies conducted on pinniped TTS responses to non-pulsed underwater or airborne sound. The first three studies described in the following text were performed in the same lab and on the same test subjects, and, therefore, the results may not be applicable to all pinnipeds or in field settings.

- Kastak and Schusterman (1996) studied the response of harbor seals to non-pulsed construction sound, reporting TTS of about 8 dB.
- Kastak *et al.* (1999) reported TTS of approximately 4–5 dB in three species of pinnipeds (harbor seal, California sea lion, and northern elephant seal [*Mirounga angustirostris*]) after underwater exposure for approximately 20 minutes to sound with frequencies ranging from 100–2,000 Hz at received levels 60–75 dB above hearing threshold. This approach allowed similar effective exposure conditions to each of the subjects, but resulted in variable absolute exposure values depending on subject and test frequency. Recovery to near baseline levels was reported within 24 hours of sound exposure.
- Kastak *et al.* (2005) followed up on their previous work, exposing the same test subjects to higher levels of sound for longer durations. The animals were exposed to octave-band sound for up to 50 minutes of net exposure. The study reported that the harbor seal experienced TTS of 6 dB after a 25-minute exposure to 2.5 kHz of octave-band sound at 152 dB (183 dB SEL).
- Bowles *et al.* (unpubl. data) exposed pinnipeds to simulated sonic booms (airborne sound). Harbor seals demonstrated TTS at 143 dB peak and 129 dB SEL.
- Kastak *et al.* (2004) used the same test subjects as in Kastak *et al.* (2005), exposing the animals to non-pulsed airborne sound (2.5 kHz octave-band sound) for 25 minutes. The harbor seal demonstrated 6 dB of TTS after exposure to 99 dB (131 dB SEL).

The sound level necessary to cause TTS in pinnipeds depends on exposure duration; with longer exposure, the level necessary to elicit TTS is reduced (Schusterman *et al.,* 2000; Kastak *et al.,*

2005, 2007). The literature has not drawn conclusions on levels of underwater non-pulsed sound (e.g., vibratory pile removal) likely to cause TTS. Although underwater sound levels produced by the DNR project may be approximately equal to the lower end of sound levels produced in studies that have induced TTS in pinnipeds, there is a general lack of controlled, quantifiable field studies related to this phenomenon, existing studies have had varied results, and there are no universally accepted standards for the amount of exposure time likely to induce TTS (Southall *et al.,* 2007).

While it may be inferred that TTS could theoretically result from the DNR project, it is highly unlikely, due to the source levels and duration of exposure possible. In summary, it is expected that elevated sound will have only a negligible probability of causing TTS in individual seals. Further, seals are likely to be disturbed via the approach of work crews and vessels long before the beginning of any pile removal operations and would be apprised of the advent of increased underwater sound via the soft start of the vibratory hammer. It is not expected that airborne sound levels would induce any form of behavioral harassment, much less TTS in individual pinnipeds.

The DNR and other organizations, such as the Cascadia Research Collective, have been monitoring the behavior of harbor seals present within the NRCA since 1977. Past disturbance observations at Woodard Bay NRCA have shown that seal harassment results from the presence of non-motorized vessels (e.g., recreational kayaks and canoes), motorized vessels (e.g., fishing boats), and people (Calambokidis and Leathery, 1991; Buettner *et al.,* 2008). Calambokidis and Leathery (1991) found that the mean distance that seals entered the water in response to any type of vessel was 56 m. Most commonly seals were disturbed when vessels were 26 to 50 m from the haul-out; however, only at distances greater than 125 m was there a sharp decrease in the proportion of groups disturbed. Seals entered the water in response to people on foot at up to 256 m although, on many occasions, people were able to pass less than 100 m from seals without noticeable disturbance while intentionally maintaining a low profile (Calambokidis and Leathery, 1991). Furthermore, the distances at which seals were disturbed varied significantly by vessel type; seals entered the water at a greater distance in response to non-motorized vessels as compared to motorized vessels. It is hypothesized that because the latter are more readily detectable than the former, seals are more readily aware of their presence at greater distances and do not react to the same extent upon close approach (Buettner *et al.,* 2008).

Buettner *et al.* (2008) also noted the difference in vigilance of seals based on float location during pupping season. For example, seals on floats located on the outer edges of the log boom area, which are thus subjected to greater amounts of vessel traffic, were indifferent to vessels unless the vessels came right up to the log booms. Contrarily, seals on the floats located in the central area of the log booms, and hence not exposed to as much traffic, were more vigilant and more sensitive to disturbances. These observations suggest that, while seals are susceptible to anthropogenic disturbance, a certain amount of habituation may occur at these haul-outs.

During emergency maintenance operations on the haul-out in 2008, seals present on the log booms flushed when the vessel first entered the haul-out area, but appeared to become habituated quickly thereafter. Maintenance operations included installation of new log booms to restore habitat. Seals initially flushed in response to onset of work but quickly acclimated to crew presence and would haul out on booms directly adjacent to the small barge used during maintenance. Furthermore, Suryan and Harvey (1991) found that harbor seals hauled-out at Puffin Island, WA, were more tolerant to subsequent harassments than they were to the initial harassment. However, sudden presence of a disturbance source (e.g., kayaker) can induce strong behavioral reactions.

In summary, based on the preceding discussion and on observations of harbor seals during past management activities in Woodard Bay, NMFS has preliminarily determined that impacts to harbor seals during restoration activities would be limited to behavioral harassment of limited duration and limited intensity (i.e., temporary flushing at most) resulting from physical disturbance. It is anticipated that seals would be initially disturbed by the presence of crew and vessels associated with the habitat restoration project. Seals entering the water following such disturbance could also be exposed to underwater SPLs greater than 120 dB (i.e., constituting harassment); however, given the short duration and low energy of vibratory extraction of 12–24 in timber piles, PTS would not occur and TTS is not likely. Abandonment of any portion of the haul-out is not expected either, as harbor seals have been documented as quickly becoming accustomed to the presence of work crews. During similar activities carried out under the previous IHAs, seals showed no signs of abandonment or of using the haul-outs to a lesser degree.

Anticipated Effects on Habitat

Marine mammal habitat would be temporarily ensonified by low sound levels resulting from habitat restoration effort. The piles designated to be removed have been treated with creosote, a wood preservative that is also toxic to the environment. Removing these piles will have beneficial impacts to the NRCA, including marine mammal habitat, by preventing the leaching of creosote chemicals, including polycyclic aromatic hydrocarbons, into the marine environment. No log booms would be removed; therefore, no impacts to the physical availability of haul-out habitat would occur. Any disturbance to substrate in the NRCA would be localized and of a temporary nature, resulting from the extraction of piles. As such, temporary impacts at most may be expected to the habitat of harbor seal prey species. No prey species are known to utilize the pilings themselves.

Summary of Previous Monitoring

DNR complied with the mitigation and monitoring required under the previous authorizations. In accordance with the 2010–11 IHAs, DNR submitted final monitoring reports, which described the monitoring effort and observations made. DNR has not exceeded authorized levels of take by Level B harassment under the IHAs.

Past IHAs have stipulated that monitoring be conducted on at least 15 days of work, to include times when we considered disturbance to be most likely, such as:

- Initial construction days of the project;
- When the contractors were mobilizing to a new location; and
- When activities were occurring closest to the haul-out areas.

At least one observer was stationed at each of two observation sites, to monitor both haul-out areas, on all monitoring days. Monitoring began 30 minutes prior to the contractor's start time (7 a.m.) and ended 30 minutes after the contractor left the site. Counts were conducted every half hour unless there was a disturbance, in which case another count was conducted. Each of the two haul-outs was counted separately and added together for the total number of seals hauled out. In the event of harassment, observers recorded the nature of the activity, proximity to haul-outs, and the number of seals that

flushed into the water (i.e., were harassed). The take number was calculated by subtracting the number of seals hauled out after the disturbance from the most recent count prior to the disturbance.

Harbor seal disturbances were recorded and broken down into disturbance types based on cause of disturbance. Each disturbance was given a code and proximity in meters from haul-outs was recorded (Table 1). Proximity in relation to haul-outs was calculated using satellite imagery. Under the 2010–11 IHA, 356 takes by harassment were observed during the 14 days of observation (Table 1) resulting in a mean of 25 seals disturbed per monitored day. Extrapolating that average out for all 35 days of restoration activity that occurred provides a total estimated take of 875, less than the authorized take (by Level B harassment) of 1,539. Under the 2011–12 IHA, 172 takes by harassment were observed during the 15 days of observation (Table 1) resulting in a mean of 11 seals disturbed per monitored day. Extrapolating that average out for all 21 days of restoration activity that occurred provides a total estimated take of 231, less than the authorized take (by Level B harassment) of 2,080. These extrapolated estimates may be biased high since monitored days were chosen in part to sample days with activities most likely to disturb seals.

TABLE 1—AGGREGATE HARBOR SEAL COUNTS AND DISTURBANCES FROM TWO HAUL-OUT SITES

Date	Year	Start time	Finish time	Conditions	Pre-activity count	Peak daily count	Disturbance code	Proximity to haul-out (m)	Total daily takes
Nov 1	2010	0930	1630	Overcast, rain	8	18	MS, PP	<10	5
Nov 2	2010	0630	1800	Sunny	97	127	DB	>300	69
Nov 9	2010	0630	1800	Overcast, rain	71	72	MS	>160	31
Nov 12	2010	0630	1730	Sunny	67	100	MS, MB	>150	76
Nov 15	2010	0630	1730	Overcast, rain	27	39		>130	0
Nov 16	2010	0630	1700	Overcast, rain	40	54	BC	<250	25
Nov 18	2010	0630	1750	Partly cloudy	8	15	BC	>130	6
Nov 19	2010	0630	1730	Partly cloudy	121	127	MS	>130	34
Nov 22	2010	0630	1730	Partly cloudy, snow	35	37	MS, BC	>130	13
Dec 8	2010	0630	1730	Overcast, rain	1	17		>300	0
Dec 10	2010	0630	1600	Partly cloudy	20	34	BC	>100	30
Dec 16	2010	0630	1730	Sunny	36	41	MS, VH	>100	38
Dec 20	2010	0630	1600	Overcast, rain	0	0		>130	0
Dec 21	2010	0630	1700	Sunny	43	43	MS, DB	>75	29
Nov 16	2011	1200	1430	Fair	1	1			0
Nov 17	2011	0630	1630	Fair	25	34	BC, MS	<500	8
Nov 18	2011	0630	1630	Fair	26	77	BC	<50	4
Nov 21	2011	0630	1630	Rain	0	1			0
Nov 22	2011	0630	1630	Rain, wind	0	0			0
Nov 28	2011	0630	1630	Fair	41	45	BC, MS	<150	44
Nov 29	2011	0630	1630	Fair	19	38			0
Nov 30	2011	0630	1630	Fair	6	6			0
Dec 1	2011	0630	1630	Fair	27	47	BC	<100	21
Dec 2	2011	0630	1630	Fair	25	51			0
Dec 5	2011	1330	1630	Fair	62	62	BC, MS	<250	51
Dec 7	2011	0630	1630	Fair	20	42	MS	<100	7
Dec 8	2011	0630	1630	Fair	1	4			0
Dec 9	2011	0630	1130	Fair	0	0			0
Dec 14	2011	0630	1630	Fair	47	55	MS	<250	37

Activity codes: MS: motorized skiff; BC: Barge/Crane; VH: Vibratory hammer; PR: Pile removal; PP: Pile painting; MB: Mobilize barge; DB: Dive boat.

Harbor seals were generally hauled out prior to the work day with the majority of seals at the south haul-out. The construction crew stayed at a distance of over 150 m from the haul-outs when maneuvering back and forth from shore to their barge anchored greater than 150 m offshore from the haul-outs. The seals appeared to be relatively unaffected by the movement of the crane barge at distances greater than 150 m. The majority of incidental harassment takes were caused by the work skiff maneuvering back and forth, despite the distance from the haul-outs. Once the seals entered the water, the majority typically did not return to the haul-out during same-day monitoring effort, although there were never large groups of seals observed in the water after a disturbance. Seals that remained on the haul-out after a disturbance showed no signs of adverse behavior. Given that there have been no dedicated observations at the NRCA during this time of year (i.e., November-February) it is difficult to say whether the decreased number of harbor seals hauled out (as compared with average October counts) was caused by construction activity or seasonal distribution. It is likely, however, that the latter is the case, as November represents the post-breeding and molting period, when harbor seals are less reliant on the haul-outs.

Proposed Mitigation

In order to issue an IHA 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.

The DNR has proposed to continue mitigation measures, as stipulated in the previous IHAs, designed to minimize disturbance to harbor seals within the action area in consideration of timing,

location, and equipment use. Foremost, pile, structure, and fill removal would only occur between November and March, outside of harbor seal pupping and molting seasons. Therefore, no impacts to pups from the specified activity during these sensitive time periods would occur. In addition, the following measures would be implemented:

- The DNR would approach the action area slowly to alert seals to their presence from a distance and would begin pulling piles at the farthest location from the log booms used as harbor seal haul-out areas;
- No piles within 30 yd (27 m) of the two main haul-out locations identified in the IHA application would be removed;
- The contractor or observer would survey the operational area for seals before initiating activities and wait until the seals are at a sufficient distance (i.e., 50 ft [15 m]) from the activity so as to minimize the risk of direct injury from the equipment or from a piling or structure breaking free;
- The DNR would require the contractor to initiate a vibratory hammer soft start at the beginning of each work day; and
- The vibratory hammer power pack would be outfitted with a muffler to reduce in-air noise levels to a maximum of 80 dB.

The soft start method involves a reduced energy vibration from the hammer for the first 15 seconds and then a 30-second waiting period. This method would be repeated twice before commencing with operations at full power.

We considered but rejected one additional mitigation measure, the requirement to conduct a sound source verification study. We have in the past required some applicants to conduct such a study to ensure that the production of increased levels of sound is no greater than the level analyzed in estimating incidental take. However, as described previously in this document, source levels produced by the vibratory hammer would be no greater than 80 dB in-air and are conservatively estimated at approximately 155–165 dB underwater. The underwater source levels would likely be lower, as those are measured levels from installation of steel piles. Underwater source levels from this project would likely be less both because the action is extraction, not installation, and because of the pile material (timber rather than steel). Further, seals exposed to sound greater than 120 dB would likely be previously disturbed by the presence of crews and vessels and by vessel noise. We acknowledge that sound source verification would be preferred; however, the applicant is funding-limited, and the significant expenditure required by such a study would result in a correspondingly lesser amount of restoration work able to be completed. The requirement of a sound source verification study would have limited utility for the harbor seals, would be impracticable for the applicant, and would result in less restoration accomplished. Thus, the end result would likely be a long-term net negative for the harbor seals considered in this document.

We have carefully evaluated the applicant's mitigation measures as proposed and considered their effectiveness in past implementation to preliminarily determine whether they are likely to effect the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures includes consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; (3) the practicability of the measure for applicant implementation, including consideration of personnel safety, and practicality of implementation.

Injury, serious injury, or mortality to pinnipeds could likely only result from startling animals inhabiting the haul-out into a stampede reaction. Even in the event that such a reaction occurred, it is unlikely that it would result in injury, serious injury, or mortality, as the activities would occur outside of the pupping season, and access to the water from the haul-outs is relatively easy and unimpeded. However, DNR has proposed to approach haul-outs gradually from a distance, and would begin daily work at the farthest distance from the haul-out in order to eliminate the possibility of such events. During the previous years of work under our authorization, implementation of similar mitigation measures has resulted in no known injury, serious injury, or mortality (other than one event considered atypical and outside the scope of the mitigation measures considered in relation to disturbing seals from the haul-outs). Based upon the DNR's record of management in the NRCA, as well as information from monitoring DNR's implementation of the improved mitigation measures as prescribed under the previous IHAs, we have preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that we 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 IHAs 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.

DNR's proposed monitoring plan adheres to protocols already established for Woodard Bay to the maximum extent practical for the specified activity. Monitoring of both the north and south haul-outs would occur for a total of 15 work days, during the first 5 days of project activities, when the contractors are mobilizing and starting use of the vibratory hammer; during 5 days when activities are occurring closest to the haul-out areas; and during 5 additional days, to include days when fill removal is occurring in Woodard Bay. It is not expected that Woodard Bay fill removal would result in seal disturbance; however, the stipulation that monitoring be conducted while this activity occurs is intended to ensure that such is the case. Monitoring of both haul-outs would be performed by at least one observer. The observer would (1) be on-site prior to crew and vessel arrival to determine the number of seals present pre-disturbance; (2) maintain a low profile during this time to minimize disturbance from monitoring; and (3) conduct monitoring beginning 30 minutes prior to crew arrival, during pile removal activities, and for 30 minutes after crew leave the site.

The observer would record incidental takes (i.e., numbers of seals flushed from the haul-out). This information would be determined by recording the number of seals using the haul-out on each monitoring day prior to the start of restoration activities and recording the number of seals that flush from the haul-out or, for animals already in the water, display adverse behavioral reactions to vibratory extraction. A description of the disturbance source, the proximity in meters of the disturbance source to the disturbed animals, and observable behavioral reactions to specific disturbances would

also be noted. In addition, the observer would record:

- The number of seals using the haul-out on each monitoring day prior to the start of restoration activities for that day;
- Seal behavior before, during and after pile and structure removal;
- Monitoring dates, times and conditions;
- Dates of all pile and structure removal activities; and
- After correcting for observation effort, the number of seals taken over the duration of the habitat restoration project.

Within 30 days of the completion of the project, DNR would submit a monitoring report that would include a summary of findings and copies of field data sheets and relevant daily logs from the contractor.

We considered but rejected an expanded monitoring plan that would require DNR to conduct monitoring as described but for every day of construction. We do not believe that monitoring need be conducted at all times during this low-level activity as there is no potential for serious injury or mortality and the probability of an animal being physically injured from the equipment is extremely low if not discountable. In addition, no other marine mammal species are likely to be present within the action area, and are therefore not likely to be affected by DNR's activities. Similar to scientific research studies, when correcting for effort, the DNR should be able to adequately determine the number of animals taken and impacts of the project on marine mammals based on the proposed monitoring plan. Should extreme reactions of seals occur (e.g., apparent abandonment of the haul-out) at any time during the project, DNR will stop removal activities and consult with us. However, as described in this notice, based on previous scientific disturbance studies at NRCA, extreme reactions are not anticipated. Finally, as described previously, funding is limited for DNR's important restoration work, requiring a balance between the level of monitoring that is necessary to adequately characterize disturbance of harbor seals and the significant funding required to implement monitoring. We feel that the proposed monitoring plan strikes the proper balance.

Estimated Take by Incidental Harassment

As described previously in this document, annual seal counts in Woodard Bay end by October. Seals utilize haul-out habitat from spring or summer until approximately October for breeding, pupping, and molting. After October, numbers of individuals at the haul-outs are expected to decline throughout the winter. From 2006 to 2009, October counts averaged 171 and ranged between 79 and 275 (Lambourn, 2010).

Under the previous IHAs, seals were monitored for 29 days during November and December of 2010 and 2011. In 2010, total peak counts ranged from 0 to 127 and averaged 52, while total peak counts in 2011 ranged from 0 to 77 and averaged 31 (Oliver and Calambokidis, 2011, 2012), confirming that seal numbers decline after October. It is unlikely that the fill removal operations taking place in Woodard Bay would result in seal disturbance, as they would be shielded by land from the harbor seal haul-outs and would have no associated vessel activity. DNR proposes that the estimated 20 days of pile and structure removal activity, as well as all fill removal activity occurring in Chapman Bay, may potentially result in incidental harassment of harbor seals. Using the average count from November-December 2010–11 (42) and the estimated number of total days of activity as described here (40) the result is an estimated incidental take of 1,680 harbor seals (40 days x 42 seals per day). We consider this to be a highly conservative estimate in comparison with the estimated actual take of 875 seals from 2010 and 231 seals from 2011, which is nonetheless based upon the best available information.

Negligible Impact and Small Numbers Analysis and Determination

We have 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.'' In determining whether or not authorized incidental take will have a negligible impact on affected species stocks, we consider a number of criteria regarding the impact of the proposed action, including the number, nature, intensity, and duration of Level B harassment take that may occur. Although DNR's restoration activities may harass pinnipeds hauled out in Woodard Bay, impacts are occurring to a small, localized group of animals. No mortality or injury is anticipated or proposed for authorization, nor will the proposed action result in long-term impacts such as permanent abandonment of the haul-out. Seals will likely become alert or, at most, flush into the water in reaction to the presence of crews and equipment. However, seals have been observed as becoming habituated to physical presence of work crews, and quickly re-inhabit haul-outs upon cessation of stimulus. In addition, the proposed restoration actions may provide improved habitat function for seals, both indirectly through a healthier prey base and directly through restoration and maintenance of man-made haul-out habitat. No impacts would be expected at the population or stock level.

No pinniped stocks known from the action area are listed as threatened or endangered under the ESA or determined to be strategic or depleted under the MMPA. Recent data suggests that harbor seal populations have reached carrying capacity.

Although the estimated take of 1,680 is 11 percent of the estimated population of 14,612 for the Washington Inland Waters stock of harbor seals, the number of individual seals harassed will be lower, with individual seals likely harassed multiple times. In addition, although the estimated take is based upon the best scientific information available, we consider the estimate to be highly conservative. For similar restoration activities in 2010–11, estimated actual take was much lower (875 seals over 35 work days in 2010 and 231 seals over 21 work days in 2011).

Mitigation measures would minimize onset of sudden and potentially dangerous reactions and overall disturbance. In addition, restoration work is not likely to affect seals at both haul-outs simultaneously, based on location of the crew and barge. Further, although seals may initially flush into the water, based on previous disturbance studies and maintenance activity at the haul-outs, the DNR expects seals will quickly habituate to piling and structure removal operations. For these reasons no long term or permanent abandonment of the haul-out is anticipated. Much of the work proposed for 2012–13 consists of fill removal, which does not require in-water work or vessel support, and is largely located in Woodard Bay, which is shielded from the haul-out locations by land. The proposed action is not anticipated to result in injury, serious injury, or mortality to any harbor seal. The DNR would not conduct habitat restoration operations during the pupping and molting season; therefore, no pups would be affected by the proposed action and no impacts to any seals would occur as a result of the specified activity during these sensitive time periods.

Based on the foregoing analysis, behavioral disturbance to pinnipeds in Woodard Bay would be of low intensity

and limited duration. To ensure minimal disturbance, DNR would implement the mitigation measures described previously, which we have preliminarily determined will serve as the means for effecting the least practicable adverse effect on marine mammal stocks or populations and their habitat. We preliminarily find that DNR's restoration activities would result in the incidental take of small numbers of marine mammals, and that the requested number of takes will have no more than a negligible impact on the affected species and stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action.

Endangered Species Act (ESA)

There are no ESA-listed marine mammals found in the action area; therefore, no consultation under the ESA is required.

National Environmental Policy Act (NEPA)

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500–1508), and NOAA Administrative Order 216–6, NMFS prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from issuance of an IHA to DNR. NMFS signed a Finding of No Significant Impact on October 27, 2010. NMFS has reviewed the proposed application and preliminarily determined that there are no substantial changes to the proposed action or new environmental impacts or concerns. Therefore, NMFS has determined that a new or supplemental EA or Environmental Impact Statement is likely unnecessary. Before making a final determination in this regard, NMFS will review public comments and information submitted by the public and others in response to this notice. The EA referenced above is available for review at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to authorize the take of marine mammals incidental to DNR's restoration activities, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 25, 2012.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–18537 Filed 7–27–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–BA75

Atlantic Highly Migratory Species; Electronic Dealer Reporting System Workshop

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

ACTION: Notice of public workshops.

SUMMARY: On June 28, 2011, NMFS published a proposed rule that considered requiring, among other things, Federal Atlantic swordfish, shark, and tunas dealers (except for dealers reporting Atlantic bluefin tuna) to report commercially-harvested Atlantic sharks, swordfish, and bigeye, albacore, yellowfin, and skipjack (BAYS) tunas through one centralized electronic reporting system. This electronic reporting system will allow dealers to submit Atlantic sharks, swordfish, and BAYS tuna data on a more real-time basis and more efficiently, which will reduce duplicative data submissions from different regions. We proposed to delay the effective date of the electronic reporting requirements until 2013 in order to give sufficient time for dealers to adjust to implementation of the new system and the additional requirements. On June 29, 2012, we announced the date and location for nine upcoming workshops in the Caribbean, Gulf of Mexico, and Atlantic area to introduce the new reporting system to Highly Migratory Species (HMS) dealers. In this notice, we announce the date and location for an additional training workshop in the Caribbean.

DATES: The additional training workshop for the new HMS electronic dealer system will be held on August 29, 2012, from 1:30 to 4:30 p.m. See **SUPPLEMENTARY INFORMATION** for additional details.

ADDRESSES: The training workshop will be held in St. Thomas, United States Virgin Islands (U.S.V.I.) at the following address: Department of Planning and Natural Resources, Office of the Commissioner, 8100 Lindberg Bay, Suite #61, Cyril E. King Airport, Terminal Bldg., Second Floor, St. Thomas, U.S.V.I., 00802. See **SUPPLEMENTARY INFORMATION** for additional details.

FOR FURTHER INFORMATION CONTACT: Delisse Ortiz or Karyl Brewster-Geisz at (301) 427–8503 (phone); or Jackie Wilson at (240) 338–3936, or (301) 713–1917 (fax); or *http://www.nmfs.noaa.gov/sfa/hms/index.htm*.

SUPPLEMENTARY INFORMATION: Atlantic HMS are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.,* and the Atlantic Tunas Convention Act, 16 U.S.C. 971 *et seq.* Under the Magnuson-Stevens Act, NMFS must ensure consistency with the National Standards and manage fisheries to maintain optimum yield, rebuild overfished fisheries, and prevent overfishing. Atlantic Tunas Convention Act authorizes the Secretary of Commerce to promulgate regulations, as may be necessary and appropriate, to implement the recommendations adopted by the International Commission for the Conservation of Atlantic Tunas. The authority to issue regulations under Magnuson-Stevens Act and Atlantic Tunas Convention Act has been delegated from the Secretary to the Assistant Administrator for Fisheries, NOAA. The implementing regulations for Atlantic HMS are at 50 CFR part 635.

Background

The current regulations and infrastructure of the Atlantic HMS quota-monitoring systems result in a delay of several weeks or more before NMFS receives dealer data. This can affect management and monitoring of small Atlantic HMS quotas and short fishing seasons. As such, on June 28, 2011 (76 FR 37750), we published a proposed rule in the **Federal Register** that considered requiring, among other things, Federal Atlantic swordfish, shark, and tunas dealers (except for dealers reporting Atlantic bluefin tuna) to report commercially-harvested Atlantic sharks, swordfish, and BAYS tunas through one centralized electronic reporting system. Under this new system, dealers would submit HMS data electronically (instead of in a paper format) and include additional information that is necessary for management of HMS (e.g., vessel and logbook information). The electronic submission of data will eliminate the delay associated with mailing in hardcopy reports. In this manner, HMS landings data will be submitted on a more real-time basis, allowing for timely

and efficient data collection for management of Atlantic HMS.

In order to give sufficient time for dealers to adjust to implementation of the new system and the additional requirements, we proposed delaying implementation of the new HMS electronic reporting system for all federally-permitted HMS dealers until 2013. Additionally, we decided to conduct outreach to HMS dealers to train them how to use the new system and help ease the transition from the current paper format to the new HMS electronic reporting system. On December 14, 2011, we conducted an initial training workshop for HMS dealers in St. Thomas, U.S.V.I. On June 29, 2012, we announced the date and location for nine upcoming workshops in the Caribbean, Gulf of Mexico, and Atlantic area to introduce the new reporting system to HMS dealers. In this notice, we announce the date and location for an additional training workshop in St. Thomas, U.S.V.I. Future training workshops will be held throughout the Northeast, Mid-Atlantic and Southeast regions at a later date and will be announced in a future notice.

These workshops will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Delisse Ortiz at (301) 425–8503, or Jackie Wilson at (240) 338–3936, at least 7 days prior to the workshop date. The public is reminded that NMFS expects participants at the workshop to conduct themselves appropriately. At the beginning of the workshop, a representative of NMFS will explain the ground rules (e.g., alcohol is prohibited from the hearing room; each attendee will have an opportunity to ask questions; and attendees should not interrupt one another). Attendees are expected to respect the ground rules; if they do not, they will be asked to leave the workshop.

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

Dated: July 25, 2012.

James P. Burgess,

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

[FR Doc. 2012–18534 Filed 7–27–12; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 12–C0008]

Burlington Coat Factory Warehouse Corporation, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the **Federal Register** in accordance with the terms of 16 CFR 1118.20(e). Published below is a provisionally accepted Settlement Agreement with Burlington Coat Factory Warehouse Corporation, containing a civil penalty of $1,500,000.00, within twenty (20) days of service of the Commission's final Order accepting the Settlement Agreement.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by August 14, 2012.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 12–C0008, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, Maryland 20814–4408.

FOR FURTHER INFORMATION CONTACT: Seth B. Popkin, Lead Trial Attorney, Division of Compliance, Office of the General Counsel, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814–4408; telephone (301) 504–7612.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: July 25, 2012.

Todd A. Stevenson,

Secretary.

UNITED STATES OF AMERICA

CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of Burlington Coat Factory Warehouse Corporation

CPSC Docket No. *12–C0008*

Settlement Agreement

1. In accordance with the Consumer Product Safety Act, 15 U.S.C. §§ 2051–2089 (''CPSA''), and 16 CFR § 1118.20, Burlington Coat Factory Warehouse Corporation (''Burlington'') and staff (''Staff'') of the U.S. Consumer Product Safety Commission (''Commission'') enter into this Settlement Agreement (''Agreement''). The Agreement and the incorporated attached Order (''Order'') resolve Staff's allegations set forth below.

Parties

2. Staff is staff of the Commission, an independent federal regulatory agency established pursuant to, and responsible for the enforcement of, the CPSA.

3. Burlington is a corporation, organized and existing under the laws of Delaware, with its principal offices located in Burlington, New Jersey.

Staff Allegations

4. On multiple occasions and during various periods from November 2003 to January 2012, Burlington and its subsidiaries sold and/or held for sale various styles, models, and quantities of children's upper outerwear products with drawstrings at the neck, including, but not limited to, the following: Liberty Apparel Company, Inc.—Jewel hooded sweatshirts; Jason Evans Associates, LLC—Bay Trading hooded sweatshirts and jackets; Koman Sportswear Manufacturing Corporation—hooded sweatshirts and jackets; Fashion Options, Inc.—Beverly Hills Polo Club hooded sweatshirts; Allura Imports, Inc.—Major Diva hooded sweatshirts; Baycreek, Inc.—Attitude Gold hooded sweatshirts; Franshaw, Inc.—Blue Heart and Just a Girl hooded sweatshirts; Bobens Trading Company, Inc.—Old Skool hooded sweatshirts; Weeplay Kids, LLC—Candy Queen and AKDMKS hooded sweatshirts; Ten West Apparel, Inc.—hooded jackets; Brand Evolution LLC—All Over Locks, All Over Skaters, and Rock Mask Hoody hooded sweatshirts; Regaliti, Inc.—Betty Blue hooded jackets; Byer California—jackets; Haselson International Trading, Inc.—Kani Gold and Roadblock hooded sweatshirts; Bubblegum USA—hooded jackets; North-Sportif, Inc.—hooded jackets; Five Star Apparel—hooded jackets; Trendset Originals LLC—Shampoo hooded jackets; Hind Fashions, Inc.—Hind leather and Lil Phat hooded jackets; Lollytogs, Ltd.—Rim Rocka hooded sweatshirts; S. Rothschild & Company, Inc.—wool coats; AJS Group LLC—Apple Bottom hooded jackets; Millennium Apparel Group Inc.—Disney Winnie the Pooh hooded jackets; and Winco USA, Inc.—Sergio Benini hooded jackets. The products identified in this paragraph are collectively referred to herein as ''Garments.''

5. Burlington sold the Garments, and/or held the Garments for sale, to consumers.

6. The Garments are ''consumer product[s],'' and, at all relevant times, Burlington was a ''retailer'' of those consumer products, which were ''distributed in commerce,'' as those terms are defined in CPSA sections 3(a)(5), (8), and (13), 15 U.S.C. § 2052(a)(5), (8), and (13).

7. In February 1996, Staff issued the Guidelines for Drawstrings on Children's Upper Outerwear (''Guidelines'') to help prevent children from strangling or entangling on neck and waist drawstrings. The Guidelines state that drawstrings can cause, and have caused, injuries and deaths when they catch on items such as playground equipment, bus doors, or cribs. In the Guidelines, Staff recommends that no children's upper outerwear in sizes 2T to 12 be manufactured or sold to consumers with hood and neck drawstrings.

8. In June 1997, ASTM adopted a voluntary standard (ASTM F1816–97) incorporating the Guidelines. The Guidelines state that firms should be aware of the hazards associated with drawstrings and should ensure that garments they sell conform to the voluntary standard.

9. On May 19, 2006, the Commission posted on its Web site a letter from the Commission's Director of the Office of Compliance to manufacturers, importers, and retailers of children's upper outerwear. The letter urges them to make certain that all children's upper outerwear sold in the United States complies with ASTM F1816–97. The letter states that Staff considers children's upper outerwear with drawstrings at the hood or neck area to be defective and to present a substantial risk of injury to young children under Federal Hazardous Substances Act (''FHSA'') section 15(c), 15 U.S.C. § 1274(c). The letter also references the CPSA's section 15(b) (15 U.S.C. § 2064(b)) reporting requirements.

10. Staff provided Burlington with multiple direct notifications of the hazards associated with drawstrings on children's upper outerwear.

11. Burlington's distribution in commerce of the Garments did not comply with the Guidelines or ASTM F1816–97, failed to comport with Staff's May 2006 defect notice, and posed strangulation hazards to children.

12. Burlington informed the Commission that there had been no reported incidents or injuries associated with the Garments.

13. The Commission, in cooperation with Burlington and/or other firms that were the Garments' manufacturers, importers, or distributors, announced recalls of the Garments.

14. Based in part on information available through the sources set forth in paragraphs 7 through 10, Burlington had presumed and actual knowledge that the Garments distributed in commerce posed strangulation hazards and presented substantial risks of injury to children under FHSA section 15(c)(1), 15 U.S.C. § 1274(c)(1). Burlington obtained information that reasonably supported the conclusion that the Garments contained defects that could create substantial product hazards or that the Garments created unreasonable risks of serious injury or death. Pursuant to CPSA sections 15(b)(3) and (4), 15 U.S.C. § 2064(b)(3) and (4), Burlington was required to inform the Commission immediately of these defects and risks.

15. Burlington knowingly and repeatedly failed to inform the Commission immediately about the Garments, as required by CPSA sections 15(b)(3) and (4), 15 U.S.C. § 2064(b)(3) and (4), and as the term ''knowingly'' is defined in CPSA section 20(d), 15 U.S.C. § 2069(d). These knowing failures violated CPSA section 19(a)(4), 15 U.S.C. § 2068(a)(4). Pursuant to CPSA section 20, 15 U.S.C. § 2069, these knowing failures subjected Burlington to civil penalties.

16. On repeated occasions from in or about September 2008 to January 2012, Burlington offered Garments for sale, sold Garments, and/or otherwise distributed Garments in commerce that were subject to voluntary corrective actions taken by the Garments' manufacturers in consultation with the Commission. The Commission had notified the public of those voluntary corrective actions.

17. Burlington knowingly engaged in the acts alleged in paragraph 16, as the term ''knowingly'' is defined in CPSA section 20(d), 15 U.S.C. § 2069(d). These knowing acts violated CPSA section 19(a)(2)(B), 15 U.S.C. § 2068(a)(2)(B). Pursuant to CPSA section 20, 15 U.S.C. § 2069, these knowing acts subjected Burlington to civil penalties.

18. Staff denies and/or does not concur with Burlington's responsive allegations below.

Burlington Responsive Allegations

19. Burlington denies Staff's allegations above, including but not limited to any claim that Burlington failed to timely report to the Commission the sale or distribution of any children's upper outerwear products with drawstrings pursuant to § 15(b) of the CPSA, or that Burlington knowingly offered Garments for sale, knowingly sold Garments, and/or otherwise knowingly distributed Garments in commerce that were subject to voluntary corrective actions.

20. Burlington enters into the Agreement to settle this matter without the expense of litigation. Burlington enters into the Agreement and agrees to pay the amount referenced below in compromise of disputed and unproven allegations. Burlington's entering into the Agreement is not an admission of liability of any kind, whether legal or factual.

21. Burlington did not manufacture the Garments. It purchased them from vendors and other suppliers. Consistent with practice in the retail industry, Burlington contractually required the Garment vendors to supply products that complied with all federal, state, and local laws, regulations, and standards, and relied on its suppliers to provide compliant products, as the suppliers were in the best position to know and understand the many legal requirements that were or potentially were applicable to their products.

22. Since the Commission first issued the Guidelines in 1996, Burlington's children's apparel purchasing policy has prohibited Burlington's apparel buyers from purchasing children's upper outerwear with drawstrings. Prior to 2009, Burlington's management had procedures in place that it reasonably believed prevented the purchase of children's upper outerwear products with drawstrings. Upon learning in 2009 that, despite such procedures, certain Garments had been discovered in Burlington's stores, Burlington undertook an extensive manual audit of all children's upper outerwear in all of its stores to determine whether it had unknowingly purchased other products subject to the Guidelines. This audit was a massive undertaking, as Burlington's personnel in all of its approximately 450 stores at that time had to visually inspect all items of children's upper outerwear, and the Guidelines and ASTM standard contain ambiguities that made it difficult to determine whether certain items failed to comply.

23. Prior to the audit, Burlington's product compliance and safety personnel and children's apparel buyers had no knowledge, whether actual or constructive, that the Garments actually supplied by Burlington's suppliers contained drawstrings. Burlington promptly notified the Commission pursuant to § 15(b) of the CPSA upon discovering as a result of the audit that it had purchased and sold many of the Garments.

24. Burlington is unaware of any incidents or injuries associated with the Garments.

Agreement of the Parties

25. Under the CPSA, the Commission has jurisdiction over this matter and over Burlington.

26. The parties enter into the Agreement for settlement purposes only. The Agreement does not constitute an admission by Burlington, or a determination by the Commission, that Burlington knowingly violated the CPSA.

27. The Agreement is a full and complete resolution between Staff and Burlington, and its parents, shareholders, divisions, subdivisions, subsidiaries, partners, sister companies and their successors and assigns of all claims for civil penalties that have been or could have been asserted based on the facts contained in Staff's allegations above, with regard to the failure to report the Garments or sale of the Garments after corrective action.

28. In settlement of Staff's allegations, Burlington shall pay a civil penalty in the amount of one million five hundred thousand dollars ($1,500,000.00). The civil penalty shall be paid within twenty (20) calendar days of service of the Commission's final Order accepting the Agreement. The payment shall be made via www.pay.gov.

29. Burlington agrees that it will not seek or accept, directly or indirectly, indemnification, reimbursement, insurance, or any other form of compensation or payment, including, but not limited to, cash, account credit, or set-off, from any vendor or supplier from which Burlington acquired the Garments, or from any other firm or person, for the civil penalty that Burlington agrees and is ordered to pay pursuant to the Agreement and Order.

30. Upon provisional acceptance of the Agreement, the Agreement shall be placed on the public record and published in the **Federal Register**, in accordance with the procedures set forth in 16 C.F.R. § 1118.20(e). In accordance with 16 C.F.R. § 1118.20(f), if within fifteen (15) calendar days, the Commission does not receive any written request not to accept the Agreement, the Agreement shall be deemed finally accepted on the sixteenth (16th) calendar day after the date it is published in the **Federal Register**.

31. Upon the Commission's final acceptance of the Agreement and issuance of the final Order, Burlington knowingly, voluntarily, and completely waives any rights it may have in this matter to the following: (1) An administrative or judicial hearing; (2) judicial review or other challenge or contest of the validity of the Order or of the Commission's actions; (3) a determination by the Commission of whether Burlington failed to comply with the CPSA and its underlying regulations; (4) a statement of findings of fact and conclusions of law; and (5) any claims under the Equal Access to Justice Act.

32. The Commission may publicize the terms of the Agreement and the Order.

33. The Agreement and the Order shall apply to, and be binding upon, Burlington and each of its successors and assigns.

34. The Commission issues the Order under the provisions of the CPSA, and a violation of the Order may subject Burlington and each of its successors and assigns to appropriate legal action.

35. The Agreement may be used in interpreting the Order. Understandings, agreements, representations, or interpretations apart from those contained in the Agreement and the Order may not be used to vary or contradict their terms. The Agreement shall not be waived, amended, modified, or otherwise altered without written agreement thereto executed by the party against whom such waiver, amendment, modification, or alteration is sought to be enforced. The Agreement may be executed in counterparts.

36. If any provision of the Agreement and the Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Agreement and the Order, such provision shall be fully severable. The balance of the Agreement and the Order shall remain in full force and effect, unless the Commission and Burlington agree that severing the provision materially affects the purpose of the Agreement and the Order.

Burlington Coat Factory Warehouse Corporation

Dated: *June 29, 2012.*

By: _____

Paul Tang,
Executive Vice President and General Counsel, 1830 Route 130, Burlington, NJ 08016.

Dated: *July 3, 2012.*

By: _____

Jeffrey B. Margulies, Esq.
William L. Troutman, Esq.
Fulbright & Jaworski L.L.P., 555 South Flower Street, 41st Floor, Los Angeles, CA 90071.
Counsel—Burlington Coat Factory Warehouse Corporation.

U.S. Consumer Product Safety Commission Staff.

Cheryl A. Falvey,
General Counsel.

Mary B. Murphy,
Assistant General Counsel, Office of the General Counsel.

Dated: *July 12, 2012*

By: _____

Seth B. Popkin,
Lead Trial Attorney, Division of Compliance, Office of the General Counsel.

UNITED STATES OF AMERICA

CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of Burlington Coat Factory Warehouse Corporation

CPSC Docket No. *12–C0008*

ORDER

Upon consideration of the Settlement Agreement entered into between Burlington Coat Factory Warehouse Corporation (''Burlington'') and U.S. Consumer Product Safety Commission (''Commission'') staff, and the Commission having jurisdiction over the subject matter and over Burlington, and it appearing that the Settlement Agreement and the Order are in the public interest, it is

Ordered, that the Settlement Agreement be, and hereby is, accepted; and it is

Further ordered, that Burlington shall pay a civil penalty in the amount of one million five hundred thousand dollars ($1,500,000.00) within twenty (20) calendar days of service of the Commission's final Order accepting the Agreement. The payment shall be made via *www.pay.gov.* Upon the failure of Burlington to make the foregoing payment when due, interest on the unpaid amount shall accrue and be paid by Burlington at the federal legal rate of interest set forth at 28 U.S.C. § 1961(a) and (b).

Provisionally accepted and provisional Order issued on the *25th* day of *July,* 2012.

By Order of the Commission:

_____

Todd A. Stevenson,
Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–18459 Filed 7–27–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

Application for New Awards; Charter Schools Program (CSP)—Charter School Exemplary Collaboration Awards

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information

Charter Schools Program (CSP)—Charter School Exemplary Collaboration Awards

Notice inviting applications for new awards for fiscal year (FY) 2012.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.282P.

DATES: *Applications Available:* July 30, 2012.

Date of Pre-Application Webinar: August 6, 2012 from 2:30 p.m. to 4:30 p.m.

Deadline for Transmittal of Applications: August 29, 2012.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Charter Schools Program (CSP) is to increase national understanding of the charter schools model by—

(1) Providing financial assistance for the planning, program design, and initial implementation of charter schools;

(2) Evaluating the effects of charter schools, including the effects on students, student academic achievement, staff, and parents;

(3) Expanding the number of high-quality charter schools available to students across the Nation; and

(4) Encouraging the States to provide support to charter schools for facilities financing in an amount that is more commensurate with the amount States have typically provided for traditional public schools.

The purpose of the Collaboration Awards competition (CFDA 84.282P) is to encourage high-quality public charter schools (as defined in this notice) to partner with non-chartered public schools and non-chartered LEAs to share and transfer best educational and operational practices, and to disseminate information about such practices. By promoting strong partnerships and supporting the dissemination of information about the activities carried out through these partnerships, these Collaboration Awards should facilitate the exchange of best practices between public charter schools, non-chartered public schools, and non-chartered LEAs; and help the United States Department of Education (Department) identify and publicize successful collaborations. The Collaboration Awards competition is designed to encourage public charter schools, non-chartered public schools, and non-chartered LEAs to share resources and responsibilities; build trust and teamwork; boost academic excellence; and provide students and their parents with a range of effective educational options. The Department, through the Collaboration Awards competition, aims to increase national understanding of the charter school model.

Priority: This notice includes one competitive preference priority from the notice of final supplemental priorities and definitions for discretionary grant programs published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637).

Competitive Preference Priority: For FY 2012 and any subsequent year in which we make awards based on the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to 5 points to an applicant, depending on how well the applicant meets this competitive preference priority.

Note: In order to receive preference under this competitive preference priority, the applicant must specify that it is responding to this competitive preference priority.

Competitive Preference Priority 1—-Turning Around Persistently Lowest-Achieving Schools (up to 5 points).

To meet this priority, projects must be designed to address one or more of the following priority areas:

(a) Improving student achievement (as defined in this notice) in persistently lowest-achieving schools (as defined in this notice).

(b) Increasing graduation rates (as defined in this notice) and college enrollment rates for students in persistently lowest-achieving schools (as defined in this notice).

(c) Providing services to students enrolled in persistently lowest-achieving schools.

Note: For purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009 or FY 2010 applications to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *http://www2.ed.gov/programs/sif/index.html.*

Definitions: In addition to the definitions in section 5210 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), which include the definition of ''charter school,'' the following definitions apply to this Collaboration Awards competition. These definitions are from the notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637); and from the final definitions, requirements, and selection criteria for this program, published elsewhere in this issue of the **Federal Register**.

Collaboration means the activities of a partnership in which two or more organizations or entities work together to accomplish a common goal, which may involve sharing or transferring best practices or strategies.

Graduation rate is the four-year or extended-year adjusted cohort graduation rate as defined by 34 CFR 200.19(b)(1) and may also include an extended-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1)(v) if the State in which the proposed project is implemented has been approved by the Secretary to use such a rate under Title I of the ESEA.

High-quality charter school means a charter school (as defined in section 5210(1) of the ESEA) that has no significant compliance issue (as defined in this notice) and shows evidence of strong academic results for the past three years (or over the life of the school if the school has been open for fewer than three years), based on the following factors:

(1) Increased student achievement (as defined in this notice) and attainment for all students, including, as applicable, educationally disadvantaged students served by the charter school.

(2) Either—

(i) Demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school; or

(ii) No significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school and significant gains in student achievement (as defined in this notice) with all populations of students served by the charter school.

(3) Results (including, where applicable and available, performance on statewide tests, attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates) for low-income and other educationally disadvantaged students served by the charter school that are above the average achievement results for such students in the State.

Persistently lowest-achieving school means, as determined by the State: (i) Any Title I school in improvement, corrective action, or restructuring that (a) is among the lowest-achieving five percent of Title I schools in improvement, corrective action, or

restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or (b) is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and (ii) any secondary school that is eligible for, but does not receive, Title I funds that (a) is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or (b) is a high school that has had a graduation rate as identified in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

To identify the persistently lowest-achieving schools, a State must take into account both: (i) The academic achievement of the ''all students'' group in a school in terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and (ii) the school's lack of progress on those assessments over a number of years in the ''all students'' group.

Non-chartered local educational agency (LEA) means an LEA that does not qualify as a charter school as defined in section 5210(1) of the ESEA or under State law.

Non-chartered public school means a public school that does not qualify as a charter school under section 5210(1) of the ESEA or under State law.

Significant compliance issue means a violation that did, will, or could lead to the revocation of a school's charter.

Student achievement means—

(a) For tested grades and subjects: (1) A student's score on the State's assessments under the ESEA; and (2) as appropriate, other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across schools.

(b) For non-tested grades and subjects: Alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools.

Program Authority: The CSP is authorized under 20 U.S.C. 7221–7221i; CSP national activities are authorized under 20 U.S.C. 7221d.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 76, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department suspension and debarment regulations in 2 CFR part 3485. (c) The notice of final definitions, requirements, and selection criteria for this program published elsewhere in this issue of the **Federal Register**. (d) The notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $500,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2013 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $50,000 to $200,000 per award.

Estimated Number of Awards: 3 to 5.

Note: The Department is not bound by any estimates in this notice.

Project Period: 12 to 24 months.

III. Eligibility Information

1. *Eligible Applicants:*

(a) Eligible applicants must be high-quality charter schools (as defined in this notice) that apply in partnership with at least one non-chartered public school (as defined in this notice) or non-chartered LEA (as defined in this notice) and have the support of the partner(s) to participate in the Collaboration Awards competition in accordance with the requirements in the Application Requirements section of this notice. Other public charter schools that do not qualify as high-quality charter schools may be included in the collaboration so long as: (1) The lead applicant is a high-quality charter school; (2) the lead applicant is separate and distinct from any other charter schools included as partners in the collaboration; and (3) at least one non-chartered public school (as defined in this notice) or non-chartered LEA (as defined in this notice) also is a part of the collaboration.

(b) The partnership must comply with the requirements for group applications set forth in 34 CFR 75.127–75.129.

Note: Only an eligible entity (a high-quality charter school) may apply for a grant or be the fiscal agent for a grant. Thus, neither a non-chartered public school (as defined in this notice) nor a non-chartered LEA (as defined in this notice) is eligible to serve as the lead applicant or fiscal agent for a Collaboration Award. Nor is a public charter school that is not a high-quality charter school eligible to serve as the lead applicant or fiscal agent.

(c) Eligible applicants may not have any significant compliance issues (as defined in this notice), including in the areas of student safety, financial management, and statutory or regulatory compliance.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:*

Nancy Paulu or Erin Pfeltz, U.S. Department of Education, 400 Maryland Avenue SW., room 4W246, Washington, DC 20202–5970. Emails and telephone numbers: *nancy.paulu@ed.gov* or (202) 205–5392; *erin.pfeltz@ed.gov* or (202) 205–3525.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting either of the program contact persons listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Additional requirements can be found under the heading, Application Requirements in this document.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. The Secretary strongly encourages applicants to limit Part III to the equivalent of no more than 30 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, you must include all of all of the application narrative in Part III.

3. *Submission of Proprietary Information:* Given the types of projects that may be proposed in an application for the Collaboration Awards competition, your application may include business information that you consider to be proprietary. The Department's regulations define ''business information'' in 34 CFR 5.11.

Note: Because the Department plans to make successful applications and information about their activities available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4 of the Freedom of Information Act. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

4. *Submission Dates and Times:*

Applications Available: July 30, 2012.

Date of Pre-Application Webinar: The Department will hold a pre-application webinar for prospective applicants on the following date: August 6, 2012 from 2:30 p.m. to 4:30 p.m. Individuals interested in attending the webinar are encouraged to pre-register by emailing their name, organization, and contact information with the subject heading COLLABORATION AWARDS PRE-APPLICATION WEBINAR to Charterschools.ed.gov. There is no registration fee for participating in the webinar.

For further information about the pre-application webinar, contact Nancy Paulu or Erin Pfeltz, U.S. Department of Education, 400 Maryland Avenue SW., room 4W246, Washington, DC 20202–5970. Emails and telephone numbers: *nancy.paulu@ed.gov* or (202) 205–5392; *erin.pfeltz@ed.gov* or (202) 205–3525.

Deadline for Transmittal of Applications: August 29, 2012.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact either of the persons listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

5. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, for this competition, intergovernmental review has been waived so that awards can be made by September 30, 2012, the end of the fiscal year.

6. *Funding Restrictions:* A Collaboration Award recipient must use the grant funds for one or more of the following:

(a) Continuing the collaboration for which it received the award, as described in its grant application;

(b) Modifying the collaboration for which it received the award, as described in the grant application;

(c) Expanding the collaboration for which it received the award by adding additional areas of collaboration, as described in the grant application;

(d) Expanding the collaboration for which it received the award by adding additional partners (i.e., non-chartered public schools (as defined in this notice), non-chartered LEAs (as defined in this notice) or public charter schools that are not high-quality charter schools (as defined in this notice)), as described in the grant application. Collaboration Award recipients also must use a portion of the grant funds to disseminate information about the collaboration activities to other public schools, including public charter schools, non-chartered public schools (as defined in this notice), and non-chartered LEAs (as defined in this notice). All activities carried out under the Collaboration Awards must fall within the scope of authorized activities set forth in section 5205(a) of the ESEA.

We reference other regulations outlining funding restrictions in the Applicable Regulations section in this notice.

7. *Data Universal Numbering System Number, Taxpayer Identification Number, Central Contractor Registry, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR)—and, after July 24, 2012, with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR or SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days to complete. Information about SAM is available at SAM.gov.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

8. *Other Submission Requirements.* Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Exemplary Charter School Collaboration Awards competition, CFDA number 84.282P, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for CSP at *www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.282, not 84.282P).

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system;

and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date

falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Nancy Paulu or Erin Pfeltz, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W246, Washington, DC 20202–5970. FAX: (202) 205–5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.282P, LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.282P, 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Application Requirements:* An applicant for a Collaboration Award must—

(a) Provide a detailed narrative describing (i) the applicant's past or existing collaboration (which may involve more than one partner); (ii) the applicant's proposal to continue, modify, or expand (by adding new areas of collaboration or new partners) the collaboration; and (iii) the applicant's plan to disseminate information about the collaboration (which may include information about best practices) to other public schools, including public charter schools, non-chartered public schools, and non-chartered LEAs. The proposed collaboration may focus on a wide range of areas within the scope of activities authorized under section 5205(a) of the ESEA. The list of potential areas includes, but is not limited to, curriculum and instruction, data management and sharing, organization and management, personnel, facilities, finances, Federal programs, standards, assessments, special education services and access to charter schools by students with disabilities, English learners, student transportation, professional development and training, and school climate.

(b) Provide written assurances from authorized officials of the entities involved in the partnership that all participants—

- Agree to submit an application for an award under the competition and have read, understand, and agree with the application for the competition; and
- Authorize the executive summary or narrative of the application, with proprietary information redacted, to be published on the U.S. Department of Education's Web site (ed.gov), data.ed.gov, the National Charter School Resource Center Web site (charterschoolcenter.org), or any other Web site or publication deemed appropriate by the Secretary;

(c) Submit a partnership agreement that meets the requirements of 34 CFR 75.128(b);

(d) Provide a clear description of the goals and desired outcomes of the proposed collaboration and current or proposed measures that would be used to gauge success in meeting those goals and desired outcomes;

(e) Describe any past, existing, or anticipated obstacles to implementing the collaboration or to disseminating information about the collaboration, and the strategies that were or will be used to overcome those obstacles;

(f) Specify how the award money will be used to implement the collaboration and to disseminate information about the collaboration in accordance with section 5205(a) of the ESEA; and

(g) Specify how the award money will be allocated between the lead applicant and the partner(s) named in the application, including the specific activities that will be carried out by the lead applicant and its partner(s).

2. *Selection Criteria:* The selection criteria for this competition (84.282P) are from the notice of final definitions, requirements, and selection criteria for this program; published elsewhere in this issue of the **Federal Register**; as well as from section 34 CFR 75.210 of EDGAR. The maximum possible score for addressing all of the criteria in this section is 95 points (up to 5 additional points can be awarded under the competitive preference priority). The maximum possible score for each criterion is indicated in parentheses following the criterion.

The Secretary may make awards to the top-rated applications proposing to carry out activities in specific areas of focus (e.g., curriculum and instruction, data management and sharing, organization and management) within the scope of authorized activities under

section 5205(a) of the ESEA. In a particular year, the Secretary may restrict applications to one or more areas of focus. Additionally, in making awards, the Secretary may fund applications out of rank order in order to ensure that the Collaboration Awards are distributed throughout each area of the Nation or a State.

In evaluating an application for a Collaboration Award, the Secretary considers the following criteria:

(a) *Record of and potential for success of collaboration (up to 15 points).*

(1) The extent to which the applicant's past or existing collaboration has improved educational outcomes and operational practices; and

(2) The extent to which the applicant's proposed collaboration and dissemination plan will achieve one or more of the following demonstrable results:

(i) Improved operational practices and productivity among all partners in such areas as financial performance and sustainability, governing board performance and stewardship, and parent and community engagement;

(ii) Improved student achievement (as defined in this notice);

(iii) Improved student attendance and retention, and improved high school graduation rates;

(iv) Improved rates of college matriculation and college graduation;

(v) Improved rates of attendance and graduation from other postsecondary (i.e., non-college) institutions or programs.

(b) *Quality of the lead applicant (up to 15 points).*

(1) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in significantly increasing student achievement (as defined in this notice) and attainment for all students, including, as applicable, educationally disadvantaged students served by the charter school.

(2) Either—

(i) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school; or

(ii) The degree, including the consistency over the past three years, to which there have not been significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter school and to which significant gains in student achievement (as defined in this notice) have been made with all populations of students served by the charter school.

(3) The degree, including the consistency over the past three years, to which the applicant has achieved results (including, where applicable and available, performance on statewide tests, student attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates) for students from low-income families and other educationally disadvantaged students served by the charter school that are above the average academic achievement results for such students attending other public schools in the State.

(c) *Quality of the project design (up to 15 points).* The extent to which the applicant proposes a high-quality plan to use its Collaboration Award funds to improve educational outcomes and operational practices in public schools, including public charter schools.

(d) *Potential for scalability (up to 15 points).* The extent to which the applicant's proposed collaboration can be replicated or adapted beyond the participating partners by other public schools or LEAs, including public charter schools and charter school LEAs, and sustained over the long-term.

(e) *Innovation (up to 15 points).* The extent to which the applicant demonstrates that its proposed collaboration, as well as its dissemination plan, are either (i) substantially different from other efforts in its area of focus; or (ii) substantially more effective than similar efforts in its area of focus.

(f) *Quality of project personnel (up to 10 points).* The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator; and

(ii) The qualifications, including relevant training and experience, of key project personnel.

(g) *Quality of the management plan (up to 10 points).* The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the Applicable Regulations section of this notice.

We reference the regulations outlining the terms and conditions of an award in the Applicable Regulations section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to

comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* One goal of the CSP is to support the creation and development of a large number of high-quality charter schools (as defined in this notice) that are free from State or local rules that inhibit flexible operation, are held accountable for enabling students to reach challenging State performance standards, and are open to all students. The Secretary has two performance indicators to measure progress toward this goal: (1) The number of high-quality charter schools in operation around the Nation, and (2) the percentage of fourth- and eighth-grade charter school students who are achieving at or above the proficient level on State examinations in mathematics and in reading/language arts. Additionally, the Secretary has established the following measure to examine the efficiency of the CSP: Federal cost per student in implementing a successful school (defined as a school in operation for three or more consecutive years).

5. *Continuation Awards:* The Secretary may make continuation awards under this competition. In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Nancy Paulu or Erin Pfeltz, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W246, Washington, DC 20202–5970. Emails and telephone numbers: *nancy.paulu@ed.gov* or (202) 205–5392; *erin.pfeltz@ed.gov* or (202) 205–3525.

If you use a TDD or TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., Braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 25, 2012.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2012–18577 Filed 7–27–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Labor Relations collection. The collection requests information from the Department of Energy Management and Operation and Facilities Management Contractors for contract administration, management oversight and cost control. The information collection will assist the Department in evaluating the implementation of the contractors' work force collective bargaining agreements, and apprise the Department of significant labor-management developments at DOE contractor sites. This information is used to ensure that Department contractors maintain good labor relations and retain a workforce in accordance with the terms of their contract and in compliance with statutory and regulatory requirements as identified by contract.

DATES: Comments regarding this collection must be received on or before August 29, 2012. 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, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4650.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503. And to: Eva M. Auman, Attorney-Advisor (Labor), GC–63, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, or by fax at 202–586–0971 or by email to *eva.auman@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: Eva M. Auman, Attorney-Advisor (Labor), GC–63, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, or by fax at 202–586–0971 or by email to *eva.auman@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5143; (2) *Information Collection Request Title:* This information collection was originally titled Legacy Management Labor Relations, but due to the transfer of this function from the Office of Legacy Management to the Office of General

Counsel, the title has been shortened to Labor Relations; (3) *Type of Request:* Renewal; (4) *Purpose:* The proposed collection will request information from the Department of Energy Facilities Management Contractors for contract administration, management oversight and cost control. This information is used to ensure that Department contractors maintain good labor relations and retain a workforce in accordance with the terms of their contract and in compliance with statutory and regulatory requirements as identified by contract. The respondents are Department Management and Operations and Facility Management Contractors; (5) *Annual Estimated Number of Respondents:* 35; (6) *Annual Estimated Number of Total Responses:* 35; (7) *Annual Estimated Number of Burden Hours:* 1.84 per respondent for total of 64.4 per year; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $8,310.80.

Statutory Authority: 42 U.S.C. 7254, 7256.

Issued in Washington, DC, on: July 25, 2012.

Jean S. Stucky,

Assistant General Counsel for Labor and Pension Law, Office of the General Counsel.

[FR Doc. 2012–18496 Filed 7–27–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Briefings on Preliminary Findings of 2012 National Electric Transmission Congestion Study

AGENCY: Office of Electricity Delivery and Energy Reliability, Department of Energy (DOE).

ACTION: Notice of upcoming webinars.

SUMMARY: Section 216(a)(1) of the Federal Power Act (FPA) requires the Department of Energy (Department or DOE) to complete a study of electric transmission congestion every three years. DOE previously issued the 2006 and 2009 studies and is currently developing the 2012 study. DOE, as part of the consultation process, will host three webinars in August 2012 to receive input and suggestions concerning the preliminary findings of the study. After the webinars, DOE will release a draft of the study for public comment. After reviewing and considering the comments received, DOE will publish a final version of the study.

DATES: The webinars are open to the public and will be held on three dates in August:

- Tuesday, August 7, from 2:00 to 3:30 p.m. Eastern.
- Thursday, August 16, from 2:00 to 3:30 p.m. Eastern.
- Tuesday, August 21, from 2:00 to 3:30 p.m. Eastern.

ADDRESSES: Those wishing to participate in these webinars should register in advance at this Web site, *http://energy.gov/node/378523* or use the link to the registration available at the Department's Congestion Study Web site, *http://energy.gov/oe/congestion-study-2012*. At these webinars, DOE will set aside time to allow participants to make comments and direct questions to the presenters. Federal law requires DOE to consult with the states in the preparation of the Congestion Study. Accordingly, although stakeholders may participate in any of the webinars, two of these webinars (August 7 and 21) will focus in particular on state officials' comments and concerns. The third Webinar (August 16) will provide an opportunity to discuss the comments and concerns of all stakeholders.

FOR FURTHER INFORMATION CONTACT: David Meyer, DOE Office of Electricity Delivery and Energy Reliability, *david.meyer@hq.doe.gov,* or call 202–586–1411.

SUPPLEMENTARY INFORMATION: The Energy Policy Act of 2005 (Pub. L. 109–58) (EPAct) added several new provisions to the Federal Power Act (16 U.S.C. 824p) (FPA), including FPA section 216. FPA section 216(a) requires the Secretary of Energy to conduct a study of electric transmission congestion (''National Electric Transmission Congestion Study'' or (Congestion Study)) within one year from the date of enactment of EPAct and every three years thereafter. The 2006 and 2009 Congestion Studies reviewed congestion nationwide except for the portion of Texas covered by the Electricity Reliability Council of Texas, to which FPA section 216 does not apply. The 2012 Congestion Study is being developed with a similar scope. FPA section 216(a) requires the congestion study be conducted in consultation with affected States and regional entities identified in FPA section 215.

DOE intends to release a draft version of the 2012 Congestion Study later in 2012 for public comment. After reviewing and considering the comments received, DOE will issue a final version of the study.

Issued in Washington, DC, on July 20, 2012.

Patricia A. Hoffman,

Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2012–18569 Filed 7–27–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Case No. RF–024]

Petition for Waiver of LG Electronics, Inc. From the Department of Energy Residential Refrigerator and Refrigerator-Freezer Test Procedure and Grant of Interim Waiver

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

ACTION: Notice of Petition for Waiver, Notice of Granting Application for Interim Waiver, and Request for Public Comments.

SUMMARY: This notice announces receipt of a petition for waiver from LG Electronics, Inc. (LG) regarding specified portions of the U.S. Department of Energy (DOE) test procedure for determining the energy consumption of electric refrigerators and refrigerator-freezers. It also grants LG with an interim waiver from that procedure. The waiver request pertains to the basic models set forth in LG's petition that incorporate dual compressors. In its petition, LG provides an alternate test procedure that addresses difficulties in testing dual compressor systems according to the DOE test procedure. DOE solicits comments, data, and information concerning LG's petition and the suggested alternate test procedure.

DATES: DOE will accept comments, data, and information with respect to the LG Petition until, but no later than August 29, 2012.

ADDRESSES: You may submit comments, identified by case number ''RF–024,'' by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Email: AS_Waiver_Requests@ee.doe.gov.* Include the case number [Case No. RF–024] in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J/1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–2945. Please submit one signed original paper copy.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Please submit one signed original paper copy.

Docket: For access to the docket to review the background documents

relevant to this matter, you may visit the U.S. Department of Energy, 950 L'Enfant Plaza SW., Washington, DC 20024; (202) 586–2945, between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. Available documents include the following items: (1) This notice; (2) public comments received; (3) the petition for waiver and application for interim waiver; and (4) prior DOE rulemakings regarding similar refrigerator-freezers. Please call Ms. Brenda Edwards at the above telephone number for additional information.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, U.S. Department of Energy, Building Technologies Program, Mail Stop EE–2J, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *Bryan.Berringer@ee.doe.gov*.

Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–71, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585–0103. Telephone: (202) 586–7796. Email: *Elizabeth.Kohl@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA), Public Law 94–163 (42 U.S.C. 6291–6309, as codified, established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances, which includes the electric refrigerators and refrigerator-freezers that are the focus of this notice.[1] Part B includes definitions, test procedures, labeling provisions, energy conservation standards, and the authority to require information and reports from manufacturers. Further, Part B authorizes the Secretary of Energy to prescribe test procedures that are reasonably designed to produce results which measure the energy efficiency, energy use, or estimated annual operating costs of a covered product, and that are not unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)). The current test procedure for electric refrigerators and electric refrigerator-freezers is contained in 10 CFR part 430, subpart B, appendix A1.

DOE's regulations for covered products contain provisions allowing a person to seek a waiver for a particular basic model from the test procedure requirements for covered consumer products when (1) the petitioner's basic model for which the petition for waiver was submitted contains one or more design characteristics that prevent testing according to the prescribed test procedure, or (2) when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1). Petitioners must include in their petition any alternate test procedures known to the petitioner to evaluate the basic model in a manner representative of its energy consumption characteristics. 10 CFR 430.27(b)(1)(iii).

The Assistant Secretary for Energy Efficiency and Renewable Energy (the Assistant Secretary) may grant a waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 430.27(l). Waivers remain in effect pursuant to the provisions of 10 CFR 430.27(m).

Any interested person who has submitted a petition for waiver may also file an application for interim waiver of the applicable test procedure requirements. 10 CFR 430.27(a)(2). The Assistant Secretary will grant an interim waiver request if it is determined that the applicant will experience economic hardship if the interim waiver is denied, if it appears likely that the petition for waiver will be granted, and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver. 10 CFR 430.27(g).

II. Petition for Waiver of Test Procedure

On May 10, 2012, LG filed a petition for waiver from the test procedure applicable to residential electric refrigerators and refrigerator-freezers set forth in 10 CFR Part 430, Subpart B, Appendix A1. On June 28, 2012, LG amended its request by revising the list of particular models covered by its request. The May 2012 request initially covered a number of LG and Kenmore-branded products; the June 2012 request revised this list to include only certain LG models. LG is seeking a waiver because it is developing new refrigerator-freezers that incorporate a dual compressor design that is not contemplated under DOE's test procedure. In its petition, LG seeks a waiver from the existing DOE test procedure applicable to refrigerators and refrigerator-freezers under 10 CFR Part 430 for LG's dual compressor products. LG states that its dual compressor products use shared compressor systems that are controlled by a 3-way valve. This type of system, LG argues, differ from the independent, sealed systems that the DOE test procedure is designed to address. In its petition, LG has set forth an alternate test procedure and notes in support of its petition that DOE has already granted Sub-Zero a similar waiver pertaining to the use of dual compressor-equipped refrigerators. See 76 FR 71335 (November 17, 2011) (interim waiver) and 77 FR 5784 (February 6, 2012) (Decision and Order).

III. Application for Interim Waiver

LG also requested an interim waiver from the existing DOE test procedure. Under 10 CFR 430.27(b)(2), each application for interim waiver must demonstrate likely success of the petition for waiver and address the economic hardship and/or competitive disadvantage that is likely to result absent a favorable determination on the application for interim waiver.'' An interim waiver may be granted if it is determined that the applicant will experience economic hardship if the application for interim waiver is denied; if it appears likely that the petition for waiver will be granted; and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. 10 CFR 430.27(g).

DOE has determined that LG's application for interim waiver does not provide sufficient market, equipment price, shipments and other manufacturer impact information to permit DOE to evaluate the economic hardship LG might experience absent a favorable determination on its application for interim waiver. DOE recognizes, however, that the DOE test procedure for dual compressor systems primarily addresses independent, sealed systems, which differ from the shared system used by the models listed in LG's petition. As a result, it is not possible to test these products using the DOE test procedure, and use of the test procedure would provide test results so unrepresentative as to provide materially inaccurate comparative data. DOE reviewed the alternate procedure and determined that it will alleviate the testing problems associated with LG's implementation of a dual compressor system. Therefore, it appears likely that LG's petition for waiver will be granted.

For the reasons stated above, DOE grants LG's application for interim waiver from testing of its refrigerator-freezer product line containing dual compressors. Therefore, *it is ordered that:*

[1] For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

The application for interim waiver filed by LG is hereby granted for LG's refrigerator-freezer product lines that incorporate dual compressors subject to the following specifications and conditions:

(1) LG shall be required to test and rate its refrigerator-freezer product line containing dual compressors according to the alternate test procedure as set forth in section IV, ''Alternate test procedure.''

(2) The interim waiver applies to the following basic model groups:

LG Brand

LFX32955**
LFX33955**
LFX34955**
LMX32955**
LMX33955**
LMX34955**

Note: Each ''*'' represents a letter.

DOE makes decisions on waivers and interim waivers for only those models specifically set out in the petition, not future models that may be manufactured by the petitioner. LG may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional models of refrigerator-freezers for which it seeks a waiver from the DOE test procedure. In addition, DOE notes that granting of an interim waiver or waiver does not release a petitioner from the certification requirements set forth at 10 CFR part 429.

Further, this interim waiver is conditioned upon the presumed validity of statements, representations, and documents provided by the petitioner. DOE may revoke or modify this interim waiver at any time upon a determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics.

IV. Alternate Test Procedure

For the duration of the interim waiver, LG shall be required to test the products listed above according to the test procedures for residential electric refrigerator-freezers prescribed by DOE at 10 CFR part 430, subpart B, Appendix A1, except that, for the LG products listed above only, replace the multiple defrost system section 5.2.1.4 of Appendix A1 with the following:

5.2.1.4 Dual Compressor Systems with Dual Automatic Defrost. The two-part test method in section 4.2.1 must be used, and the energy consumption in kilowatt-hours per day shall be calculated equivalent to:

$$ET = (144O \times EP1/T1) + \sum_{i=1}^{D} [(EP2_i - (EP1 \times T2_i/T1)) \times (12/CT_i)]$$

Where:

- 1440 = number of minutes in a day;
- ET is the test cycle energy (kWh/day);
- i is the variable that can equal to 1, 2 or more that identifies the compartment with distinct defrost system;
- D is the total number of compartments with distinct defrost systems;
- EP1 is the dual compressor energy expended during the first part of the test (it is calculated for a whole number of freezer compressor cycles at least 24 hours in duration and may be the summation of several running periods that do not include any precool, defrost, or recovery periods);
- T1 is the length of time for EP1 (minutes);
- EP2i is the total energy consumed during the second (defrost) part of the test being conducted for compartment i. (kWh);
- T2i is the length of time (minutes) for the second (defrost) part of the test being conducted for compartment i.
- CTi is the compressor on time between defrosts for only compartment i. CTi for compartment i with long time automatic defrost system is calculated as per 10 CFR Part 430, Subpart B, Appendix A1 clause 5.2.1.2. CTi for compartment i with variable defrost system is calculated as per 10 CFR part 430 subpart B appendix A1 clause 5.2.1.3. (hours rounded to the nearest tenth of an hour).

Stabilization:

The test shall start after a minimum 24 hours stabilization run for each temperature control setting.

Steady State for EP1:

The temperature average for the first and last compressor cycle of the test period must be within 1.0 [degrees] F (0.6 [degrees] C) of the test period temperature average for each compartment. Make this determination for the fresh food compartment for the fresh food compressor cycles closest to the start and end of the test period. If multiple segments are used for test period 1, each segment must comply with above requirement.

Steady State for EP2i:

The second (defrost) part of the test must be preceded and followed by regular compressor cycles. The temperature average for the first and last compressor cycle of the test period must be within 1.0 [degrees] F (0.6 [degrees] C) of the EP1 test period temperature average for each compartment.

Test Period for EP2i, T2i:

EP2i includes precool, defrost, and recovery time for compartment i, as well as sufficient dual compressor steady state run cycles to allow T2i to be at least 24 hours. The test period shall start at the end of a regular freezer compressor on-cycle after the previous defrost occurrence (refrigerator or freezer). The test period also includes the target defrost and following regular freezer compressor cycles, ending at the end of a regular freezer compressor on-cycle before the next defrost occurrence (refrigerator or freezer). If the previous condition does not meet 24 hours time, additional EP1 steady state segment data could be included. Steady state run cycle data can be utilized in EP1 and EP2i.

Test Measurement Frequency Measurements shall be taken at regular interval not exceeding 1 minute.
[End of 5.2.1.4]

V. Summary and Request for Comments

Through today's notice, DOE grants LG an interim waiver from the specified portions of the test procedure applicable to LG's line of refrigerator-freezers with dual compressors and announces receipt of LG's petition for waiver from those same portions of the test procedure. DOE publishes LG's petition for waiver pursuant to 10 CFR 430.27(b)(1)(iv). The petition includes a suggested alternate test procedure to determine the energy consumption of LG's specified refrigerator-freezers with dual compressors. LG is required to follow this alternate procedure as a condition of its interim waiver, and DOE is considering including this alternate procedure in its subsequent Decision and Order.

DOE solicits comments from interested parties on all aspects of the petition, including the suggested alternate test procedure and calculation methodology. Pursuant to 10 CFR 430.27(b)(1)(iv), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is: John I. Taylor, Vice President, Government Relations and Communications, LG Electronics USA, Inc., 1776 K Street NW., Washington,

DC 20006. All submissions received must include the agency name and case number for this proceeding. Submit electronic comments in WordPerfect, Microsoft Word, Portable Document Format (PDF), or text (American Standard Code for Information Interchange (ASCII)) file format and avoid the use of special characters or any form of encryption. Wherever possible, include the electronic signature of the author. DOE does not accept telefacsimiles (faxes).

According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies to DOE: one copy of the document including all the information believed to be confidential, and one copy of the document with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Issued in Washington, DC, on July 16, 2012.

Kathleen B. Hogan,

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

May 10, 2012
The Honorable David Danielson
Assistant Secretary, Energy Efficiency and Renewable Energy
United States Department of Energy
Mail Station EE–1
Forrestal Building
1000 Independence Avenue SW
Washington, DC 20585
Re: Petition for Waiver and Application for Interim Waiver, *Test Procedure for Refrigerators, Refrigerator-Freezers, and Freezers*
Dear Assistant Secretary Danielson:

LG Electronics, Inc. (LG) respectfully submits this Petition for Waiver and Application for Interim Waiver, pursuant to 10 C.F.R. § 430.27, as related to DOE's test procedure for refrigerators, refrigerator-freezers, and freezers. 10 C.F.R. Part 430, Subpart B, Appendix A1. This request concerns LG refrigerator-freezers that use dual compressors. DOE has already granted Sub-Zero such waivers. 77 Fed. Reg. 5784 (Feb. 6, 2012) (waiver); 76 Fed. Reg. 71335 (Nov. 17, 2011) (interim waiver). LG requests expedited treatment of the Petition and Application.

LG is a manufacturer of refrigerator-freezers and other products sold worldwide, including in the United States. LG's U.S. operations are LG Electronics USA, Inc., with headquarters at 1000 Sylvan Avenue, Englewood Cliffs, NJ 07632 (tel. 201–816–2000). Its worldwide headquarters are located at LG Twin Towers 20, Yoido-dong, Youngdungpo-gu Seoul, Korea 150–721; (tel. 011–82–2–3777–1114); URL: *http.www.LGE.com.* LG's principal brands include LG® and OEM brands, including GE® and Kenmore®.

As DOE states in its grant of a waiver to Sub-Zero, DOE's test procedure for dual compressors under 10 C.F.R. Part 430 assumes independent, sealed systems. In contrast, Sub-Zero's dual compressor products have shared systems. In such circumstances, DOE recognized that it is not possible to test such dual compressor products using the DOE test procedure, and use of the test procedure would provide test results so unrepresentative as to provide materially inaccurate comparative data. 77 Fed. Reg. at 5784–85. DOE determined that an alternative test procedure set forth in the waiver would alleviate the testing problems associated with Sub-Zero's implementation of a dual compressor system while accurately measuring the energy consumption of these dual products. Id. at 5785.

The factors in the Sub-Zero waiver apply equally to LG dual compressor products. LG's dual compressor products have shared compressor systems, controlled by a 3-way valve, and do not have the independent, sealed systems assumed under the DOE test procedure. Therefore, as recognized by DOE, it is not possible to test such products using the DOE test procedure, and use of the test procedure would provide test results so unrepresentative as to provide materially inaccurate comparative data.

LG requests that DOE grant a waiver that would provide for its dual compressor products set forth in Appendix I of this waiver request the following alternative test procedure consistent with the waiver provided to Sub-Zero:

LG shall be required to test the products listed in Appendix I of this waiver request according to the test procedures for electric refrigerator-freezers prescribed by DOE at 10 CFR Part 430, Subpart B, Appendix A1, except that, for the LG products listed in Appendix I of this waiver request only, replace the multiple defrost system section 5.2.1.4 of Appendix A1 with the following:

5.2.1.4 Dual Compressor Systems with Dual Automatic Defrost. The two-part test method in section 4.2.1 must be used, and the energy consumption in kilowatt-hours per day shall be calculated equivalent to:

$$ET = (144O \times EP1/T1) + \sum_{i=1}^{D} [(EP2_i - (EP1 \times T2_i/T1)) \times (12/CT_i)]$$

Where:

- **1440 = number of minutes in a day**
- **ET is the test cycle energy (kWh/day);**
- **i is the variable that can equal to 1, 2 or more that identifies the compartment with distinct defrost system;**
- **D is the total number of compartments with distinct defrost systems;**
- **EP1 is the dual compressor energy expended during the first part of the test (it is calculated for a whole number of freezer compressor cycles at least 24 hours in duration and may be the summation of several running periods that do not include any precool, defrost, or recovery periods);**
- **T1 is the length of time for EP1 (minutes);**
- **EP2i is the total energy consumed during the second (defrost) part of the test being conducted for compartment i. (kWh);**
- **T2i is the length of time (minutes) for the second (defrost) part of the test being conducted for compartment i.**
- **CTi is the compressor on time between defrosts for only compartment i. CTi for compartment i with long time automatic defrost system is calculated as per 10 CFR Part 430, Subpart B, Appendix A1 clause 5.2.1.2. CTi for compartment i with variable defrost system is calculated as per 10 CFR part 430 subpart B appendix A1 clause 5.2.1.3. (hours rounded to the nearest tenth of an hour).**

Stabilization:

The test shall start after a minimum 24 hours stabilization run for each temperature control setting.

Steady State for EP1:

The temperature average for the first and last compressor cycle of the test

period must be within 1.0 [degrees] F (0.6 [degrees] C) of the test period temperature average for each compartment. Make this determination for the fresh food compartment for the fresh food compressor cycles closest to the start and end of the test period. If multiple segments are used for test period 1, each segment must comply with above requirement.

Steady State for EP2i:

The second (defrost) part of the test must be preceded and followed by regular compressor cycles. The temperature average for the first and last compressor cycle of the test period must be within 1.0 [degrees] F (0.6 [degrees] C) of the EP1 test period temperature average for each compartment.

Test Period for EP2i, T2i:

EP2i includes precool, defrost, and recovery time for compartment i, as well as sufficient dual compressor steady state run cycles to allow T2i to be at least 24 hours. The test period shall start at the end of a regular freezer compressor on-cycle after the previous defrost occurrence (refrigerator or freezer). The test period also includes the target defrost and following regular freezer compressor cycles, ending at the end of a regular freezer compressor on-cycle before the next defrost occurrence (refrigerator or freezer). If the previous condition does not meet 24 hours time, additional EP1 steady state segment data could be included. Steady state run cycle data can be utilized in EP1 and EP2i.

Test Measurement Frequency Measurements shall be taken at regular interval not exceeding 1 minute.

* * * * *

The waiver should continue until DOE adopts an applicable amended test procedure.

LG also requests an interim waiver for its testing and rating of the foregoing models. The petition for waiver is likely to be granted, as evidenced not only by its merits, but also because DOE has granted such a waiver and interim waiver to Sub-Zero. Hence, grant of an interim waiver for LG is appropriate.

We would be pleased to discuss this request with DOE and provide further information as needed.

LG requests expedited treatment of the Petition and Application. In that regard, DOE states in its March 7, 2011 notice concerning its certification, compliance and enforcement rule, ''The Department renews its commitment to act swiftly on waiver requests.'' 76 Fed. Reg. 12422, 12442.[2] LG appreciates this commitment by DOE.

We hereby certify that all manufacturers of domestically marketed units of the same product type have been notified by letter of this petition and application, copies of which letters are set forth in Appendix II hereto.

Sincerely,
John I. Taylor,
Vice President, Government Relations and Communications, LG Electronics USA, Inc., 1776 K Street NW., Washington, DC 20006, Phone: 202–719–3490, Fax: 847–941–8177, Email: john.taylor@lge.com.

Of counsel:

John A. Hodges,
Wiley Rein LLP, 1776 K Street NW., Washington, DC 20006, Phone: 202–719–7000, Fax: 202–719–7049, Email: jhodges@wileyrein.com.

Appendix I

The waiver and interim waiver requested herein should apply to testing and rating of the following model series of refrigerator-freezers. Please note that the actual model numbers will vary to account for such factors as year of manufacture, product color, or other features. Nonetheless, they will always have dual compressors.

(In the chart below, ''#'' represents a number; ''*'' represents a letter.)

LG Brand

LFX3#9##**
LMX3#9##**
LFC3#7##**
LFX2#9##**
LMX2#9##**
LFC2#7##**

Kenmore Brand

795.71###
795.72###
795.73###
795.74###

Appendix II

June 28, 2012
The Honorable David Danielson
Assistant Secretary, Energy Efficiency and Renewable Energy
United States Department of Energy
Mail Station EE–1
Forrestal Building
1000 Independence Avenue SW
Washington, DC 20585
Re: Petition for Waiver and Application for Interim Waiver, *Test Procedure for Refrigerators, Refrigerator-Freezers, and Freezers*
Dear Assistant Secretary Danielson:

LG Electronics, Inc. (LG) hereby respectfully amends its May 10, 2012 Petition for Waiver and Application for Interim Waiver, pursuant to 10 C.F.R. § 430.27, as related to DOE's test procedure for refrigerators, refrigerator-freezers, and freezers. 10 C.F.R. Part 430, Subpart B, Appendix A1. Specifically, LG requests that DOE grant a waiver that would provide for its dual compressor products set forth in Appendix I hereto (rather than the products set forth in Appendix I to its May 10, 2012 submission).

Thank you for consideration of LG's waiver request.

Sincerely,
John I. Taylor,
Vice President, Government Relations and Communications, LG Electronics USA, Inc., 1776 K Street NW., Washington, DC 20006, Phone: 202–719–3490, Fax: 847–941–8177, Email: john.taylor@lge.com.
Of counsel:
John A. Hodges,
Wiley Rein LLP, 1776 K Street NW., Washington, DC 20006, Phone: 202–719–7000, Fax: 202–719–7049, Email: jhodges@wileyrein.com.

Appendix I

The waiver and interim waiver requested herein should apply to testing and rating of the following model series of refrigerator-freezers. Please note that the actual model numbers will vary to account for such factors as year of manufacture, product color, or other features. Nonetheless, they will always have dual compressors.

(In the chart below, ''*'' represents a letter.)

LG Brand

LFX32955**
LFX33955**
LFX34955**
LMX32955**
LMX33955**
LMX34955**

[FR Doc. 2012–18497 Filed 7–27–12; 8:45 am]

BILLING CODE 6450–01–P

[2] DOE goes on to state that ''DOE, as a matter of policy, will refrain from enforcement actions related to a waiver request that is pending with the Department.'' Id.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–2159–001.
Applicants: Canadian Hills Wind, LLC.
Description: Amendment to MBR Application and Tariff Revision to be effective 8/28/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5033.
Comments Due: 5 p.m. ET 8/9/12.

Docket Numbers: ER12–2265–000.
Applicants: Canandaigua Power Partners, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5044.
Comments Due: 5 p.m. ET 8/9/12.

Docket Numbers: ER12–2266–000.
Applicants: Canandaigua Power Partners II, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5046.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2267–000.
Applicants: Evergreen Wind Power, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5049.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2268–000.
Applicants: Evergreen Wind Power III, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5051.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2269–000.
Applicants: Stetson Wind II, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5052.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2270–000.
Applicants: Milford Wind Corridor Phase I, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5054.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2271–000.
Applicants: First Wind Energy Marketing, LLC.
Description: Revisions to Market-Based Rate Tariff to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5055.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2272–000.
Applicants: New York Independent System Operator, Inc.
Description: NYISO Tariff Amendment to Reflect Revisions to ETAs to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5056.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2273–000.
Applicants: Public Service Company of Colorado.
Description: 2012–7–19–Form of Svc Agmt T–L Intercon Svc Filing to be effective 8/1/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5057.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2274–000.
Applicants: Public Service Electric and Gas Company, PJM Interconnection, L.L.C.
Description: PSE&G revises OATT Att H–10A re BRH Abandoned Costs to be effective 9/17/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5121.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2275–000.
Applicants: Lexington Power & Light, LLC.
Description: Baseline New Filing to be effective 7/20/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5131.
Comments Due: 5 p.m. ET 8/9/12.
Docket Numbers: ER12–2276–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM SA No. 3350—Queue #X1–097—Diamond State Gen & Delmarva Pwr & Light to be effective 6/19/2012.
Filed Date: 7/19/12.
Accession Number: 20120719–5134.
Comments Due: 5 p.m. ET 8/9/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 20, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–18502 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–878–000.
Applicants: Tennessee Gas Pipeline Company, LLC.
Description: Clean Up Revenue Sharing Report to be effective 2/1/2012.
Filed Date: 7/23/12.
Accession Number: 20120723–5178.
Comments Due: 5 p.m. ET 8/6/12.
Docket Numbers: RP12–879–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: 2012–07–23 NC Mieco, Cima, Concord to be effective 7/24/2012.
Filed Date: 7/23/12.
Accession Number: 20120723–5198.
Comments Due: 5 p.m. ET 8/6/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP12–245–002.
Applicants: TransColorado Gas Transmission Company L.
Description: Compliance to Filing Reservation Charge Credit to be effective 6/16/2012.
Filed Date: 7/23/12.
Accession Number: 20120723–5149.
Comments Due: 5 p.m. ET 8/6/12.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 24, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–18503 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP12–874–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: 2012–07–19 NCs Concord to be effective 7/20/2012.

Filed Date: 7/19/12.

Accession Number: 20120719–5133.

Comments Due: 5 p.m. ET 7/31/12.

Docket Numbers: RP12–876–000.

Applicants: Ruby Pipeline, L.L.C.

Description: Winter-Time Only Capacity Clarification to be effective 8/20/2012.

Filed Date: 7/20/12.

Accession Number: 20120720–5152.

Comments Due: 5 p.m. ET 8/1/12.

Docket Numbers: RP12–877–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: 2012–07–20 NC Cima, Mieco to be effective 7/21/2012.

Filed Date: 7/20/12.

Accession Number: 20120720–5153.

Comments Due: 5 p.m. ET 8/1/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 23, 2012.

Nathaniel J. Davis, Sr.

Deputy Secretary

[FR Doc. 2012–18445 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner and Staff Attendance at the National Association of Regulatory Utility Commissioners 2012 Summer Committee Meetings

The Federal Energy Regulatory Commission (FERC or Commission) hereby gives notice that members of the Commission and/or Commission staff may attend the following meetings:

Gas and Electricity Interdependencies,July 24, 2012 (10:30 a.m.–1:15 p.m.),Hilton Portland and Executive Tower,921 SW 6th Avenue,Portland, OR 97204;

FERC/National Association of Regulatory Utility Commissioners Forum onReliability and the Environment,July 25, 2012 (8:00 a.m.–12:00 p.m.),Hilton Portland and Executive Tower,921 SW 6th Avenue,Portland, OR 97204.

Further information may be found at *http://summer.narucmeetings.org/agenda.cfm*

The discussions at these meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. AD12–12–000, Coordination between Natural Gas and Electricity Markets.

Docket No. ER12–1178–001, PJM Interconnection, L.L.C.

Docket Nos. ER11–4081–001 and ER11–4081–002, Midwest Independent Transmission System Operator, Inc.

Dated: July 20, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–18439 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–87–000]

Los Angeles Department of Water and Power v. PacifiCorp; Notice of Complaint

Take notice that on July 23, 2012, pursuant to section 206 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission (Commission), 18 CFR 385.206 and section 206 of the Federal Power Act, 16 U.S.C. 824(e), the Los Angeles Department of Water and Power (Complainant) filed a formal complaint against PacifiCorp (Respondent) alleging that, the Respondent is in violation of its Commission approved Open Access Transmission Tariff in attempting to collect unreserved use penalties from the Complainant that function to compensate the Respondent for the difference between its maximum path transfer capacity and the system Operating limits recognized by the Western Electricity Coordinating Council, the regional reliability coordinator.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 13, 2012.

Dated: July 23, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–18504 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR12–31–000]

Enbridge Pipelines (North Texas) L.P.; Notice of Compliance Filing

Take notice that on July 13, 2012, Enbridge Pipelines (North Texas) L.P. filed a revised Statement of Operating Conditions to comply with a Commission order issued in Docket No. PR09–26–000 on June 13, 2012, (139 FERC ¶ 61,216) as more fully detailed in the filing.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on Monday, July 30, 2012.

Dated: July 23, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–18501 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2662–012–CT; Project No. 12968–001–CT]

Notice of Availability of Draft Environmental Assessment

FirstLight Hydro Generating Company, Project No. 2662–012–CT.
City of Norwich Dept. of Public Utilities, Project No. 12968–001–CT.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed competing applications for a new license for the Scotland Hydroelectric Project (Commission Project Nos. 2662–012 and 12968–001). The Scotland Hydroelectric Project is located on the Shetucket River, in Windham County, Connecticut. The existing licensee for the Scotland Hydroelectric Project No. 2662 is FirstLight Hydro Generating Company (FirstLight). The competitor applicant for the Scotland Hydroelectric Project No. 12968 is the City of Norwich Department of Public Utilities (Norwich Public Utilities).

Staff prepared a draft environmental assessment (EA), which analyzes the potential environmental effects of licensing the project with either FirstLight's or Norwich Public Utilities' proposals, and concludes that licensing the project with either proposal, with appropriate environmental protection measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the draft EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *www.ferc.gov* using the ''eLibrary'' link. Enter the docket number for either project, excluding the last three digits, in the docket number field to access the document. For assistance, contact Commission Online Support at *CommissionOnlineSupport@ferc.gov;* toll-free at 1–866–208–3676; or for TTY, 202–502–8659.

You may also register online at *www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to these or other pending projects. For assistance, contact Commission Online Support.

Any comments should be filed within 30 days from the date of this notice. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/doc-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 Commission Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please affix Scotland Hydroelectric Project, P–2662–012 and P–12968–001 to all comments.

For further information, contact Janet Hutzel at (202) 502–8675 or by email at *janet.hutzel@ferc.gov*.

Dated: July 20, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–18438 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC08–5–003]

Notice of Filing; North American Electric Reliability Corporation

Take notice that on July 18, 2012, North American Electric Reliability Corporation (NERC) submitted a filing to comply with the Commission's directive in its April 19, 2012 Order to show cause why the Ohio Valley Electric Corporation (OVEC) should not be registered as a load-serving entity, if NERC did not register OVEC through its compliance registration process. *U.S. Department of Energy, Portsmouth/*

Paducah Project Office, 139 FERC ¶ 61,054 (2012).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 8, 2012.

Dated: July 20, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–18437 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–2261–000]

Russell City Energy Company, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Russell City Energy Company, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is August 13, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 23, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–18505 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of International Meeting

The Federal Energy Regulatory Commission hereby gives notice that the agency will host an international meeting of the Asia Pacific Energy Regulatory (APER) Forum on August 1–2, 2001 at its headquarters, 888 First Street NE., Washington, DC 20426. Commissioners and staff will take part in this event. Commissioner Philip Moeller and Commissioner John R. Norris are co-chairs of the event.

The meetings are expected to begin at 8:30 a.m. and end at 5:00 p.m. Eastern Time on both days. An agenda of the conference is attached to this notice.

Those wishing to attend this event are encouraged to register using the on-line form located at: *https://www.ferc.gov/aper-forum/aper-8-1-12-form.asp.*

The APER Forum was established as a recommendation at the 3rd Energy Regulatory and Market Development Forum, which operated under the Asia-Pacific Partnership on Clean Development and Climate (APP). The APP was an international partnership between the United States, South Korea, Japan, India, Canada, China and Australia aimed at addressing the challenges of climate change, energy security and air pollution in a way that encouraged economic development and reduced poverty. The APER Forum builds upon the work begun under the APP.

The APER Forum is designed to bring together policymakers, regulators, energy industry participants, academics, regulatory research organizations, and grid and market operators from Asian and Pacific countries to engage in meaningful information exchanges on matters relating both to electricity and to natural gas. The APER Forum is voluntary in nature and intends to provide an ongoing experience for information exchange on the development and application of best practices in regulatory and market arrangements. The first meeting was sponsored by Australia and held in 2010.

This year marks the second biennial meeting of the APER Forum. The event will include delegations from the United States, Canada, Australia, China, India, New Zealand, Thailand and Singapore. Other attendees include regulators from Pakistan, Ghana and the Czech Republic. It will focus on three major issues:

Transitioning to a Low-Carbon Economy—examining policy, regulatory arrangements and standards that encourage energy efficiency and clean energy technologies and promote clean investment/delivery (including renewable and alternative energy) with the aim of reducing greenhouse gas emissions.

Energy Infrastructure and Market Regulatory Arrangements—examining challenges and reforms to the operation and design of energy systems within the context of a market.

Competition Reform—examining regulatory, policy and standards matters that influence and encourage competition (wholesale and retail) growth in the market.

The conference will not be transcribed. However, there will be a free webcast. Anyone with Internet access who desires to watch the conference and download presentations can do so by going to the calendar of events on the FERC Web site (*www.ferc.gov*). The Capitol Connection provides technical support for webcasts and offers the option of listening to the meeting via phone-bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or call 703–993–3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

For more information, please contact:

Sarah McKinley, Secretariat, APER Forum, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8004 or 8368, *Sarah.McKinley@ferc.gov.*

Dated: July 20, 2012.

Kimberly D. Bose,

Secretary.

Asia Pacific Energy Regulatory (APER) Forum, Meeting Agenda, Sponsored by the Federal Energy Regulatory Commission

August 1–2, 2012

Day 1, Wednesday, August 1, 2012—Morning

8:30 a.m. Opening Remarks
- Philip Moeller, Commissioner, U.S. Federal Energy Regulatory Commission
- John R. Norris, Commissioner, U.S. Federal Energy Regulatory Commission
- Joseph T. Kelliher, Executive Vice President, Federal Regulatory Affairs, NextEra Energy, former Chairman, U.S. Federal Energy Regulatory Commission and Head of U.S. Delegation, 2010 APER Forum Meeting

Theme—Overview of Energy and Regulatory Structures/APER Members

9:00 a.m. Energy and Regulatory Overview of the United States: Philip Moeller, Commissioner, U.S. Federal Energy Regulatory Commission

9:20 a.m. Energy and Regulatory Overview of Australia: Brendan Morling, Head of Energy and Environment Division, Department of Resources, Energy and Tourism, Australia

9:40 a.m. Energy and Regulatory Overview of China: HE Yang, Director, Department of Power Market Regulation, State Electricity Regulatory Commission, China

10:00 a.m. Break

10:20 a.m. Energy and Regulatory Overview of Canada: John Foran, Director, Natural Resources Canada

10:40 a.m. Energy/Electricity Regulatory Overview of India: Dr. Pramod Deo, Chairman, Central Electricity Regulatory Commission, India

11:00 a.m. Energy and Regulatory Overview of Thailand: Dr. Pallapa Ruanrong, Commissioner, Energy Regulatory Commission

11:20 a.m. Energy and Regulatory Overview of New Zealand: Carl Hansen, Chief Executive, Electricity Authority of New Zealand

12:15 noon Lunch Break

Day 1, Wednesday, August 1, 2012—Afternoon

Theme—Transitioning to a Low-Carbon Economy

2:00 p.m. Carbon Trading and Policies for Low-Carbon Consumption
- Panel Moderator: Brendan Morling, Head of Energy and Environment Division, Department of Resources, Energy and Tourism, Australia
- ○ Presentation on regional carbon trading in California and the U.S. Northeast: Dallas Burtraw, Darius Gaskins Senior Fellow, Resources for the Future, United States
- ○ Guided discussion about carbon policies with the heads of all the delegations

3:00 p.m. Break

3:15 p.m. Smart Grid Technologies that Enhance Efficiency
- Panel Moderator: W. Terry Boston, President and Chief Executive Officer, PJM Interconnection, L.L.C., U.S.
- ○ Presentation: Working toward industry standards for interoperability—David Wollman, Deputy Director, Smart Grid and Cyber-Physical Systems Programs Office, U.S. National Institute of Standards and Technology
- ○ Presentation: Canada smart grid roadmap standards—Michel Fernand Girard, Vice-President, Policy and Stakeholder Relations, Standards Council of Canada
- ○ Presentation: Impacts of new technologies on security of supply—Dr. Brian Spalding, Commissioner, Australian Energy Market Commission (AEMC)
- ○ Discussion with heads of delegation

5:00 p.m. Adjourn

Day 2, Thursday, August 2, 2012—Morning

8:30 a.m. Opening Remarks—Day 2
- Philip Moeller, Commissioner, U.S. Federal Energy Regulatory Commission
- John R. Norris, Commissioner, U.S. Federal Energy Regulatory Commission
- David A. Wright, President, South Carolina Public Service Commission and President of the National Association of Regulatory Utility Commissioners (NARUC)

Theme—Energy Infrastructure and Market Regulations

9:00 a.m. Grid Reliability
- Panel Moderator: John R. Norris, Commissioner, U.S. Federal Energy Regulatory Commission
- ○ Enhancing grid reliability: Cheryl LaFleur, Commissioner, U.S. Federal Energy Regulatory Commission
- ○ Presentation: Network Investments for the Long-Term Interests of Consumers—Andrew Reeves, Chairman, Australian Energy Regulator
- ○ Discussion with heads of delegation

10:00 a.m. Break

10:15 a.m. Renewables in the New Markets
- Panel Moderator: John Pierce, Chairman, Australian Energy Market Commission
- ○ Presentation: Integrating variable energy resources into existing grids—Jon Wellinghoff, Chairman, U.S. Federal Energy Regulatory Commission
- ○ Presentation: Integrating renewables from a reliability perspective—Darren Finkbeiner, Manager, Market Development, Ontario Independent Electricity System Operator (IESO), Canada
- ○ Presentation: Incorporating new technologies onto the grid—Kai

XIE, President, New York Office, State Grid Corporation of China (SGCC)

○ Discussion with heads of delegation

11:45 p.m. Lunch Break

Day 2, Thursday, August 2, 2012—Afternoon

Theme—Competition Reform

1:30 p.m. Market Regulation—Oil and Gas Developments

Panel Moderator: S. Krishnan, Chairperson, Petroleum and Natural Gas Regulatory Board (PNGRB), India

○ Oil Developments in Canada: John Foran, Director, Natural Resources Canada

○ Presentation: Regulatory Framework in Oil & Natural Gas Sector in India—Challenges & Opportunities: Konedana Rajeswara Rao, Petroleum & Natural Gas Regulatory Board (PNGRB), India

○ Impacts of the Shale Gas Revolution Mike McGehee, Director, Division of Pipeline Certificates, Office of Energy Projects, U.S. Federal Energy Regulatory Commission

○ Discussion with heads of delegation

3:00 p.m. Break

3:15 p.m. Impact of Competition on Reliability of Supply

Panel Moderator: Carl Hansen, Chief Executive, Electricity Authority of New Zealand

○ Presentation: Energy network regulation policy and consumer prices—Mr. Brendan Morling, Head of Energy and Environment Division, Department of Resources, Energy and Tourism, Australia

○ Presentation: Building efficient wholesale markets, the RTO/ISO model—Andrew L. Ott, Senior Vice President for Markets, PJM Interconnection L.L.C., United States

○ Discussion with heads of delegation

4:45 p.m. Concluding Remarks

Philip Moeller, Commissioner, U.S. Federal Energy Regulatory Commission

John R. Norris, Commissioner, U.S. Federal Energy Regulatory Commission

[FR Doc. 2012–18440 Filed 7–27–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2012–0579; FRL–9706–3]

Notice of Availability of the External Review Draft of Framework for Human Health Risk Assessment To Inform Decision Making

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a 60-day public comment period for the external review draft of ''*A Framework for Human Health Risk Assessment to Inform Decision Making.''* This document was developed as part of an agencywide program by the EPA Risk Assessment Forum. The EPA is releasing this draft document solely for the purpose of seeking public comment prior to external peer review. The document will undergo independent peer review during an expert peer review meeting that will be convened, organized, and conducted by a contractor of the EPA in 2012. The date of the external peer review meeting will be announced in a subsequent **Federal Register** notice. All comments received by the docket closing date September 28, 2012, will be shared with the external peer review panel for their consideration. Comments received after the close of the comment period may be considered by the agency when it finalizes the document. This document has not been formally disseminated by the EPA. This draft document does not represent and should not be construed to represent the EPA policy, viewpoint, or determination. Members of the public may obtain the external review draft from *www.regulations.gov;* or *www.epa.gov/raf/FrameworkHHRA.htm* or from Julie Fitzpatrick via the contact information below.

This draft document describes a framework for conducting human health risk assessments that are responsive to the needs of decision making processes at the EPA. The document was developed by the EPA, to provide guidance to scientists and decision makers in the EPA.

DATES: All comments received by the docket closing date September 28, 2012 will be shared with the external peer review panel for their consideration. Comments received beyond that time may be considered by the EPA when it finalizes the document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2012–0579, and by one of the following methods:

- *Internet:* Follow the online instructions for submitting comments in *www.regulations.gov.*
- *Email: ORD.Docket@epa.gov.*
- *Mail:* ORD Docket, U.S. Environmental Protection Agency, Mail Code: 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.
- *Hand Delivery:* The EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue NW., Washington, DC 20004, Attention Docket ID EPA–HQ–ORD–2012–0579. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID EPA–HQ–ORD–2012–0579. The EPA policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected by statute through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA, without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly

available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the ORD Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Julie Fitzpatrick, Office of the Science Advisor, Mail Code 8105R, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4212; fax number: (202) 564–2070, Email: *fitzpatrick.julie@epa.gov*.

SUPPLEMENTARY INFORMATION: The EPA has an established history of conducting human health risk assessments. The *Framework* is intended to foster increased implementation of existing agency guidance for conducting human health risk assessments and improve the utility of risk assessment in the decision making process.

In developing the *Framework* the recommendations presented in the National Research Council's report *Science and Decisions: Advancing Risk Assessment* have been taken into consideration. Specifically, this *Framework* addresses the recommendations that the EPA formalize and implement planning, scoping and problem formulations in the risk assessment process and that the agency adopt a framework for risk-based decision making.

The *Framework* highlights the important roles of planning and scoping as well as problem formulation in designing a risk assessment. In accordance with longstanding agency policy, it also emphasizes the importance of scientific review and public involvement. The *Framework* presents the concept of ''fit for purpose'' to address the development of risk assessments and associated products that are suitable and useful for informing risk management decisions. This *Framework* will enhance the agency's emphasis on the importance of transparency of the human health risk assessment and decision making.

This document is not intended to supersede existing agency guidance; rather by citing and discussing existing guidance in the context of the framework it is intended to foster increased implementation of agency guidance.

Dated: July 20, 2012.

Glenn Paulson,

Science Advisor.

[FR Doc. 2012–18409 Filed 7–27–12; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application to support the export of approximately $2.3 billion in U.S. petrochemical equipment and services to expand petrochemical production at an existing facility in India. The financed amount associated with the U.S. export contract is expected to total approximately $2 billion.

The U.S. exports will enable the foreign buyer to increase its annual production of the following products: 550,000 metric tons of linear low density polyethylene (LLDPE); 400,000 metric tons of low density polyethylene (LDPE); 733,000 metric tons of monoethylene glycol (MEG); 1,800,000 metric tons of paraxylene (PX); and 152,000 metric tons of polypropylene (PP). Available information indicates the Indian petrochemical producer plans to sell its output as follows: the majority of LDPE will be consumed in India with the balance exported to China, Europe and Africa; about half of LLDPE production will be consumed in India with the remainder going to China, Europe and Africa; the entire MEG production will be consumed in India; the PX production will be exported to South and North East Asia; and the majority of the PP production will be consumed in India with the balance exported to China, Africa and Europe.

Interested parties may submit comments on this application by email to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue NW., Room 432, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Kathryn Hoff-Patrinos,

Deputy General Counsel.

[FR Doc. 2012–18489 Filed 7–27–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). 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 burden for 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 Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 28, 2012. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov*. To submit your PRA comments by email send them to: *PRA@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0999.

Title: Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

Form Number: FCC Form 655.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 925 respondents; 925 responses.

Estimated Time per Response: 13.041081 hours per response (average).

Frequency of Response: On occasion and annual reporting requirements and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151, 154(i), 157, 160, 201, 202, 214, 301, 303, 308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 12,063 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: Information requested in the reports may include confidential information. However, covered entities are allowed to request that such materials submitted to the Commission be withheld from public inspection.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB) as a revision after this comment period to obtain the three year clearance from them.

The Commission is modifying the FCC Form 655 to collect information that is relevant to the newly effective provision of the rule and to clarify and streamline existing fields. Specifically, manufacturers and service providers will be asked to provide new or different responses on the FCC Form 655 in the following areas:

(1) The FCC Form 655 currently collects information on which version of the ANSI standard was used to test the handsets offered during a reporting period. The 2011 ANSI standard will be added as an option on the Handset Model Information portion of FCC Form 655. In addition, the order of the questions has been changed so that manufacturers will only have to specify once what version of the ANSI standard was used for each handset.

(2) The *de minimis* exception section will be expanded by adding questions necessary to determine whether a filer is eligible under the new version of the exception that becomes effective on September 8, 2012. These questions will address whether a filer is a small entity and how long it has been offering handsets. In addition, the text of the existing question will be modified to make clear that manufacturers must report all handsets that they offer in the United States.

(3) The Air Interfaces and Frequency Bands fields on the Handset Model Information portion of FCC Form 655 will be expanded to add ''LTE'', ''Wi-FI'', ''WiMax'', ''2.4 GHz'', and ''2.5 GHz''. In addition, the question whether the handset operates over additional air interfaces and frequency bands will be eliminated as no longer necessary.

(4) A new question will be added to the Handset Model Information portion of FCC Form 655 asking whether the handset meets the criteria for a M3 rating for operations over GSM at 1900 MHz by enabling the user optionally to reduce the maximum power at which the handset will operate by no more than 2.5 decibels, except for emergency calls to 911. This information will help the Commission ensure that such handsets are counted correctly, as well as to monitor compliance with related disclosure requirements.

(5) In order to determine whether a filer is fully in compliance with the disclosure requirements, the Product Labeling portion of FCC Form 655 will be expanded. New questions will be added to determine whether appropriate disclosure/labeling was met for any handsets that let the consumer reduce maximum transmit power for GSM operations in the 1900 MHz band by up to 2.5 decibels, any handsets that a manufacturer may have tested under the 2011 version of the ANSI standard and found not to meet hearing aid compatibility criteria for those operations, and any handsets that were certified for inductive coupling under the 2011 ANSI standard without testing VoLTE transmissions.

Federal Communications Commission.

Bulah P. Wheeler,

Deputy Manager,Office of the Secretary,Office of Managing Director.

[FR Doc. 2012–18422 Filed 7–27–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 12–1171]

Notice of Debarment

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Enforcement Bureau (the ''Bureau'') debars Ms. Gloria F. Harper from the schools and libraries universal service support mechanism (or ''E-Rate Program'') for a period of three years. The Bureau takes this action to protect the E-Rate Program from waste, fraud, and abuse.

DATES: Debarment commences on the date Ms. Gloria F. Harper receives the debarment letter or August 29, 2012, whichever date comes first, for a period of three years.

FOR FURTHER INFORMATION CONTACT: Joy M. Ragsdale, Attorney Advisor, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554. Joy Ragsdale may be contacted by telephone at (202) 418–1697 or by email at *Joy.Ragsdale@fcc.gov.* If Ms. Ragsdale is unavailable, you may contact Ms. Theresa Cavanaugh, Chief, Investigations and Hearings Division, by telephone at (202) 418–1420 and by email at *Theresa.Cavanaugh@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau debarred Ms. Gloria F. Harper from the schools and libraries service support mechanism for a period of three years pursuant to 47 CFR 54.8. Attached is the debarment letter, DA 12–1171, which was mailed to Ms. Harper and released on July 20, 2012. The complete text of the notice of debarment is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. In addition, the complete text is available on the FCC's Web site at *http://www.fcc.gov.* The text may also be purchased from the Commission's duplicating inspection and copying during regular business hours at the contractor, Best Copy and Printing, Inc., Portal II, 445 12th Street SW., Room CY–B420, Washington, DC 20554, telephone (202) 488–5300 or (800) 378–3160, facsimile (202) 488–5563, or via email *http://www.bcpiweb.com.*

Federal Communications Commission.

Theresa Z. Cavanaugh,

Chief, Investigations and Hearings Division, Enforcement Bureau.

July 20, 2012

DA 12–1171

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED AND EMAIL

Ms. Gloria F. Harper, c/o Ms. Cynthia Marie Cimino, Federal Public Defender, Hale Boggs Federal Building, 500 Poydras Street, Room 318, New Orleans, LA 70130.

Re: Notice of Debarment, File No. EB–12–IH–0400

Dear Ms. Harper: The Federal Communications Commission (Commission)

hereby notifies you that, pursuant to § 54.8 of its rules, you are prohibited from participating in the schools and libraries universal service support mechanism (E-Rate program) for three years from either the date of your receipt of this Notice of Debarment, or of its publication in the **Federal Register**, whichever is earlier in time (Debarment Date).[1]

On March 22, 2012, the Commission's Enforcement Bureau (Bureau) sent you a Notice of Suspension and Initiation of Debarment Proceeding (Notice of Suspension)[2] that was published in the **Federal Register** on April 23, 2012.[3] The Notice of Suspension suspended you from participating in activities associated with or relating to the E-Rate program. It also described the basis for initiating debarment proceedings against you, the applicable debarment procedures, and the effect of debarment.

As discussed in the Notice of Suspension, in June 2011 you pled guilty to conspiring with others to fraudulently obtain $4.5 million in E-Rate contracts through your companies, Computer Training and Associates and Global Networking Technologies.[4] In addition, you admitted to bribing school officials in exchange for control of the E-Rate application and competitive bidding process.[5] Your fraudulent scheme adversely affected 20 schools and school districts located throughout six states.[6] Pursuant to § 54.8(c) of the Commission's rules, your conviction of criminal conduct in connection with the E-Rate program is the basis for this debarment.[7]

In accordance with the Commission's debarment rules, you were required to file with the Commission any opposition to your suspension or its scope, or to your proposed debarment or its scope, no later than 30 calendar days from either the date of your receipt of the Notice of Suspension or of its publication in the **Federal Register**, whichever date occurred first.[8] The Commission did not receive any such opposition.

For the foregoing reasons, you are debarred from participating in the E-Rate program for three years from the Debarment Date.[9] During this period, you are excluded from participating in any activities associated with or related to the E-Rate program, including the receipt of funds or discounted services through the E-Rate program, or consulting with, assisting, or advising applicants or service providers regarding the E-Rate program.[10]

Sincerely,

Theresa Z. Cavanaugh,

Chief, Investigations and Hearings Division, Enforcement Bureau.

cc: Johnnay Schrieber, Universal Service Administrative Company (via email)
Rashann Duvall, Universal Service Administrative Company (via email)
Juan Rodriguez, Antitrust Division, United States Department of Justice (via email)
Stephanie Toussaint, Antitrust Division, United States Department of Justice (via email)

APPENDIX

Schools and School Districts[11]	City and State
All Saints School	New Orleans, LA.
St. Augustine High School	New Orleans, LA.
St. David School	New Orleans, LA.
St. Monica School	New Orleans, LA.
Gould Public School District	Gould, AR.
Holly Grove Public School District	Holly Grove, AR.
Antioch Center—St. Stephen's Lutheran Church	Antioch, IL.
Fairfield Center	Round Lake Beach, IL.
Ingleside Center—Ingleside United Methodist Church	Ingleside, IL.
St. Mary's Center—Libertyville Covenant Church	Libertyville, IL.
Waukegan Center	Waukegan, IL.
Zion Center—Zion Benton High School	Zion, IL.
Niles Terrace Center	Waukegan IL.
Wilmer—Hutchins Independent School District	Dallas, TX.
Innovation Child Development Center	Tallahassee, FL.
Innovation School of Excellence	Tallahassee, FL.
Capital City School (also known as Covenant Academy Preparatory School)	Tallahassee, FL.
Whole Word Christian Academy	Miami, FL.
Twin Buttes Elementary School	Halliday, ND.
White Shield School	Roseglen, ND.

[FR Doc. 2012–18430 Filed 7–27–12; 8:45 am]

BILLING CODE 6712–01–P

[1] 47 CFR 54.8(g). *See also* 47 CFR 0.111 (delegating authority to the Enforcement Bureau to resolve universal service suspension and debarment proceedings).

[2] Letter from Theresa Z. Cavanaugh, Acting Chief, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, to Ms. Gloria F. Harper, Notice of Suspension and Initiation of Debarment Proceeding, 27 FCC Rcd 2888 (Enf. Bur. 2012) (Attachment 1).

[3] 77 Fed Reg 24202 (Apr. 23, 2012).

[4] *United States* v. *Gloria F. Harper,* Criminal Docket No. 2:10–cr–00326–CJB–ALC, Plea Agreement at 3–5 (E.D. La. entered June 6, 2011).

[5] *Id.* at 4.

[6] *Id.* at 5. See Appendix.

[7] 47 CFR 54.8(c).

[8] 47 CFR 54.8(e)(3), (4). Any opposition had to be filed no later than April 21, 2012.

[9] *Id.* 54.8(e)(5), (g).

[10] *Id.* 54.8(a)(1), (5), (d).

[11] *United States* v. *Gloria F. Harper,* Criminal Docket No. 2:10–cr–00326–CJB–ALC, Factual Basis at 2–3.

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewals; Comment Request; Activities and Investments of Insured State Banks; Privacy of Consumer Financial Information

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, 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 renewal of existing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments on renewal of the information collections described below.

DATES: Comments must be submitted on or before September 28, 2012.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name of the collection in the subject line of the message.
- *Mail:* Leneta G. Gregorie (202–898–3719), Counsel, Room NYA–5050, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Leneta Gregorie, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

1. *Title:* Activities and Investments of Insured State Banks.

OMB Number: 3064–0111.

Form Numbers: None.

Frequency of Response: On occasion.

Affected Public: Insured state nonmember banks.

Estimated Number of Respondents: 110.

Estimated Time per Response: 8 hours.

Total Annual Burden: 880 hours.

General Description of Collection: With certain exceptions, section 24 of the FDI Act (12 U.S.C. 1831a) limits the direct equity investments of state chartered banks to equity investments that are permissible for national banks. In addition, the statute prohibits an insured state bank from directly engaging as principal in any activity that is not permissible for a national bank or indirectly through a subsidiary in an activity that is not permissible for a subsidiary of a national bank unless the bank meets its minimum capital requirements and the FDIC determines that the activity does not pose significant risk to the Deposit Insurance Fund. The FDIC can make such a determination for exception by regulation or by order. The FDIC's implementing regulation for section 24 is 12 CFR part 362. It details the activities that insured state nonmember banks or their subsidiaries may engage in, under certain criteria and conditions, and identifies the information that banks must furnish to the FDIC in order to obtain the FDIC's approval or non-objection.

2. *Title:* Privacy of Consumer Financial Information.

OMB Number: 3064–0136.

Form Numbers: None.

Frequency of Response: On occasion.

Affected Public: Insured state nonmember banks, state savings & loan institutions, and consumers.

Estimated Number of Respondents: Initial notice, 208; annual notice and change in terms 5,156; opt-out notice, 866; consumer opt-out/status update, 212,432.

Estimated Average Time per Response: Initial notice, 80 hours; annual notice and change in terms, 8 hours; opt-out notice, 8 hours; consumer opt-out/status update, 30 minutes.

Estimated Number of Responses: 218,662.

Total Annual Burden: 171,032 hours.

General Description of Collection: The elements of this collection are required under section 504 of the Gramm-Leach-Bliley Act, Public Law l06–102. The collection mandates notice requirements and restrictions on a financial institution's ability to disclose nonpublic personal information about consumers to nonaffiliated third parties. The collection also identifies affirmative actions that consumers must take to exercise their right to prevent banks from sharing their information with nonaffiliated parties.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the 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; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 25th day of July 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–18473 Filed 7–27–12; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

AGENCY: Federal Election Commission.

DATE & TIME: Thursday, August 2, 2012 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

Items To Be Discussed

Correction and Approval of the Minutes for the Meeting of June 21, 2012.

Draft Advisory Opinion 2012–22: skimmerhat.

Draft Advisory Opinion 2012–23: Snake River Sugar Company, Nyssa-Nampa Sugarbeet Growers Association, Inc., Elwyhee Sugarbeet Growers Association, Inc., Upper Snake River Valley Sugarbeet Growers Association, Inc., Minidoka County Sugarbeet Growers Association, Inc., Cassia County Sugarbeet Growers Association, Inc., Twin Falls County Sugarbeet Growers Association, Inc., and Northside Sugarbeet Growers Association, Inc.

Draft Advisory Opinion 2012–24: Dean Peterson.

Draft Advisory Opinion 2012–26: m-Qube, Inc., ArmourMedia, Inc. and Cooper for Congress Committee.

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign

language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2012–18686 Filed 7–26–12; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 14, 2012.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. *Muhammad Habib, Kusnacht, Switzerland; Hamza Habib, and Khadijah Jumani, both of Dubai, United Arab Emirates; and Fazilat Jumani,* London, England; to retain control of Maham Beteiligungsgessellschaft AG, Zurich, Switzerland, and thereby indirectly retain control of Habib American Bank, New York, New York.

Board of Governors of the Federal Reserve System, July 25, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–18510 Filed 7–27–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns the World Trade Center Health Program Outreach and Education Plan RFA–OH12–1201, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 8:00 a.m.–5:00 p.m., August 28, 2012 (Closed).

Place: Embassy Suites—Old Town Alexandria, 1900 Diagonal Road, Alexandria, Virginia 22314, Telephone: (703) 684–5900.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''World Trade Center Health Program Outreach and Education Plan RFA–OH12–1201.''

Contact Person for More Information: Nina Turner, Ph.D., Scientific Review Officer, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Mailstop G800, Morgantown, West Virginia 26505–2845, Telephone: (304) 285–5976.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 18, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–18427 Filed 7–27–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1433–N]

RIN 0938–AR21

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2013

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice updates the payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2013 (for discharges occurring on or after October 1, 2012 and on or before September 30, 2013) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). Section 1886(j)(5) of the Act requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF prospective payment system's (PPS) case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

DATES: *Effective Date:* The updated IRF prospective payment rates are effective for IRF discharges occurring on or after October 1, 2012 and on or before September 30, 2013 (FY 2013).

FOR FURTHER INFORMATION CONTACT: Gwendolyn Johnson, (410) 786–6954, for general information about the notice. Susanne Seagrave, (410) 786–0044, for information about the payment policies and payment rates.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose

This notice updates the payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2013 (for discharges occurring on or after October 1, 2012 and on or before September 30, 2013) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). Section 1886(j)(5) of the Act requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF prospective payment system's (PPS) case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

Summary of Major Provisions

In this notice, we use the methods described in the FY 2012 IRF PPS final rule (76 FR 47836) to update the Federal prospective payment rates for FY 2013 using updated FY 2011 IRF claims and the most recent available IRF cost report data. No policy changes are being proposed in this notice. Furthermore, we explain the self-implementing changes resulting from the provisions in section 1886(j)(3)(C) and (D) of the Act.

Summary of Cost and Benefits

Provision description	Total costs	Total benefits
FY 2013 IRF PPS payment rate update	The overall economic impact of this notice is an estimated $140 million in increased payments to IRFs during FY 2013.	The benefits of this notice include a net increase in payments to IRF providers. Overall, no IRFs are estimated to experience a net decrease in payments as a result of the updates in this notice.

In the past, the Addenda referred to throughout the preamble of our annual IRF PPS proposed and final rules and notices were included in the printed **Federal Register**. However, effective with the FY 2013 IRF notice, the IRF Addenda will no longer appear in the **Federal Register**. Instead these Addenda to the annual proposed and final rules and notices will be available through the Internet. The IRF PPS Addenda along with other supporting documents and tables referenced in this notice are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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I. Background

A. Historical Overview of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)

Section 1886(j) of the Social Security Act (the Act) provides for the implementation of a per discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (hereinafter referred to as IRFs).

Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs) but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for fiscal years (FYs) 2002 through 2012.

Under the IRF PPS from FY 2002 through FY 2005, as described in the FY 2002 IRF PPS final rule (66 FR 41316), the Federal prospective payment rates were computed across 100 distinct Case-Mix Groups (CMGs). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed 5 special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the Federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget neutral conversion factor). For a detailed discussion of the budget neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted Federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRF's unadjusted Federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002 and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the Federal IRF PPS rate and the payment that the IRF would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the Federal IRF PPS rate. The transition methodology expired as of cost reporting periods

beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the Federal IRF PPS rate.

We established a CMS Web site as a primary information resource for the IRF PPS. The Web site URL is *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/* and may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917) until it was rebased and revised in the FY 2012 IRF PPS final rule (76 FR 47838), the IRF PPS used the 2002-based market basket as the market basket index to reflect the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this notice also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the Federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF Federal prospective payment rates.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA, Pub. L. 110–173, enacted December 29, 2007), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act requires the Secretary to develop an increase factor to update the IRF Federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 Federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF Federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007 and on or before March 31, 2008; and the revised FY 2008 IRF Federal prospective payment rates were effective for discharges occurring on or after April 1, 2008 and on or before September 30, 2008. The revised FY 2008 Federal prospective payment rates are available on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.*

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of ''New England deemed'' counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (''the 60 percent rule'') and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF Federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the Federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, and teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this notice also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF Federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010) (Affordable Care Act), as amended by section 10319 of the same act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereafter referred to as ''The Affordable Care Act''), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to estimate a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010–2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to

section 1886(j)(3) of the Act, we adjusted the FY 2010 Federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010 and on or before September 30, 2010. Thus, the final FY 2010 IRF Federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009 and on or before March 31, 2010; and the adjusted FY 2010 IRF Federal prospective payment rates applied to discharges occurring on or after April 1, 2010 and on or before September 30, 2010. The adjusted FY 2010 Federal prospective payment rates are available on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.*

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of $13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of $13,627. In order to maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010. The revised IRF outlier threshold amount for FY 2010 was $10,721.

Sections 1886(j)(3)(ii)(II) and 1886(j)(3)(D)(i) also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013, November 16, 2010) described the required adjustments to the FY 2011 and FY 2010 IRF PPS Federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010 and on or before September 30, 2011. It also updated the FY 2011 Federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this proposed rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF Federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulations text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF Federal prospective payment rates.

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. Section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) of the Act (providing for a ''productivity adjustment'' for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment and the 0.1 percentage point reduction are both discussed in section V.A. of this notice. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously-designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains new requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner, and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) will require application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s). Under section 1886(j)(7)(D)(iii) of the Act, the Secretary is required to publish the measures that will be used in FY 2014 no later than October 1, 2012.

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public. Future rulemaking will address these public reporting obligations.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A fee-for-service patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI). In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF–PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF–PAI software product. Generally, the software product includes patient classification programming called the GROUPER software. The GROUPER software uses specific IRF–PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The GROUPER software produces a five-digit CMG number. The first digit is an alpha-character that indicates the comorbidity tier. The last four digits

represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the GROUPER software, are available on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

Once a patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted August 21, 1996)(HIPAA), compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted December 27, 2002)(ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-digit CMG number and sends it to the appropriate Medicare fiscal intermediary (FI) or Medicare Administrative Contractor (MAC). Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22) which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services ''for which a claim is submitted other than in an electronic form specified by the Secretary.'' Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial ''in such unusual cases as the Secretary finds appropriate.'' For more information we refer the reader to the final rule, ''Medicare Program; Electronic Submission of Medicare Claims'' (70 FR 71008, November 25, 2005). CMS instructions for the limited number of Medicare claims submitted on paper are available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads//clm104c25.pdf.*)

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR, parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered healthcare providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the program claim memoranda issued and published by CMS at: *http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/index.html?redirect=/ElectronicBillingEDITrans/* and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The Medicare FI or MAC processes the claim through its software system. This software system includes pricing programming called the ''PRICER'' software. The PRICER software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

II. Summary of Provisions of the Notice

In this notice, we use the methods described in the FY 2012 IRF PPS final rule (76 FR 47836) to update the Federal prospective payment rates for FY 2013 using updated FY 2011 IRF claims and the most recent available IRF cost report data. No policy changes are being proposed in this notice. Furthermore, we explain the self-implementing changes resulting from the provisions in section 1886(j)(3)(C) and (D) of the Act, as described above and in section V.A. of this notice.

In summary, this notice will:

- Update the FY 2013 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget neutral manner, as discussed in section III of this notice.
- Update the FY 2013 IRF PPS payments rates by a market basket increase factor, based upon the most current data available, with a 0.1 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act and a 0.8 percent productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V.A. of this notice.
- Discuss the Secretary's Recommendation for updating IRF PPS payments for FY 2013, in accordance with the statutory requirements, as described in section V.A. of this notice.
- Update the FY 2013 IRF PPS payment rates by the FY 2013 wage index and the labor-related share in a budget neutral manner, as discussed in sections V.B and V.C of this notice.
- Describe the calculation of the IRF Standard Payment Conversion Factor for FY 2013, as discussed in section V.D of this notice.
- Update the outlier threshold amount for FY 2013, as discussed in section VI.A. of this notice.
- Update the cost-to-charge ratio (CCR) ceilings and urban/rural average CCRs for FY 2013, as discussed in section VI.B. of this notice.

This notice does not contain any revisions to existing regulation text.

III. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2013

As specified in 42 CFR 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care as well as provider efficiency.

As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2013, we used FY 2011 IRF claims and the most recent available IRF cost report data. These data are the most current and most complete data available at this time. Currently, only a small portion of the FY 2011 IRF cost report data are available for analysis, but the majority of the FY 2011 IRF claims data are available for analysis.

We will apply these data using the methodologies that we have used to update the CMG relative weights and average length of stay values in the FY 2010 IRF PPS final rule (74 FR 39762), the FY 2011 notice (75 FR 42836), and the FY 2012 final rule (76 FR 47836). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this notice is as follows:

Step 1. We calculate the CMG relative weights by estimating the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2013 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2012 IRF PPS final rule (76 FR 47836).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we are updating the CMG relative weights for FY 2013 in such a way that total estimated aggregate payments to IRFs for FY 2013 are the same with or without the changes (that is, in a budget neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2013 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2013 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2013 by applying the changes to the CMG relative weights (as discussed above).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0000) that maintains the same total estimated aggregate payments in FY 2013 with and without the updates to the CMG relative weights.

Step 4. Apply the budget neutrality factor (1.0000) to the FY 2012 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section V.D of this notice, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2013.

The CMG relative weights and average length of stay values for FY 2013 are presented in Table 1. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS

CMG	CMG Description (M = motor, C = cognitive, A = age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.8027	0.7192	0.6541	0.6254	10	10	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5.	0.9980	0.8942	0.8132	0.7776	12	10	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5.	1.1622	1.0414	0.9471	0.9056	12	13	12	12
0104	Stroke M>38.85 and M<44.45	1.2323	1.1041	1.0041	0.9602	13	12	12	12
0105	Stroke M>34.25 and M<38.85	1.4378	1.2883	1.1716	1.1203	15	16	14	14
0106	Stroke M>30.05 and M<34.25	1.6373	1.4670	1.3342	1.2758	17	18	16	16
0107	Stroke M>26.15 and M<30.05	1.8381	1.6469	1.4978	1.4322	18	19	17	18
0108	Stroke M<26.15 and A>84.5	2.2975	2.0585	1.8721	1.7901	23	23	22	21
0109	Stroke M>22.35 and M<26.15 and A<84.5.	2.1226	1.9018	1.7296	1.6539	20	22	20	20
0110	Stroke M<22.35 and A<84.5	2.7303	2.4463	2.2248	2.1274	30	29	25	25
0201	Traumatic brain injury M>53.35 and C>23.5.	0.8313	0.6948	0.6199	0.5869	10	10	8	8
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5.	1.0169	0.8499	0.7583	0.7179	12	11	10	10
0203	Traumatic brain injury M>44.25 and C<23.5.	1.1804	0.9865	0.8803	0.8334	14	13	12	11
0204	Traumatic brain injury M>40.65 and M<44.25.	1.2938	1.0813	0.9648	0.9134	14	13	12	12
0205	Traumatic brain injury M>28.75 and M<40.65.	1.5550	1.2996	1.1596	1.0978	16	15	14	14
0206	Traumatic brain injury M>22.05 and M<28.75.	1.9383	1.6200	1.4455	1.3684	20	20	18	17
0207	Traumatic brain injury M<22.05	2.5535	2.1341	1.9042	1.8027	33	25	22	21
0301	Non-traumatic brain injury M>41.05	1.1218	0.9563	0.8462	0.7852	11	12	11	10
0302	Non-traumatic brain injury M>35.05 and M<41.05.	1.4026	1.1957	1.0579	0.9816	14	14	13	12
0303	Non-traumatic brain injury M>26.15 and M<35.05.	1.6605	1.4155	1.2525	1.1621	17	16	15	14
0304	Non-traumatic brain injury M<26.15	2.2065	1.8810	1.6643	1.5443	25	22	19	18
0401	Traumatic spinal cord injury M>48.45	1.0393	0.8778	0.7864	0.7109	13	12	11	10
0402	Traumatic spinal cord injury M>30.35 and M<48.45.	1.4824	1.2521	1.1218	1.0141	17	15	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35.	2.3870	2.0161	1.8063	1.6329	31	23	22	20
0404	Traumatic spinal cord injury M<16.05 and A>63.5.	4.3665	3.6881	3.3043	2.9870	60	41	33	35
0405	Traumatic spinal cord injury M<16.05 and A<63.5.	3.3893	2.8627	2.5648	2.3186	41	41	29	24
0501	Non-traumatic spinal cord injury M>51.35	0.8436	0.6828	0.6306	0.5624	9	9	8	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35.	1.1283	0.9132	0.8434	0.7521	11	11	11	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15.	1.4284	1.1561	1.0677	0.9522	15	14	13	12

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG Description (M = motor, C = cognitive, A = age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25.	1.7220	1.3937	1.2872	1.1479	22	16	15	14
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25.	1.9656	1.5909	1.4693	1.3103	22	18	18	16
0506	Non-traumatic spinal cord injury M<23.75	2.7707	2.2425	2.0711	1.8470	30	26	24	22
0601	Neurological M>47.75	0.9703	0.7915	0.7304	0.6647	10	10	9	9
0602	Neurological M>37.35 and M<47.75	1.2695	1.0356	0.9557	0.8697	13	12	11	11
0603	Neurological M>25.85 and M<37.35	1.6243	1.3250	1.2228	1.1128	16	15	14	14
0604	Neurological M<25.85	2.1537	1.7568	1.6213	1.4755	22	20	18	17
0701	Fracture of lower extremity M>42.15	0.9343	0.7841	0.7481	0.6772	11	10	10	9
0702	Fracture of lower extremity M>34.15 and M<42.15.	1.2477	1.0471	0.9990	0.9044	13	13	12	12
0703	Fracture of lower extremity M>28.15 and M<34.15.	1.4984	1.2575	1.1996	1.0860	16	15	14	14
0704	Fracture of lower extremity M<28.15	1.8994	1.5940	1.5207	1.3767	19	18	18	17
0801	Replacement of lower extremity joint M>49.55.	0.7445	0.6142	0.5608	0.5156	8	8	8	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55.	0.9839	0.8117	0.7412	0.6814	10	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5.	1.3381	1.1039	1.0080	0.9266	13	12	13	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5.	1.1889	0.9807	0.8955	0.8233	13	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65.	1.4728	1.2150	1.1094	1.0199	15	14	13	13
0806	Replacement of lower extremity joint M<22.05.	1.7966	1.4821	1.3533	1.2441	17	17	15	15
0901	Other orthopedic M>44.75	0.9086	0.7488	0.6954	0.6289	11	10	9	8
0902	Other orthopedic M>34.35 and M<44.75	1.1916	0.9820	0.9120	0.8248	12	12	11	11
0903	Other orthopedic M>24.15 and M<34.35	1.5421	1.2709	1.1803	1.0674	16	15	14	13
0904	Other orthopedic M<24.15	1.9596	1.6149	1.4998	1.3564	20	19	17	16
1001	Amputation, lower extremity M>47.65	1.0168	0.9097	0.8224	0.7491	11	11	10	10
1002	Amputation, lower extremity M>36.25 and M<47.65.	1.2813	1.1464	1.0364	0.9440	14	14	13	12
1003	Amputation, lower extremity M<36.25	1.8523	1.6572	1.4983	1.3647	18	19	17	16
1101	Amputation, non-lower extremity M>36.35.	1.1553	1.1084	1.1084	0.9005	13	18	12	11
1102	Amputation, non-lower extremity M<36.35.	1.6083	1.5429	1.5429	1.2536	17	24	16	16
1201	Osteoarthritis M>37.65	0.9031	0.9031	0.8675	0.8070	9	12	11	10
1202	Osteoarthritis M>30.75 and M<37.65	1.0652	1.0652	1.0232	0.9518	10	13	12	12
1203	Osteoarthritis M<30.75	1.3740	1.3740	1.3199	1.2278	12	17	15	15
1301	Rheumatoid, other arthritis M>36.35	1.2084	1.0270	0.9058	0.8066	13	12	11	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35.	1.5720	1.3360	1.1783	1.0492	16	15	14	13
1303	Rheumatoid, other arthritis M<26.15	2.0006	1.7003	1.4996	1.3354	19	20	17	16
1401	Cardiac M>48.85	0.8930	0.7627	0.6877	0.6266	9	9	9	8
1402	Cardiac M>38.55 and M<48.85	1.1528	0.9847	0.8877	0.8089	12	12	11	10
1403	Cardiac M>31.15 and M<38.55	1.3890	1.1864	1.0696	0.9747	14	14	13	12
1404	Cardiac M<31.15	1.7811	1.5213	1.3716	1.2498	19	18	16	15
1501	Pulmonary M>49.25	0.9698	0.8491	0.7773	0.7364	10	10	9	9
1502	Pulmonary M>39.05 and M<49.25	1.2118	1.0610	0.9712	0.9201	12	12	11	11
1503	Pulmonary M>29.15 and M<39.05	1.4875	1.3025	1.1922	1.1295	16	14	13	13
1504	Pulmonary M<29.15	1.8834	1.6491	1.5095	1.4301	19	18	16	16
1601	Pain syndrome M>37.15	1.0499	0.9155	0.8350	0.7581	10	11	10	10
1602	Pain syndrome M>26.75 and M<37.15	1.3826	1.2056	1.0997	0.9984	15	14	13	12
1603	Pain syndrome M<26.75	1.7346	1.5124	1.3796	1.2525	14	18	16	15
1701	Major multiple trauma without brain or spinal cord injury M>39.25.	1.0736	0.9323	0.8505	0.7574	11	12	11	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25.	1.4056	1.2206	1.1136	0.9916	14	15	13	12
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05.	1.6353	1.4201	1.2956	1.1537	18	17	15	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55.	2.0887	1.8138	1.6547	1.4735	22	21	19	18
1801	Major multiple trauma with brain or spinal cord injury M>40.85.	1.2365	0.9356	0.8675	0.7592	14	13	12	10

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG Description (M = motor, C = cognitive, A = age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85.	1.8710	1.4158	1.3127	1.1488	18	17	16	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05.	3.3167	2.5096	2.3269	2.0364	38	32	25	23
1901	Guillain Barre M>35.95	1.0467	0.9509	0.9185	0.8749	13	12	12	11
1902	Guillain Barre M>18.05 and M<35.95	1.9189	1.7433	1.6839	1.6041	23	20	18	19
1903	Guillain Barre M<18.05	3.3119	3.0088	2.9062	2.7685	41	33	33	34
2001	Miscellaneous M>49.15	0.8744	0.7276	0.6680	0.6095	9	9	9	8
2002	Miscellaneous M>38.75 and M<49.15	1.1796	0.9815	0.9012	0.8222	12	12	11	10
2003	Miscellaneous M>27.85 and M<38.75	1.4817	1.2329	1.1320	1.0328	15	14	13	13
2004	Miscellaneous M<27.85	1.9594	1.6304	1.4970	1.3659	21	19	17	16
2101	Burns M>0	2.1947	1.9009	1.9009	1.6414	24	22	17	17
5001	Short-stay cases, length of stay is 3 days or fewer.				0.1494				3
5101	Expired, orthopedic, length of stay is 13 days or fewer.				0.5866				7
5102	Expired, orthopedic, length of stay is 14 days or more.				1.5325				18
5103	Expired, not orthopedic, length of stay is 15 days or fewer.				0.7091				8
5104	Expired, not orthopedic, length of stay is 16 days or more.				1.9053				22

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how the application of the revisions for FY 2013 will affect particular CMG relative weight values, which affect the overall distribution of payments within CMGs and tiers. Note that, because we are implementing the CMG relative weight revisions in a budget neutral manner (as described above), total estimated aggregate payments to IRFs for FY 2013 will not be affected as a result of the CMG relative weight revisions. However, the revisions will affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS

[FY 2012 values compared with FY 2013 values]

Percentage change	Number of cases affected	Percentage of cases affected
Increased by 15% or more	1,894	0.5
Increased by between 5% and 15%	3,932	1.0
Changed by less than 5%	359,907	95.5
Decreased by between 5% and 15%	11,307	3.0
Decreased by 15% or more	0	0.0

Note: Percentages may not sum to 100% due to rounding.

As Table 2 shows, over 95 percent of all IRF cases are in CMGs and tiers that will experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2013. The largest increase in the CMG relative weight values affecting the most cases is a 2.8 percent increase in the CMG relative weight value for CMG 0802—Replacement of Lower Extremity Joint, with a motor score between 37.05 and 49.55—in the ''no comorbidity'' tier. In the FY 2011 data, 9,851 IRF discharges were classified into this CMG and tier. We believe that the higher costs reported by IRFs for this CMG and tier in FY 2011, compared with the costs reported in FY 2010, may continue to reflect the IRF trend away from admitting lower-severity joint replacement cases in favor of higher-severity joint replacement cases. We believe that this may be evidence of a response, at least in part, to Medicare's ''60 percent'' rule, and the increased focus on the medical review of IRF cases. These policies likely increase the complexity of patients being admitted to IRFs, especially among the lower-extremity joint replacement cases with no comorbidities, which often do not meet the 60 percent rule criteria and have been the focus of a lot of the medical review activities.

The largest decrease in a CMG relative weight value affecting the most cases is a 2.3 percent decrease in the CMG relative weight for CMG D2004—Miscellaneous, with motor score less than 27.85. In the FY 2011 IRF claims data, this change affects 6,967 cases.

The changes in the average length of stay values for FY 2013, compared with the FY 2012 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

IV. Updates to the Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate ''by such * * * factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.'' For example, we adjust the Federal prospective payment amount

associated with a CMG to account for facility-level characteristics such as an IRF's LIP percentage, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

In the FY 2010 IRF PPS final rule (74 FR 39762), we updated the adjustment factors for calculating the rural, LIP, and teaching status adjustments based on the most recent three consecutive years worth of IRF claims data (at that time, FY 2006, FY 2007, and FY 2008) and the most recent available corresponding IRF cost report data. As discussed in the FY 2010 IRF PPS proposed rule (74 FR 21060 through 21061), we observed relatively large year-to-year fluctuations in the underlying data used to compute the adjustment factors, especially the teaching status adjustment factor. Therefore, we implemented a 3-year moving average approach to updating the facility-level adjustment factors in the FY 2010 IRF PPS final rule (74 FR 39762) to provide greater stability and predictability of Medicare payments for IRFs.

Each year, we review the major components of the IRF PPS to maintain and enhance the accuracy of the payment system. For FY 2010, we implemented a change to our methodology that was designed to decrease the IRF PPS volatility by using a 3-year moving average to calculate the facility-level adjustment factors. For FY 2011, we issued a notice to update the payment rates, which did not include any policy changes or changes to the IRF facility-level adjustments. However, in the FY 2012 IRF PPS proposed rule (76 FR 24214 at 24225 through 24226), we analyzed the use of a weighting methodology, which assigns greater weight to some facilities than to others, in the regression analysis used to estimate the facility-level adjustment factors. As we found that this weighting methodology inappropriately exaggerated the cost differences among different types of IRF facilities, we proposed to remove the weighting factor from our analysis and update the IRF facility-level adjustment factors for FY 2012 using an un-weighted regression analysis. However, after carefully considering all of the comments that we received on the proposed FY 2012 updates to the facility-level adjustment factors, we decided to hold the facility-level adjustment factors at FY 2011 levels for FY 2012 in order to conduct further research on the underlying data and the best methodology for calculating the facility-level adjustment factors. We based this decision, in part, on comments we received about the financial hardships that the proposed updates would create for facilities with teaching programs and a higher disproportionate share of low-income patients. Thus, in the FY 2012 final rule (76 FR 47836 at 47845), we held the FY 2012 facility-level adjustment factors at FY 2011 levels. We also stated in the FY 2012 final rule that we would conduct further research on the underlying data and the best methodology for calculating the facility level adjustment factors. Our research efforts are still ongoing, as we continue to consider the best methodology for calculating the facility level adjustment factors. As a result, we are not making changes to the facility-level adjustments for FY 2013.

V. FY 2013 IRF PPS Federal Prospective Payment Rates

A. Market Basket Increase Factor, Productivity Adjustment, Other Adjustment, and Secretary's Recommendation for FY 2013

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF Federal prospective payment rates for each FY. Sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act require the application of a 0.1 percentage point reduction to the market basket increase factor for FYs 2012 and 2013. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. Thus, in this notice, we are updating the IRF PPS payments for FY 2013 by a market basket increase factor based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, as described below, and a 0.1 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act.

For this notice, we have used the same methodology described in the FY 2012 IRF PPS final rule (76 FR 47836 at 47848 through 47863) to compute the FY 2013 market basket increase factor and labor-related share. In that final rule, we rebased the RPL market basket from a 2002 base year to a 2008 base year. Using this method and the IHS Global Insight, Inc. forecast for the second quarter of 2012 of the 2008-based RPL market basket, the FY 2013 RPL market basket increase factor is 2.7 percent. IHS Global Insight (IGI) is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

In accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859), we apply a productivity adjustment to the FY 2013 RPL market basket increase factor. 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 FY cost reporting period, or other annual period)(the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* to obtain the historical BLS-published MFP data. The projection of MFP is currently produced by IGI, using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). The MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) that we apply to the market basket increase factor for FY 2013 is 0.7 percent, which was calculated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859) and is based on IGI's second quarter 2012 forecast.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we will base the FY 2013 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the second quarter 2012 forecast of the FY 2008-based RPL market basket (estimated to be 2.7 percent). This percentage increase is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.7 percent, which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859) and based on IGI's second quarter 2012 forecast. Following application of the productivity adjustment, the applicable percentage increase is further reduced by 0.1 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act. Therefore, the final FY 2013 IRF update is 1.9 percent (2.7 percent market basket update less 0.7 percentage point MFP adjustment less 0.1 percentage point legislative adjustment).

Secretary's Final Recommendation

For FY 2013, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0 percent update be

applied to IRF PPS payment rates for FY 2013. As discussed above, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is updating IRF PPS payment rates for FY 2013 by an adjusted market basket increase factor of 1.9 percent because section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2013.

B. Labor-Related Share for FY 2013

Using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47860 through 47863), we are updating the IRF labor-related share for FY 2013. Using this method and the IHS Global Insight, Inc. forecast for the second quarter of 2012 of the 2008-based RPL market basket, the IRF labor-related share for FY 2013 is the sum of the FY 2013 relative importance of each labor-related cost category. This figure reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2013. As shown in Table 3, the FY 2013 labor-related share is 69.981 percent.

TABLE 3—FY 2013 IRF RPL LABOR-RELATED SHARE RELATIVE IMPORTANCE

Cost category	FY 2013 IRF labor-related share relative importance
Wages and Salaries	48.796
Employee Benefits	13.021
Professional Fees: Labor-Related	2.070
Administrative and Business Support Services	0.417
All Other: Labor-Related Services	2.077
SUBTOTAL	66.381
Labor-Related Share of Capital Costs (.46)	3.600
TOTAL	69.981

Source: IHS GLOBAL INSIGHT, INC, 2nd QTR, 2012; Historical Data through 1st QTR, 2012.

C. Area Wage Adjustment

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustments or updates made under section 1886(j)(6) of the Act for a FY are made in a budget neutral manner.

In the FY 2009 IRF PPS final rule (73 FR 46378), we maintained the methodology described in the FY 2006 IRF PPS final rule to determine the wage index, labor market area definitions, and hold harmless policy consistent with the rationale outlined in the FY 2006 IRF PPS final rule (70 FR 47880, 47917 through 47933).

For FY 2013, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule relating to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we are using the CBSA labor market area definitions and the FY 2012 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2012 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2007 and before October 1, 2008 (that is, 2008 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We will continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the FY 2013 IRF PPS wage index.

If applicable, we will continue to use the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage data used to determine the current IRF PPS wage index. The OMB bulletins are available online at *http://www.whitehouse.gov/omb/bulletins/index.html*.

To calculate the wage-adjusted facility payment for the payment rates set forth in this notice, we multiply the unadjusted Federal payment rate for IRFs by the FY 2013 labor-related share based on the FY 2008-based RPL market basket (69.981 percent) to determine the labor-related portion of the standard payment amount. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this notice. These tables are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*. Table A is for urban areas and Table B is for rural areas.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget neutral manner. We calculate a budget neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2013 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2008 hospital cost report data) and the labor-related share in a budget neutral manner:

Step 1. Determine the total amount of the estimated FY 2012 IRF PPS rates, using the FY 2012 standard payment conversion factor and the labor-related share and the wage indexes from FY 2012 (as published in the FY 2012 IRF PPS final rule (76 FR 47836)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2012 standard payment conversion factor and the FY 2013 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2013 budget neutral wage adjustment factor of 1.0000.

Step 4. Apply the FY 2013 budget neutral wage adjustment factor from step 3 to the FY 2012 IRF PPS standard payment conversion factor after the application of the adjusted market

basket update to determine the FY 2013 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2013 in section V.D. of this notice.

D. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2013

To calculate the standard payment conversion factor for FY 2013, as illustrated in Table 4, we begin by applying the adjusted market basket increase factor for FY 2013 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2012 ($14,076). Applying the 1.9 percent adjusted market basket increase factor for FY 2013 to the revised standard payment conversion factor for FY 2012 of $14,076 yields a standard payment amount of $14,343. Then, we apply the budget neutrality factor for the FY 2013 wage index and labor related share of 1.0000, which keeps the standard payment amount at $14,343. Finally, we apply the budget neutrality factor for the revised CMG relative weights of 1.0000, which results in a final standard payment conversion factor of $14,343 for FY 2013.

TABLE 4—CALCULATIONS TO DETERMINE THE FINAL FY 2013 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2012	$14,076
Market Basket Increase Factor for FY 2013 (2.7 percent), reduced by 0.1 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and a 0.7 percent reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	× 1.019
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0000
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000
Final FY 2013 Standard Payment Conversion Factor	= $14,343

After the application of the CMG relative weights described in section III of this notice, the resulting unadjusted IRF prospective payment rates for FY 2013 are shown below in Table 5, ''FY 2013 Payment Rates.''

TABLE 5—FY 2013 PAYMENT RATES

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0101	$11,513.13	$10,315.49	$9,381.76	$8,970.11
0102	14,314.31	12,825.51	11,663.73	11,153.12
0103	16,669.43	14,936.80	13,584.26	12,989.02
0104	17,674.88	15,836.11	14,401.81	13,772.15
0105	20,622.37	18,478.09	16,804.26	16,068.46
0106	23,483.79	21,041.18	19,136.43	18,298.80
0107	26,363.87	23,621.49	21,482.95	20,542.04
0108	32,953.04	29,525.07	26,851.53	25,675.40
0109	30,444.45	27,277.52	24,807.65	23,721.89
0110	39,160.69	35,087.28	31,910.31	30,513.30
0201	11,923.34	9,965.52	8,891.23	8,417.91
0202	14,585.40	12,190.12	10,876.30	10,296.84
0203	16,930.48	14,149.37	12,626.14	11,953.46
0204	18,556.97	15,509.09	13,838.13	13,100.90
0205	22,303.37	18,640.16	16,632.14	15,745.75
0206	27,801.04	23,235.66	20,732.81	19,626.96
0207	36,624.85	30,609.40	27,311.94	25,856.13
0301	16,089.98	13,716.21	12,137.05	11,262.12
0302	20,117.49	17,149.93	15,173.46	14,079.09
0303	23,816.55	20,302.52	17,964.61	16,668.00
0304	31,647.83	26,979.18	23,871.05	22,149.89
0401	14,906.68	12,590.29	11,279.34	10,196.44
0402	21,262.06	17,958.87	16,089.98	14,545.24
0403	34,236.74	28,916.92	25,907.76	23,420.68
0404	62,628.71	52,898.42	47,393.57	42,842.54
0405	48,612.73	41,059.71	36,786.93	33,255.68
0501	12,099.75	9,793.40	9,044.70	8,066.50
0502	16,183.21	13,098.03	12,096.89	10,787.37
0503	20,487.54	16,581.94	15,314.02	13,657.40
0504	24,698.65	19,989.84	18,462.31	16,464.33
0505	28,192.60	22,818.28	21,074.17	18,793.63
0506	39,740.15	32,164.18	29,705.79	26,491.52
0601	13,917.01	11,352.48	10,476.13	9,533.79
0602	18,208.44	14,853.61	13,707.61	12,474.11
0603	23,297.33	19,004.48	17,538.62	15,960.89
0604	30,890.52	25,197.78	23,254.31	21,163.10
0701	13,400.66	11,246.35	10,730.00	9,713.08
0702	17,895.76	15,018.56	14,328.66	12,971.81
0703	21,491.55	18,036.32	17,205.86	15,576.50
0704	27,243.09	22,862.74	21,811.40	19,746.01
0801	10,678.36	8,809.47	8,043.55	7,395.25

TABLE 5—FY 2013 PAYMENT RATES—Continued

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0802	14,112.08	11,642.21	10,631.03	9,773.32
0803	19,192.37	15,833.24	14,457.74	13,290.22
0804	17,052.39	14,066.18	12,844.16	11,808.59
0805	21,124.37	17,426.75	15,912.12	14,628.43
0806	25,768.63	21,257.76	19,410.38	17,844.13
0901	13,032.05	10,740.04	9,974.12	9,020.31
0902	17,091.12	14,084.83	13,080.82	11,830.11
0903	22,118.34	18,228.52	16,929.04	15,309.72
0904	28,106.54	23,162.51	21,511.63	19,454.85
1001	14,583.96	13,047.83	11,795.68	10,744.34
1002	18,377.69	16,442.82	14,865.09	13,539.79
1003	26,567.54	23,769.22	21,490.12	19,573.89
1101	16,570.47	15,897.78	15,897.78	12,915.87
1102	23,067.85	22,129.81	22,129.81	17,980.38
1201	12,953.16	12,953.16	12,442.55	11,574.80
1202	15,278.16	15,278.16	14,675.76	13,651.67
1203	19,707.28	19,707.28	18,931.33	17,610.34
1301	17,332.08	14,730.26	12,991.89	11,569.06
1302	22,547.20	19,162.25	16,900.36	15,048.68
1303	28,694.61	24,387.40	21,508.76	19,153.64
1401	12,808.30	10,939.41	9,863.68	8,987.32
1402	16,534.61	14,123.55	12,732.28	11,602.05
1403	19,922.43	17,016.54	15,341.27	13,980.12
1404	25,546.32	21,820.01	19,672.86	17,925.88
1501	13,909.84	12,178.64	11,148.81	10,562.19
1502	17,380.85	15,217.92	13,929.92	13,196.99
1503	21,335.21	18,681.76	17,099.72	16,200.42
1504	27,013.61	23,653.04	21,650.76	20,511.92
1601	15,058.72	13,131.02	11,976.41	10,873.43
1602	19,830.63	17,291.92	15,773.00	14,320.05
1603	24,879.37	21,692.35	19,787.60	17,964.61
1701	15,398.64	13,371.98	12,198.72	10,863.39
1702	20,160.52	17,507.07	15,972.36	14,222.52
1703	23,455.11	20,368.49	18,582.79	16,547.52
1704	29,958.22	26,015.33	23,733.36	21,134.41
1801	17,735.12	13,419.31	12,442.55	10,889.21
1802	26,835.75	20,306.82	18,828.06	16,477.24
1803	47,571.43	35,995.19	33,374.73	29,208.09
1901	15,012.82	13,638.76	13,174.05	12,548.69
1902	27,522.78	25,004.15	24,152.18	23,007.61
1903	47,502.58	43,155.22	41,683.63	39,708.60
2001	12,541.52	10,435.97	9,581.12	8,742.06
2002	16,919.00	14,077.65	12,925.91	11,792.81
2003	21,252.02	17,683.48	16,236.28	14,813.45
2004	28,103.67	23,384.83	21,471.47	19,591.10
2101	31,478.58	27,264.61	27,264.61	23,542.60
5001	.....	.....	.....	2,142.84
5101	.....	.....	.....	8,413.60
5102	.....	.....	.....	21,980.65
5103	.....	.....	.....	10,170.62
5104	.....	.....	.....	27,327.72

E. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the Federal prospective payments (as described in sections V.A through V.D of this notice). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 5 above.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a disproportionate share hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0228), a wage index of 0.8551, and a rural adjustment of 18.4 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0666), a wage index of 0.8900, and a teaching status adjustment of 0.0610.

To calculate each IRF's labor and non-labor portion of the Federal prospective payment, we begin by taking the unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5 above. Then, we multiply the labor-related share for FY 2013 (69.981 percent) described in section V.B of this notice by the unadjusted Federal prospective payment rate. To determine the non-labor portion of the Federal prospective payment rate, we subtract the labor

portion of the Federal payment from the unadjusted Federal prospective payment.

To compute the wage-adjusted Federal prospective payment, we multiply the labor portion of the Federal payment by the appropriate wage index found in Table A and Table B. These tables are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted Federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted Federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted Federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0610, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted Federal prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2013 FEDERAL PROSPECTIVE PAYMENT

Steps		Rural Facility A (Spencer Co., IN)	Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment	$30,513.30	$30,513.30
2	Labor Share	× 0.69981	× 0.69981
3	Labor Portion of Federal Payment	= $21,353.51	= $21,353.51
4	CBSA Based Wage Index (shown in the Addendum, Tables 1 and 2)	× 0.8551	× 0.8900
5	Wage-Adjusted Amount	= $18,259.39	= $19,004.63
6	Nonlabor Amount	+ $9,159.79	+ $9,159.79
7	Wage-Adjusted Federal Payment	= $27,419.18	= $28,164.41
8	Rural Adjustment	× 1.184	× 1.000
9	Wage- and Rural-Adjusted Federal Payment	= $32,464.30	= $28,164.41
10	LIP Adjustment	× 1.0228	× 1.0666
11	FY 2013 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	= $33,204.49	= $30,040.16
12	FY 2013 Wage- and Rural-Adjusted Federal Prospective Payment	$32,464.30	$28,164.41
13	Teaching Status Adjustment	× 0	× 0.0610
14	Teaching Status Adjustment Amount	= $0.00	= $1,718.03
15	FY 2013 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+ $33,204.49	+ $30,040.16
16	Total FY 2013 Adjusted Federal Prospective Payment	= $33,204.49	= $31,758.19

Thus, the adjusted payment for Facility A would be $33,204.49 and the adjusted payment for Facility B would be $31,758.19.

VI. Update to Payments for High-Cost Outliers Under the IRF PPS

A. Update to the Outlier Threshold Amount for FY 2013

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also, adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2012 IRF PPS final rules (70 FR 47880, 70 FR 57166, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 75 FR 42836, and 76 FR 47836, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2013, we use FY 2011 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2012. Based on an analysis of this updated data, we estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.8 percent in FY 2012. Therefore, we will update the outlier threshold amount to $10,466 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2013.

B. Update to the IRF Cost-to-Charge Ratio Ceilings

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2013, based

on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2013, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2013, we estimate a national average CCR of 0.659 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we estimate a national average CCR of 0.514 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this notice, we have used the most recent available cost report data (FY 2010). This includes all IRFs whose cost reporting periods began on or after October 1, 2009, and before October 1, 2010. If, for any IRF, the FY 2010 cost report was missing or had an ''as submitted'' status, we used data from the latest settled cost report for FY 2004 through FY 2009. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the national CCR ceiling is set at 1.57 for FY 2013. This means that, if an individual IRF's CCR exceeds this ceiling of 1.57 for FY 2013, we would replace the IRF's CCR with the appropriate national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculate the national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as discussed above) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

VII. Collection of Information Requirements

This document does not impose any new information collection requirements. However, it does provide detailed information about a currently approved information collection request pertaining to the IRF PPS. Specifically, section I.C. of this notice references the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI). As stated in section I.C of this notice, IRFs are required to complete the IRF–PAI upon the admission and discharge of a Medicare Part A fee-for-service patients and upon admission and discharge of each Medicare Part C (Medicare Advantage) patient. The IRF–PAI is currently approved under OMB control number: 0938–0842.

VIII. Waiver of Notice and Comment

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect. We can waive this procedure, however, if we find good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and we incorporate a statement of finding and its reasons in the notice. We find that it is unnecessary to undertake notice and comment rulemaking for the updates in this notice because the updates contained in this Notice do not make any substantive changes in policy, but merely reflect the application of previously established methodologies. In addition, we applied the statutorily-required adjustments to the update to the IRF–PPS increase factor in sections 1886(j)(3)(C) and (D) of the Act in this notice. We find that notice and comment rulemaking is unnecessary to implement these statutory provisions because they are self-implementing provisions of law, not requiring the exercise of any discretion on the part of the Secretary. Finally, in accordance with 1886(e)(5)(B), we noted MEDPAC's recommendations regarding an appropriate update for the FY 2013 IRF PPS, and the Secretary's inability to implement those recommendations due to the requirements in 1886(j) regarding the establishment of an update factor. As such, the Secretary's recommendation (to follow the statutory requirements thereby applying a 1.9 percent update rather than MEDPAC's recommended 0 percent update) need not be published in a proposed and final rule as such publication is unnecessary in the absence of any discretion regarding the establishment of the update factor. Therefore, under 5 U.S.C. 553(b)(3)(B), for good cause, we waive notice and comment procedures.

IX. Regulatory Impact Analysis

A. Statement of Need

This notice updates the IRF prospective payment rates for FY 2013 as required under section 1886(j)(3)(C) of the Act. It responds to Section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This notice also implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

B. Overall Impact

We have examined the impacts of this notice as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 (January 18, 2011, Improving Regulation and Regulatory Review), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major notice with

economically significant effects ($100 million or more in any one year). We estimate the total impact of the updates described in this notice by comparing the estimated payments in FY 2013 with those in FY 2012. This analysis results in an estimated $140 million increase for FY 2013 IRF PPS payments. As a result, this notice is designated as economically ''significant'' under section 3(f)(1) of Executive Order 12866, and hence a major notice under the Congressional Review Act.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $7 million to $34.5 million in any 1 year, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf,* effective March 26, 2012.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,200 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 7, we estimate that the net revenue impact of this notice on all IRFs is to increase estimated payments by approximately 2.1 percent, with three categories of IRFs (6 rural IRFs in the New England region, 29 rural IRFs in the West North Central region, and 8 rural IRFs in the Mountain region) estimated to receive an increase in estimated payments of 3 percent or more (3.2 percent, 3.0 percent, and 3.1, respectively). As a result, we anticipate this notice would have a positive impact on a substantial number of small entities. Medicare fiscal intermediaries, Medicare Administrative Contractors, and carriers are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this notice will not have an adverse impact on rural hospitals based on the data of the 169 rural units and 20 rural hospitals in our database of 1,139 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately $139 million. This notice will not impose spending costs on State, local, or tribal governments, in the aggregate, or by the private sector, of greater than $139 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As stated above, this notice will not have a substantial effect on State and local governments, preempt State law, or otherwise have a Federalism implication.

C. Anticipated Effects of the Notice

1. Basis and Methodology of Estimates

This notice sets forth updates to the IRF PPS rates contained in the FY 2012 final rule (76 FR 47836). Specifically, this notice sets forth updates to the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This notice also applies a productivity adjustment to the FY 2013 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.1 percentage point reduction to the FY 2013 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act.

We estimate that the FY 2013 impact will be a net increase of $140 million in payments to IRF providers. The impact analysis in Table 7 of this notice represents the projected effects of the updates to IRF PPS payments for FY 2013 compared with the estimated IRF PPS payments in FY 2012. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2013, we are implementing standard annual revisions described in this notice (for example, the update to the wage and market basket indexes used to adjust the Federal rates). We are also implementing a productivity adjustment to the FY 2013 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.1 percentage point reduction to the FY 2013 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act. We estimate the total increase in payments to IRFs in FY 2013, relative to FY 2012, will be approximately $140 million.

This estimate is derived from the application of the FY 2013 RPL market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.1 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act, which yields an increase of aggregate payments to IRFs of $130 million. Furthermore, there is an additional estimated $10 million increase in aggregate payments to IRFs due to the update in the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.8 percent in FY 2012 to 3.0 percent in FY 2013. Therefore, summed together, these

updates will result in a net increase in estimated payments of $140 million from FY 2012 to FY 2013.

The effects of the updates that impact IRF PPS payment rates are shown in Table 7. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.8 percent to 3.0 percent of total estimated payments for FY 2013, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the RPL market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and (D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.1 percentage point reduction in accordance with sections 1886(j)(3)(C) and (D) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2013 payment updates relative to the estimated FY 2012 payments.

2. Description of Table 7

The table below categorizes IRFs by geographic location, including urban or rural location, and location with respect to CMS's nine census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of the table shows the overall impact on the 1,139 IRFs included in the analysis.

The next 12 rows of Table 7 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 950 IRFs located in urban areas included in our analysis. Among these, there are 739 IRF units of hospitals located in urban areas and 211 freestanding IRF hospitals located in urban areas. There are 189 IRFs located in rural areas included in our analysis. Among these, there are 169 IRF units of hospitals located in rural areas and 20 freestanding IRF hospitals located in rural areas. There are 383 for-profit IRFs. Among these, there are 324 IRFs in urban areas and 59 IRFs in rural areas. There are 697 non-profit IRFs. Among these, there are 579 urban IRFs and 118 rural IRFs. There are 59 government-owned IRFs. Among these, there are 47 urban IRFs and 12 rural IRFs.

The remaining four parts of Table 7 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized with respect to their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized with respect to their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each payment update described in this notice to the facility categories listed above are shown in the columns of Table 7. The description of each column is as follows:

- Column (1) shows the facility classification categories described above.
- Column (2) shows the number of IRFs in each category in our FY 2011 analysis file.
- Column (3) shows the number of cases in each category in our FY 2011 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF PPS payment rates, which includes a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.1 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act.
- Column (6) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget neutral manner.
- Column (7) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget neutral manner.
- Column (8) compares our estimates of the payments per discharge, incorporating all of the payment updates reflected in this notice for FY 2013 to our estimates of payments per discharge in FY 2012.

The average estimated increase for all IRFs is approximately 2.1 percent. This estimated net increase includes the effects of the RPL market basket increase factor for FY 2013 of 2.7 percent, reduced by a productivity adjustment of 0.7 percent in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.1 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act. It also includes the approximate 0.2 percent overall estimated increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will affect the estimated distribution of payments among providers.

TABLE 7—IRF IMPACT TABLE FOR FY 2013

[Columns 4–8 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2013 [1]	FY 2013 CBSA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Total	1,139	377,040	0.2	1.9	0.0	0.0	2.1
Urban unit	739	182,873	0.2	1.9	−0.1	0.1	2.2
Rural unit	169	27,487	0.2	1.9	−0.1	0.2	2.3
Urban hospital	211	160,712	0.1	1.9	0.1	−0.2	1.9
Rural hospital	20	5,968	0.1	1.9	−0.1	−0.1	1.7
Urban For-Profit	324	150,510	0.1	1.9	0.1	−0.1	1.9
Rural For-Profit	59	10,972	0.2	1.9	−0.3	0.1	1.8
Urban Non-Profit	579	180,668	0.2	1.9	0.0	0.1	2.1
Rural Non-Profit	118	20,321	0.2	1.9	0.0	0.2	2.3
Urban Government	47	12,407	0.3	1.9	−0.2	0.0	1.9
Rural Government	12	2,162	0.2	1.9	0.3	0.4	2.8
Urban	950	343,585	0.2	1.9	0.0	0.0	2.0
Rural	189	33,455	0.2	1.9	−0.1	0.2	2.2
Urban by region [2]							
Urban New England	32	15,790	0.1	1.9	0.2	−0.1	2.2
Urban Middle Atlantic	142	58,285	0.1	1.9	0.1	0.1	2.2
Urban South Atlantic	132	62,379	0.1	1.9	−0.1	−0.1	1.8
Urban East North Central	184	53,412	0.2	1.9	−0.3	0.0	1.7
Urban East South Central	50	24,111	0.1	1.9	−0.4	−0.1	1.5
Urban West North Central	72	17,926	0.2	1.9	−0.1	0.1	2.1
Urban West South Central	170	65,263	0.1	1.9	0.5	0.1	2.6
Urban Mountain	68	22,572	0.2	1.9	0.0	−0.1	2.0
Urban Pacific	100	23,847	0.3	1.9	0.1	0.0	2.2
Rural by region [2]							
Rural New England	6	1,279	0.3	1.9	0.9	0.1	3.2
Rural Middle Atlantic	15	2,807	0.1	1.9	−0.2	0.1	1.9
Rural South Atlantic	23	5,699	0.1	1.9	−0.7	0.0	1.4
Rural East North Central	31	5,498	0.1	1.9	−0.3	0.2	1.9
Rural East South Central	23	3,944	0.1	1.9	−0.5	0.2	1.7
Rural West North Central	29	3,857	0.3	1.9	0.5	0.3	3.0
Rural West South Central	50	9,336	0.2	1.9	0.2	0.2	2.5
Rural Mountain	8	656	0.3	1.9	0.3	0.5	3.1
Rural Pacific	4	379	0.6	1.9	0.3	0.1	2.9
Teaching Status							
Non-teaching	1,024	330,504	0.1	1.9	0.0	0.0	2.1
Resident to ADC less than 10%	64	30,956	0.2	1.9	−0.2	0.1	2.0
Resident to ADC 10%–19%	39	13,961	0.2	1.9	0.2	−0.1	2.3
Resident to ADC greater than 19%	12	1,619	0.2	1.9	0.2	0.2	2.5
Disproportionate Share Patient Percentage (DSH PP)							
DSH PP = 0%	49	13,420	0.1	1.9	0.2	0.0	2.3
DSH PP less than 5%	175	51,699	0.2	1.9	0.0	0.1	2.1
DSH PP 5%–10%	347	129,038	0.1	1.9	0.0	0.0	2.0
DSH PP 10%–20%	339	121,832	0.2	1.9	−0.1	0.0	2.0

TABLE 7—IRF IMPACT TABLE FOR FY 2013—Continued

[Columns 4–8 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2013 [1]	FY 2013 CBSA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
DSH PP greater than 20%	229	61,051	0.2	1.9	0.0	−0.1	2.0

[1] This column reflects the impact of the RPL market basket increase factor for FY 2013 of 1.9 percent, which includes a market basket update of 2.7 percent, a 0.1 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act and a 0.7 percent reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

[2] A map of states that comprise the 9 geographic regions can be found at: *http://www.census.gov/geo/www/us_regdiv.pdf*.

3. Impact of the Update to the Outlier Threshold Amount

The outlier threshold adjustment is presented in column 4 of Table 7. In the FY 2012 IRF PPS final rule (76 FR 47867 through 47868), we used FY 2010 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2012 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2012.

For this notice, we are updating our analysis using FY 2011 IRF claims data and, based on this updated analysis, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.8 percent in FY 2012. Thus, we are adjusting the outlier threshold amount in this notice to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2013. The estimated change in total IRF payments for FY 2013, therefore, includes an approximate 0.2 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.8 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 7) is to increase estimated overall payments to IRFs by about 0.2 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 0.6 percent for rural IRFs in the Pacific region. We do not estimate that any group of IRFs will experience a decrease in payments from this update.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates

The adjusted market basket update to the IRF PPS payment rates is presented in column 5 of Table 7. In the aggregate the update would result in a net 1.9 percent increase in overall estimated payments to IRFs. This net increase reflects the estimated RPL market basket increase factor for FY 2013 of 2.7 percent, reduced by the 0.1 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act, and further reduced by a 0.7 percent productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

5. Impact of the CBSA Wage Index and Labor-Related Share

In column 6 of Table 7, we present the effects of the budget neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section V.B of this notice, the labor-related share decreased from 70.199 percent in FY 2012 to 69.981 percent in FY 2013.

In the aggregate, since these updates to the wage index and the labor-related share are applied in a budget-neutral manner as required under section 1886(j)(6) of the Act, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. For example, we estimate the largest increase in payments from the update to the CBSA wage index and labor-related share of 0.9 percent for rural IRFs in the New England region. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 0.7 percent decrease for rural IRFs in the South Atlantic region.

6. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values

In column 7 of Table 7, we present the effects of the budget neutral update of the CMG relative weights and average length of stay values. In the aggregate we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. The largest estimated decrease in payments as a result of these updates is a 0.2 percent decrease to urban freestanding IRFs. The largest estimated increase in payments as a result of these updates is a 0.5 percent increase to rural IRFs in the Mountain region.

D. Alternatives Considered

As stated in section 1X. B of this notice, the notice results in a positive economic impact on IRFs. The overall impact on all IRFs is an estimated increase in FY 2013 payments of 2.1 percent, relative to FY 2012, with three categories of IRFs (6 rural IRFs in the New England region, 29 rural IRFs in the West North Central region, and 8 rural IRFs in the Mountain region) estimated to receive an increase in estimated payments of 3 percent or more (3.2 percent, 3.0 percent, 3.1 percent, respectively). The following is a discussion of the alternatives considered to the IRF PPS updates contained in this notice.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Thus, we did not consider alternatives to updating payments using the estimated RPL market basket increase factor for FY 2013. However, as noted previously in this notice, section 1886(j)(3)(C)(ii)(I) requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2013 and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act require the Secretary to apply a 0.1 percentage point reduction to the market basket increase factor for FY 2013. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are updating IRF Federal prospective payments in this notice by

1.9 percent (which equals the 2.7 percent estimated RPL market basket increase factor for FY 2013 reduced by 0.1 percentage points, and further reduced by a 0.7 percent productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2013. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered maintaining the existing outlier threshold amount for FY 2013. However, analysis of updated FY 2011 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2012, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this notice to reflect a 0.2 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.8 percent, of aggregate estimated payments in FY 2013.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 8 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this notice. This table provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this notice based on the data for 1,139 IRFs in our database.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2012 IRF PPS FISCAL YEAR TO THE 2013 IRF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$140 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2013 are projected to increase by 2.1 percent, compared with the estimated payments in FY 2012, as reflected in column 8 of Table 7. IRF payments per discharge are estimated to increase 2.0 percent in urban areas and 2.2 percent in rural areas, compared with estimated FY 2012 payments. Payments per discharge to rehabilitation units are estimated to increase 2.2 percent in urban areas and 2.3 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.9 percent in urban areas and 1.7 percent in rural areas.

Overall, no IRFs are estimated to experience a net decrease in payments as a result of the updates in this notice. The largest payment increase is estimated to be a 3.2 percent increase for rural IRFs located in the New England region. This is due to the larger than average positive effect of the FY 2013 CBSA wage index and labor-related share updates for rural IRFs in this region.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: May 10, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 16, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–18433 Filed 7–25–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 29, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) into law. This law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants FDA authority to

regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 904(a)(3) of the FD&C Act (21 U.S.C. 387d(a)(3)) requires each tobacco product manufacturer or importer, or an agent, to begin reporting to FDA no later than June 22, 2012, ''all constituents, including smoke constituents, identified by [FDA] as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product.'' Reports must be by the brand and by quantity in each brand and subbrand. Section 904(c)(1) of the FD&C Act states that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify harmful and potentially harmful constituents (HPHCs) to be reported under sections 904(a)(3) and (c)(1) of the FD&C Act, including issuing a final guidance discussing FDA's current thinking on the meaning of ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement (76 FR 5387, January 31, 2011). The guidance is available on the Internet at *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm.* In addition, in the **Federal Register** of April 3, 2012 (77 FR 20034), FDA published a notice (the HPHC list notice) announcing the established list of HPHCs as required by section 904(e) of the FD&C Act and describing the criteria we used in identifying the HPHCs for the established list. Previously, FDA sought comment on both the criteria that would be used to identify HPHCs for the established list and a list of chemicals and chemical compounds that met the proposed criteria.

In the **Federal Register** of April 3, 2012 (77 FR 20030), FDA announced the availability of a draft guidance entitled ''Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act'' (904(a)(3) draft guidance) discussing the information to be reported on HPHCs in tobacco products and tobacco smoke under sections 904(a)(3) and (c)(1) of the FD&C Act. The 904(a)(3) draft guidance discusses, among other things: The statutory requirement for testing and reporting quantities of HPHCs, who tests and reports quantities of HPHCs to FDA, what HPHCs will be the focus of FDA enforcement at this time, when reports are submitted to FDA, what information is reported to FDA, and how the reports should be submitted to FDA. The 904(a)(3) draft guidance notifies manufacturers and importers that, at this time, while industry is developing laboratory capacity to comply with section 904(a)(3) of the FD&C Act, FDA does not intend to enforce the statutory requirement to submit quantities of all constituents identified by FDA as HPHCs by June 22, 2012, where manufacturers or importers complete testing and reporting for an abbreviated list of HPHCs as set forth in the 904(a)(3) draft guidance. In particular, at this time, for products that were first marketed before June 22, 2012, FDA does not intend to enforce the section 904(a)(3) requirement to test and report quantities of all HPHCs on FDA's established list where: (1) A manufacturer or importer (or agents thereof), other than a small tobacco product manufacturer, submits quantities of the HPHCs on an abbreviated list described in the guidance for all of its products, by brand and subbrand, no later than September 22, 2012 or (2) a small tobacco product manufacturer (or agents thereof) submits quantities of HPHCS on the abbreviated list for all of its products, by brand and subbrand, by December 22, 2012. In addition, for products first marketed on or after June 22, 2012, the 904(a)(3) draft guidance explains that FDA does not intend, at this time, to enforce the requirement in section 904(c)(1) of the FD&C Act to test and report quantities of all HPHCs on FDA's established list for products not previously on the market if a manufacturer or importer reports quantities for the abbreviated list of HPHCs at least 90 days prior to marketing the product in the United States. The 904(a)(3) draft guidance explains that, at this time, FDA intends to enforce the HPHC reporting requirements with respect to manufacturers of finished tobacco products for consumer use—cigarettes, smokeless tobacco, and roll-your-own tobacco—and not with respect to manufacturers and importers of other products, such as components sold to manufacturers or consumers for incorporation into finished products.

The purpose of the proposed information collection is for FDA to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by quantity in each brand and subbrand. The 904(a)(3) draft guidance provides an abbreviated list of HPHCs on which FDA intends to focus enforcement at this time for each of the following: Cigarette smoke, smokeless tobacco products, and roll-your-own tobacco and cigarette filler.

To facilitate the submission of HPHC information, FDA has developed Form 3787 in both paper and electronic formats. Manufacturers or importers, or an agent, may submit information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs. Users of eSubmitter may also populate an Excel file and import data into eSubmitter. FDA also provides paper forms for the submission of section 904(a)(3) reports. FDA placed draft copies of the paper forms and screen shots of the electronic form and spreadsheet in this docket. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for filling out and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information (including the specific HPHCs identified in the 904(a)(3) draft guidance).

The **Federal Register** notice announcing the availability of the 904(a)(3) draft guidance included a 60-day notice requesting public comment on the proposed collection of information. FDA received 16 comments that were PRA-related, including but not limited to the following issues:

- Suggestions to enhance the quality, utility, and clarity of the information to be collected (i.e., comments specific to FDA's eSubmitter tool and paper forms);
- Cost associated with the collection of information to comply with section 904(a)(3) of the FD&C Act, particularly for small tobacco product manufacturers; and
- Use of the proposed information collection, especially because specific test methods are not prescribed to determine HPHC quantities.

Section 904(a)(3) of the FD&C Act requires HPHC testing and reporting. We have stated that we intend to exercise enforcement discretion for manufacturers who test for 20 rather than 93 HPHCs at this time. In addition, we have recognized that small tobacco product manufacturers are likely to rely on contract testing laboratories and intend to exercise enforcement discretion for those who submit quantities of HPHCs 6 months after the statutory deadline (i.e., December 22, 2012), and 3 months after submissions by other tobacco product manufacturers. Our abbreviated list of HPHCs, along with the timeframes described in the

draft guidance, represent a reasonable approach to implementing section 904(a)(3) of the FD&C Act.

Based on comments received, FDA has revised the instructions for FDA Form 3787 to explain that if the HPHC quantity is below the limit of detection or limit of quantitation, zero should be entered in the space identified for form. We have also made minor cosmetic changes to clarify instructions and to allow accurate data entry. FDA has not revised the burden estimate for this collection of information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collected	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Part 1—Section 904(a)(3) of the FD&C Act (Annualized estimate of one-time reporting) [2]					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	120	10.10	1,212	2	2,424
Roll-Your-Own	46	3.22	148	2	296
Smokeless	200	1.44	288	2	576
Total					3,296
2. Testing of HPHC Quantities in Products					
Cigarette Filler	120	10.1	1,212	9.42	11,417
Roll-Your-Own	46	3.22	148	9.42	1,394
Smokeless	200	1.44	288	12.06	3,473
Total					16,284
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: International Organization for Standardization (ISO) Regimen	120	10.1	1,212	23.64	28,652
Cigarette: Health Canada Regimen	120	10.1	1,212	23.64	28,652
Total					57,304
Total Section 904(a)(3) Annualized One-Time Burden					76,884
Part 2—Reporting of Section 904(c)(1) New Products (15% of One-Time Burden Totals) [3]					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	18	10.10	182	2	364
Roll-Your-Own	7	3.22	23	2	46
Smokeless	30	1.44	43	2	86
Total					496
2. Reporting of HPHC Quantities in Products					
Cigarette Filler	18	10.1	182	9.42	1,714
Roll-Your-Own	7	3.22	23	9.42	217
Smokeless	30	1.44	43	12.06	519
Total					2,450
3. Reporting of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	18	10.1	182	23.64	4,302
Cigarette: Health Canada Regimen	18	10.1	182	23.64	4,302
Total					8,604
Total Section 904(c)(1) Burden					11,550
Total Reporting Burden Hours					88,434

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

[2] One-time actual first year burden hours have been annualized over the 3-year OMB period of approval to avoid over counting the burden each year.

[3] Annual new product reporting under section 904(c)(1) of the FD&C Act is estimated to be 15 percent of the annualized one-time burden.

FDA estimates the one-time reporting burden for this guidance would be 230,652 hours during the first year for section 904(a)(3) of the FD&C Act reporting plus ongoing annual burden of 11,550 hours for section 904(c)(1) reporting. The burden estimate for this collection of information includes the time it will take to read the guidance document, test the products, and prepare the HPHC report.

To avoid overcounting the one-time reporting burden, FDA has annualized the one-time burden over the 3-year expected OMB period of approval. The annualized one-time burden of 76,884 hours is located in part one of table 1 of this document, and includes burden for collections of information gathered under section 904(a)(3) of the FD&C Act. The total annual burden for this collection of information is estimated to be 88,434 hours, which is the annualized one-time burden estimate for section 904(a)(3) of the FD&C Act associated with the submission of HPHC reports and the annual burden estimate for section 904(c)(1). Table 1 of this document estimates 366 respondents will submit HPHC reports on a one-time basis. Table 1 of this document addresses the time required for manufacturers and importers to report their company information. We estimate that the burden is no more than 2 hours per response to report company and product information, regardless of whether the paper or electronic form (Form FDA 3787) is used. This estimate is not dependent on product type, so the estimated burden is the same for cigarettes, roll-your-own tobacco, and smokeless tobacco products. We also estimate that 3,636 cigarette subbrands, 445 roll-your-own tobacco subbrands, and 861 smokeless tobacco subbrands (4,942 total subbrands) must comply with section 904(a)(3) of the FD&C Act. Therefore, the total annualized burden for reporting company and product information is 3,296 hours.

Table 1 of this document also addresses the time required for manufacturers and importers to report quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, draft the report for FDA, and submit the report to FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to test the product, draft testing reports, draft the report for FDA, and submit the report to FDA to be 16,284 annualized burden hours. The burden for each product type reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work).

In addition to addressing the time required to report quantities of HPHCs in tobacco products, table 1 of this document addresses the time required for manufacturers and importers to report quantities for HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, drafting the report for FDA, and submitting the report to FDA. We estimate the annualized burden for this section to be 57,304 hours. The annualized burden reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two recommended smoking regimens. The total annualized burden for part one of table 1 (section 904(a)(3) reporting) is 76,884 hours.

Table 1 of this document also contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers and importers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. We estimate that approximately 15 percent of FDA currently regulated tobacco products in any given year will require submission of this information. The estimated total annual burden for section 904(c)(1) of the FD&C Act is 11,550 hours, which includes reporting manufacturer/importer company and product information, reporting HPHC quantities in products, and reporting HPHC quantities in mainstream smoke.

The estimated total annual burden for the reporting of HPHC under section 904(a)(3) and (c)(1) of the FD&C Act is 88,434 hours, which includes the section 904(a)(3) annualized reporting burden plus the section 904(c)(1) annual reporting burden.

We have not estimated any capital costs because we do not believe there are any capital costs associated with this collection. However, you may comment on any specific capital costs that you have identified.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18442 Filed 7–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2012, from 8:30 a.m. to 4 p.m.

Location: DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD. 20993, 301–796–0885, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 11, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107–109) and the Pediatric Research Equity Act (Public Law 108–155), for Kapvay (clonidine hydrochloride), Vyvanse (lisdexamfetamine dimesylate), Ofirmev (acetaminophen), ella (ulipristal acetate), Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Lo

Loestrin Fe (norethindrone acetate and ethinyl estradiol ethinyl estradiol and ferrous fumarate), Aridol (mannitol inhalation powder), Augmentin XR (amoxicillin/clavulanate potassium), Afinitor (everolimus), Moxeza (moxifloxacin hydrochloride), and Lastacaft (alcaftadine).

As mandated by the Food and Drug Administration Amendments Act, Title III, Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85), the committee will discuss the safety of and the ongoing propriety of the humanitarian device exemption for the Melody Transcatheter Pulmonary Valve and Ensemble Delivery System and the Elana Surgical Kit.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 4, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on September 11, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 24, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 27, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg (*walter.ellenberg@fda.hhs.gov*) or 301–796–0885 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–18509 Filed 7–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Rodent Testing to Identify Pharmacotherapies for Substance Dependence (8908).

Date: August 23, 2012.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 24, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18475 Filed 7–27–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel Clinical Trials at the NHLBI.

Date: August 20, 2012.

Time: 11:00 a.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: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–435–0288, *cjoyce@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pathogen Inactivation for Blood Components.

Date: August 20, 2012.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases

and Resources Research, National Institutes of Health, HHS)

Dated: July 24, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18477 Filed 7–27–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2012–0001]

Critical Infrastructure Private Sector Clearance Program Request

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-day notice and request for comments;

Reinstatement, with change, of a previously approved collection.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). NPPD is soliciting comments concerning Reinstatement, with change, of a previously approved ICR for the Critical Infrastructure Private Sector Clearance Program (PSCP). DHS previously published this ICR in the **Federal Register** on April 12, 2012, for a 60-day public comment period. DHS received no comments. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until August 29, 2012. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to OMB Desk Officer, DHS, Office of Civil Rights and Civil Liberties. Comments must be identified by DHS–2012–0001 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Email: oira_submission@omb.eop.gov*. Include the docket number in the subject line of the message.
- *Fax:* (202) 395–5806.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov*, including any personal information provided.

OMB 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.

FOR FURTHER INFORMATION CONTACT: Monika Junker, DHS/NPPD/IP, *monika.junker@dhs.gov*, (703) 235–8229.

SUPPLEMENTARY INFORMATION: PSCP sponsors clearances for private sector partners who are responsible for critical infrastructure protection but would not otherwise be eligible for a clearance under Executive Order 12829. These partners are subject matter experts within specific industries and sectors. The PSCP requires individuals to complete a clearance request form that initiates the clearance process. DHS Sector Specialists or Protective Security Advisors email the form to the individual who then emails back the completed form, minus their date and place of birth and social security number. The clearance request form is signed by both the Federal official who nominated the applicant and the Assistant Secretary for Infrastructure Protection. Upon approval to process, the PSCP Administrator contacts the nominee to obtain the social security number, date and place of birth, and will then enter this data into e-QIP—Office of Personnel Management's secure portal for investigation processing. Once the data is entered in e-QIP, the applicant can complete the online security questionnaire. The PSCP maintains all applicants' information in the Master Roster, which contains all the information found on the clearance request form in addition to their clearance information (date granted, level of clearance, date non-disclosure agreements signed, and type/date of investigation). The Administrator of the Master Roster maintains the information to track clearance processing and investigation information and to have the most current contact information for the participants from each sector.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection.

Title: Critical Infrastructure Private Sector Clearance Program.

OMB Number: 1670–0013.

Frequency: Once.

Affected Public: Designated private sector employees of critical infrastructure entities or organizations.

Number of Respondents: 450 (estimate).

Estimated Time Per Respondent: 10 minutes.

Total Burden Hours: 75.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $0.

Dated: July 24, 2012.

Scott Libby,

Acting Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2012–18546 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2012–0037]

President's National Security Telecommunications Advisory Committee

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of an Open Federal Advisory Committee Teleconference.

SUMMARY: The President's National Security Telecommunications Advisory Committee (NSTAC) will meet on Thursday, August 16, 2012, via a conference call. The meeting will be open to the public.

DATES: The NSTAC will meet Thursday, August 16, 2012, from 2:00 p.m. to 3:15 p.m. Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held via a conference call. For access to the

conference bridge, contact Ms. Deirdre Gallop-Anderson by email at *deirdre.gallop-anderson@dhs.gov* by 5:00 p.m. on August 9, 2012.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the ''Supplementary Information'' section below. Documents associated with the issues to be discussed during the conference will be available at *www.ncs.gov/nstac* for review by August 10, 2012. Written comments must be received by the NSTAC Designated Federal Officer no later than August 30, 2012 and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting written comments.
- *Email: NSTAC@hq.dhs.gov*. Include the docket number in the subject line of the email message.
- *Fax:* (703) 235–4981.
- *Mail:* Alternate Designated Federal Officer, National Communications System, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, Mail Stop 0615, Arlington, VA 20598–0615.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *www.regulations.gov*, including any personal information provided.

Docket: For access to the docket, including all documents and comments received by the NSTAC, go to *www.regulations.gov*.

A public comment period will be held during the meeting on August 16, 2012, from 2:55 p.m. to 3:10 p.m. Speakers who wish to participate in the public comment period must register in advance no later than 5:00 p.m. on August 9, 2012, by emailing Deirdre Gallop-Anderson at *deirdre.gallop-anderson@dhs.gov*. Speakers are requested to limit their comments to three minutes and will speak in order of registration as time permits. Please note that the public comment period may end before the time indicated, following the last call for comments.

FOR FURTHER INFORMATION CONTACT: Allen F. Woodhouse, NSTAC Alternate Designated Federal Officer, Department of Homeland Security, telephone (703) 235–4900.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The NSTAC advises the President on matters related to national security and emergency preparedness telecommunications policy.

Agenda: The NSTAC members will receive an update on progress made to date by the Nationwide Public Safety Broadband Network (NPSBN) Research Subcommittee. The NPSBN Research Subcommittee is focusing on what National Security Emergency Preparedness (NS/EP) policy changes should be considered in order to: (1) Facilitate priority access that may be required across the diverse community of potential NPSBN users, particularly during NS/EP situations; (2) support NPSBN access, interoperability, security, reliability, and resiliency; and (3) help ensure the deployment and evolution of the NPSBN is in such a manner that accounts for each state and local jurisdiction's diverse capabilities, while helping to ensure scalability to the national level.

Next, NSTAC members will discuss the findings of their review of the Department of Homeland Security's (DHS) National Cybersecurity and Communications Integration Center (NCCIC). During the NSTAC meeting on May 15, 2012, the National Security Staff asked the NSTAC to conduct a review of the NCCIC to determine if it is operating in ways consistent with the NSTAC's proposed Joint Collaboration Center that the NSTAC envisioned in its 2009 Cybersecurity Collaboration Report.

The NSTAC, in coordination with senior leaders from the White House and DHS, will also address potential NSTAC taskings such as the National Security Staff's request for the NSTAC to examine how commercial off-the-shelf technologies and private sector best practices can be used to secure unclassified communications between and among Federal civilian departments and agencies.

Additionally, there will be a discussion regarding whether further study is warranted of the NSTAC's recommendation to develop a separate ''out-of-band'' data network supporting communications among carriers, Internet service providers, vendors, and additional critical infrastructure owners and operators during a severe cyber incident that renders the Internet unusable.

Dated: July 23, 2012.

Michael Echols,

Alternate Designated Federal Officer for the NSTAC.

[FR Doc. 2012–18536 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0045]

Privacy Act of 1974; Department of Homeland Security U.S. Customs and Border Protection-DHS/CBP–009 Electronic System for Travel Authorization (ESTA) System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current DHS system of records titled, ''Department of Homeland Security/U.S. Customs and Border Protection-DHS/CBP–009 Electronic System for Travel Authorization (ESTA) System of Records.'' This system collects and maintains a record of nonimmigrant aliens seeking to travel to the United States under the Visa Waiver Program. The system is used to determine whether the applicant is eligible to travel to the United States under the Visa Waiver Program by vetting the application information against selected security and law enforcement databases using U.S. Customs and Border Protection (CBP) TECS and the Automated Targeting System (ATS). In addition, ATS retains a copy of ESTA application data to identify potential high-risk ESTA applicants. DHS/CBP is updating this system of records notice to clarify the categories of individuals and remove unnecessary language, add the Internet Protocol address associated with the submitted ESTA application as a category of records, provide more specific legal authorities, clarify the purposes to include the identification of high-risk applicants, include an additional routine use for judicial proceedings and update and clarify other routine uses, clarify the retention of records in ESTA and the Nonimmigrant Information System (DHS/CBP–016—Nonimmigrant Information System December 19, 2008 73 FR 77739), update the notification procedures to explain the extension of access procedures to international travelers, allow limited direct access and amendment of ESTA application data, and add the CPB access request address; eliminate unnecessary language from the record source categories, and clarify which exemptions will be used for which provisions of the Privacy Act.

The Department of Homeland Security issued a Final Rule to exempt this system of records from certain provisions of the Privacy Act on August 31, 2009 (74 Fed. Reg. 45069). These regulations remain in effect. This updated system will be included in the DHS inventory of record systems.

DATES: Submit comments on or before August 29, 2012. This revised system will be effective August 29, 2012.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–0045 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 703–483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202) 325–0280, CBP Privacy Officer, Office of International Trade, U.S. Customs and Border Protection, Mint Annex, 799 Ninth Street NW., Washington, DC 20229. For privacy issues please contact: Mary Ellen Callahan (703) 235–0780, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) proposes to update and reissue an existing DHS system of records titled, ''DHS/CBP–009 Electronic System for Travel Authorization (ESTA) System of Records.''

ESTA is a web-based system that DHS/CBP developed in 2008 to determine the eligibility of aliens to travel under the Visa Waiver Program (VWP) to the United States by air or sea. The authority to collect information required in an ESTA application may be found in Section 217(h)(3) of the Immigration and Nationality Act (INA), 8 U.S.C. 1187(h)(3). An eligibility determination under ESTA is made prior to a visitor boarding a carrier en route to the United States, and is accomplished by vetting the information against selected security and law enforcement databases using CBP TECS and the Automated Targeting System (ATS) to determine whether such travel poses a law enforcement or security risk. In addition, ATS retains a copy of ESTA application data to identify potential high-risk ESTA applicants. DHS/CBP previously issued an updated SORN for ESTA on November 2, 2011 (76 FR 67751).

In order to determine whether the applicant is eligible to travel to the United States under the VWP, an applicant provides biographic and other requested information, as well as payment information, using the online application process available at *https://esta.cbp.dhs.gov.* CBP vets applicant information against various security and law enforcement databases. Payment information is sent to the Department of the Treasury's Pay.gov, and CBP a payment status and tracking number in return. CBP is updating the category of records in this system of records to now include the Internet Protocol address (IP address) associated with the submitted ESTA application. As of the effective date of this updated SORN, the IP address will be used as part of the DHS/CBP vetting process. A copy of the application data, including the IP address, will be sent to the ATS in order to identify possible high risk applicants as part of the vetting process.

DHS/CBP is updating this system of records notice to clarify the categories of individuals and remove unnecessary language. DHS/CBP is updating the categories of records for this system of records notice to permit the collection and use of the IP address associated with an ESTA application. DHS/CBP is also providing more specific legal authorities to collect ESTA information, and clarifying the purposes to include the identification of high-risk applicants.

The routine uses are being updated to add general language ensuring that ''[a]ny disclosure of information must be made consistent with the official duties of the person making the disclosure.'' Routine uses A, D, E, and J are being reworded to provide greater clarity and make non-substantive grammatical changes. Routine use C is being updated to change ''other federal government agencies'' to ''General Services Administration'' to better reflect the statutory authorities and the fact that records will be shared with the National Archives and Records Administration (NARA) where NARA maintains the records as permanent records. Routine uses G, K, and M are being reworded to provide greater clarity and remove the now superfluous condition that the ''disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.'' Finally, a new routine use P is being inserted to permit DHS to share this information with a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a subpoena, or in connection with criminal law proceedings.

DHS/CBP is also updating this SORN by clarifying the retention of records in ESTA and the Non-Immigrant Information System (NIIS) into which ESTA data may be incorporated based on actual travel to the United States; updating and clarifying the notification procedures to explain the extension of access procedures to international travelers, allow limited direct access and amendment of ESTA application data, and add the CPB access request address; eliminating unnecessary language from the record source categories describing the use of payment information between ESTA, Pay.gov, and the CBP Credit and Debit Card Data System for payment reconciliation purposes; and clarifying that the Department is exempting the system from sections (c)(3), (e)(8), and (g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2), and is exempting the system from (c)(3) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).

DHS previously published a Final Rule exempting this system of records from certain provisions of the Privacy Act. 74 FR 45069 (Aug. 31, 2009). That Final Rule remains in effect and applicable to this updated system.

The purpose of this system of records is to determine the eligibility of aliens to travel under the VWP to the United States by air or sea. DHS/CBP has authority to operate this system under Title IV of the Homeland Security Act of 2002, 6 U.S.C. 201, et. seq., and Section 217(h)(3) of the Immigration and Nationality Act, 8 U.S.C. 1187(h)(3).

Consistent with DHS' information sharing mission, information stored in ESTA may be shared with other DHS components, as well as appropriate federal, state, local, tribal, territorial, foreign, or international government agencies. This sharing will only take place after DHS determines that the recipient has a need to know the information to carry out functions consistent with the exceptions under

the Privacy Act of 1974, 5 U.S.C. 552a(b), and the routine uses set forth in this system of records notice.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the federal government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. This system only collects information pertaining to persons in nonimmigrant status, that is, persons who are not covered by the protections of the Privacy Act at the time they provide their information. However, given the importance of providing privacy protections to international travelers, DHS has decided to administratively apply the privacy protections and safeguards outlined in this notice to all international travelers subject to ESTA.

This newly-updated system will be included in the Department of Homeland Security's inventory of record systems.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)—009

SYSTEM NAME:

DHS/CBP–009 Electronic System for Travel Authorization (ESTA)

SECURITY CLASSIFICATION:

Unclassified. The data may be retained on the classified networks but this does not change the nature and character of the data until it is combined with classified information.

SYSTEM LOCATION:

Records are maintained in the operational system at CBP Headquarters in Washington, DC and at CBP field offices. Records are replicated from the operational system and maintained on the DHS unclassified and classified networks.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include foreign nationals who seek to enter the United States by air or sea under the VWP.

CATEGORIES OF RECORDS IN THE SYSTEM:

- Full Name (First, Middle, and Last);
- Date of birth;
- Gender;
- Email address;
- Phone number;
- Travel document type (e.g., passport), number, issuance date, expiration date and issuing country;
- Country of Citizenship;
- IP address;
- ESTA application number;
- Department of Treasury Pay.gov Payment Tracking Number (i.e., confirmation of payment; absence of payment confirmation will result in a ''not cleared'' determination);
- Country of Birth;
- Date of Anticipated Crossing;
- Airline and Flight Number;
- City of Embarkation;
- Address while visiting the United States (Number, Street, City, State);
- Whether the individual has a communicable disease, physical or mental disorder, or is a drug abuser or addict;
- Whether the individual has been arrested or convicted for a moral turpitude crime, drug possession or use, or has been sentenced for a period longer than five years;
- Whether the individual has engaged in espionage, sabotage, terrorism or Nazi activity between 1933 and 1945;
- Whether the individual is seeking work in the U.S.;
- Whether the individual has been excluded or deported, or attempted to obtain a visa or enter U.S. by fraud or misrepresentation;
- Whether the individual has ever detained, retained, or withheld custody of a child from a U.S. citizen granted custody of the child;
- Whether the individual has ever been denied a U.S. visa or entry into the U.S., or had a visa cancelled, and, if so, the location and date of that denial or cancellation;
- Whether the individual has ever asserted immunity from prosecution;
- Any change of address while in the U.S.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title IV of the Homeland Security Act of 2002, 6 U.S.C. 201 *et seq.;* the INA, as amended, including 8 U.S.C. 1187(a)(11) and (h)(3), and implementing regulations contained in Part 217, title 8, Code of Federal Regulations; and the Travel Promotion Act of 2009, Public Law 111–145, 22 U.S.C. 2131.

PURPOSE(S):

The purpose of this system is to collect and maintain a record of nonimmigrant aliens who want to travel to the United States under the VWP, and to determine whether applicants are eligible to travel to the United States under the VWP by vetting their information against various security and law enforcement databases and identifying high-risk applicants. This vetting includes consideration of IP address, along with the other application data.

The Department of Treasury Pay.gov tracking number (associated with the payment information provided to Pay.gov and stored in the Credit/Debit Card Data System, DHS/CBP–003—Credit/Debit Card Data System (CDCDS), 76 Fed. Reg. 67755 (November 2, 2011)) will be used to process ESTA and third party administrator fees and to reconcile issues regarding payment between ESTA, CDCDS, and Pay.gov. Payment information will not be used for vetting purposes and is stored in a separate system (CDCDS) from the ESTA application data.

DHS maintains a replica of some or all of the data in the operating system on the unclassified and classified DHS networks to allow for analysis and vetting consistent with the above stated purposes and this published notice.

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

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3). Any disclosure of information must be made consistent with the official duties of the person making the disclosure. The routine uses are as follows:

A. To the Department of Justice (DOJ), including the United States Attorney Offices, or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee of DHS in his/her official capacity;

3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to a written inquiry from that congressional office made pursuant to a Privacy Act waiver from the individual to whom the record pertains.

C. To NARA or the General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906 and for records that NARA maintains as permanent records.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individuals that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations.

H. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations for the purpose of protecting the vital health interests of a data subject or other persons (e.g., to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantinable disease or to combat other significant public health threats; appropriate notice will be provided of any identified health threat or risk);

I. To third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation;

J. To a federal, state, tribal, local, international, or foreign government agency or entity for the purpose of consulting with that agency or entity: (1) To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program; (2) for the purpose of verifying the identity of an individual seeking redress in connection with the operations of a DHS component or program; or (3) for the purpose of verifying the accuracy of information submitted by an individual who has requested such redress on behalf of another individual;

K. To federal and foreign government intelligence or counterterrorism agencies or components where DHS becomes aware of an indication of a threat or potential threat to national or international security to assist in countering such threat, or to assist in anti-terrorism efforts;

L. To the Department of State in the processing of petitions or applications for benefits under the Immigration and Nationality Act, and all other immigration and nationality laws including treaties and reciprocal agreements;

M. To an organization or individual in either the public or private sector, either foreign or domestic, where there is a reason to believe that the recipient is or could become the target of a particular terrorist activity or conspiracy, to the extent the information is relevant to the protection of life or property;

N. To the carrier transporting an individual to the United States, but only to the extent that CBP provides information that the ESTA status is not applicable to the traveler, or, if applicable, that the individual is authorized to travel, not authorized to travel, pending, or has not applied.

O. To the Department of Treasury's Pay.gov, for payment processing and payment reconciliation purposes.

P. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in response to a subpoena, or in connection with criminal law proceedings;

Q. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically in the operational system as well as on the unclassified and classified network or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

These records may be retrieved by any of the data elements supplied by the applicant. The Pay.gov payment tracking number may be used to track the amount of payment associated with an ESTA application and to reconcile payment discrepancies.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information stored. Access to the computer system containing the records is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

Application information submitted to ESTA generally expires and is deemed ''inactive'' two years after the initial submission of information by the applicant. In the event that a traveler's passport remains valid for less than two years from the date of the ESTA approval, the ESTA travel authorization will expire concurrently with the passport. Information in ESTA will be retained for one year after the ESTA travel authorization expires. After this period, the inactive account information will be purged from online access and archived for 12 years. Data linked at any time during the 15-year retention period (generally 3 years active, 12 years archived), to active law enforcement lookout records, CBP matches to enforcement activities, and/or investigations or cases, including ESTA applications that are denied authorization to travel, will remain accessible for the life of the law enforcement activities to which they may become related. NARA guidelines for retention and archiving of data will apply to ESTA and CBP continues to negotiate with NARA for approval of the ESTA data retention and archiving plan. Records replicated on the unclassified and classified networks will follow the same retention schedule.

Payment information is not stored in ESTA, but is forwarded to Pay.gov and stored in CBP's financial processing system, CDCDS, pursuant to the DHS/CBP–018, CDCDS system of records notice.

In those instances where a VWP traveler's ESTA data is used for purposes of processing their application for admission to the United States, the ESTA data will be used to create a corresponding admission record in the DHS/CBP–016 Non-Immigrant Information System (NIIS). This corresponding admission record will retained in accordance with the NIIS retention schedule, which is 75 years.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Automated Systems, U.S. Customs and Border Protection Headquarters, 1300 Pennsylvania Avenue NW., Washington, DC 20229.

NOTIFICATION PROCEDURE:

This system only collects information pertaining to persons in nonimmigrant status, that is, persons who are not covered by the protections of the Privacy Act at the time they provide their information. However, given the importance of providing privacy protections to international travelers, DHS has decided to administratively apply the privacy protections and safeguards outlined in this notice to all international travelers subject to ESTA.

Applicants may access their ESTA information to view and amend their applications by providing their ESTA number, birth date, and passport number. Once they have provided their ESTA number, birth date, and passport number, applicants may view their ESTA status (authorized to travel, not authorized to travel, pending) and submit limited updates to their travel itinerary information. If an applicant does not know his/her application number, he/she can provide his or her name, passport number, date of birth, and passport issuing country to retrieve his/her application number.

In addition to using the ESTA system directly to access information provided to DHS/CBP, individuals may submit requests and receive information maintained in this system as it relates to data submitted by or on behalf of a person who travels to the United States and crosses the border, as well as the resulting determination (authorized to travel, pending, or not authorized to travel). However, the Secretary of Homeland Security has exempted portions of this system from certain provisions of the Privacy Act related to providing the accounting of disclosures to individuals, because it is a law enforcement system. CBP will, however, consider individual requests to determine whether or not information may be released. In processing requests for access to information in this system, CBP will review not only the records in the operational system but also the records that were replicated on the unclassified and classified networks, and based on this notice provide appropriate access to the information.

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528. Requests under the Privacy Act and FOIA specifically for CBP should be addressed to: U.S. Customs and Border Protection (CBP), Freedom of Information Act (FOIA) Division, 1300 Pennsylvania Avenue NW., Washington, DC 20229.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. § 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

The system obtains information from the online ESTA application submitted by the applicant. This information is processed by the Automated Targeting System (ATS) to identify terrorists or threats to aviation and border security, and TECS (for matches to persons identified to be of law enforcement interest), and the vetting result of ''authorized to travel,'' ''not authorized to travel,'' or ''pending'' is maintained in ESTA. ''Pending'' will be resolved to ''authorized to travel'' or ''not authorized to travel'' based on further research by CBP. Pay.gov provides the Pay.gov tracking number once payment

information has been forwarded to it and processed.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemption shall be asserted with respect to information maintained in the system as it relates to data submitted by or on behalf of a person who travels to visit the United States and crosses the border, nor shall an exemption be asserted with respect to the resulting determination (authorized to travel, pending, or not authorized to travel). Information in the system may be shared with law enforcement and/or intelligence agencies pursuant to the above routine uses. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agency has sought and been provided particular records may affect ongoing law enforcement activities. As such, pursuant to 5 U.S.C. 552a(j)(2), DHS will claim exemption from Sections (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information. Further, DHS will claim exemption from Section (c)(3) of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(k)(2) as is necessary and appropriate to protect this information.

Dated: July 18, 2012.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2012–18552 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2012–0024; OMB Number 1660–0108]

Agency Information Collection Activities: Proposed Collection; Comment Request, National Emergency Family Registry and Locator System (NEFRLS)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, 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 revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the FEMA National Emergency Family Registry and Locator System (NEFRLS), which allows adults that have been displaced by a Presidentially-declared disaster or emergency to reunify with their families.

DATES: Comments must be submitted on or before September 28, 2012.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2012–0024. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., Room 835, Washington, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Earnest Poindexter, Information Technology Specialist, Recovery Directorate, Individual Assistance Division, (202) 212–4883. You may contact the Records Management Division for copies of the proposed collection of information at facsimile number (202) 646–3347 or email address: *FEMA-Information-Collections-Management@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Post-Katrina Emergency Management Reform Act of 2006, in Title VI of the DHS Appropriations Act of 2007 (the Post Katrina Reform Act), Public Law 109–295, Section 689c, 120 Stat. 1355 at 1451 is the legal basis for FEMA to provide a National Emergency Family Registry and Locator System (NEFRLS). NEFRLS allows adults (including medical patients), that have been displaced by a Presidentially-declared major disaster or emergency, to voluntarily register by submitting personal information to be entered into a database that could be used by others to help reunify them with their families. Children who are traveling with their families during a Presidentially-declared major disaster or emergency can be listed in NEFRLS. NEFRLS allows a registrant to designate up to 7 individuals who are authorized to search for and access the registrant's information in the system. The ability to list children within NEFRLS is only to indicate which family members are together and safe.

Collection of Information

Title: National Emergency Family Registry and Locator System.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0108.

Form Titles and Numbers: None.

Abstract: NEFRLS is a Web-based database enabling FEMA to provide a nationally available and recognized database allowing adults (including medical patients) that have been displaced by a Presidentially-declared major disaster or emergency to voluntarily register via the Internet or a toll-free number. This database will then allow designated individuals to search for displaced friends, family, and household members.

Affected Public: Individuals and households.

Number of Respondents: 56,000.

Number of Responses: NEFRLS Tele-registration: 42,000; NEFRLS Internet Registration: 14,000.

Estimated Total Annual Burden Hours: 4,600 hours.

Estimated Cost: There are no annual record keeping, capital, startup, nor maintenance costs associated with this information collection.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses.

Dated: July 24, 2012.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2012–18574 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3345–EM; Docket ID FEMA–2012–0002]

West Virginia; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of West Virginia (FEMA–3345–EM), dated June 30, 2012, and related determinations.

DATES: Effective Date: July 10, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective July 10, 2012.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18532 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3346–EM; Docket ID FEMA–2012–0002]

Ohio; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Ohio (FEMA–3346–EM), dated June 30, 2012, and related determinations.

DATES: *Effective Date:* July 2, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective July 2, 2012.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18480 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4068–DR; Docket ID FEMA–2012–0002]

Florida; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–4068–DR), dated July 3, 2012, and related determinations.

DATES: *Effective Date:* July 3, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 3, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Florida resulting from Tropical Storm Debby beginning on June 23, 2012, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Florida.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gracia B. Szczech, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Florida have been designated as adversely affected by this major disaster:

Baker, Bradford, Columbia, Pasco, and Wakulla Counties for Individual Assistance.

All counties and Indian Tribes within the State of Florida are eligible to apply for

assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18487 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4067–DR; Docket ID FEMA–2012–0002]

Colorado; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Colorado (FEMA–4067–DR), dated June 28, 2012, and related determinations.

DATES: *Effective Date:* July 11, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 11, 2012.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18479 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4068–DR; Docket ID FEMA–2012–0002]

Florida; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4068–DR), dated July 3, 2012, and related determinations.

DATES: *Effective Date:* July 9, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the Public Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 3, 2012.

Baker, Clay, Columbia, Hernando, Pasco, Suwannee, and Wakulla Counties for Public Assistance (already designated for Individual Assistance).

Charlotte, Citrus, Dixie, Gulf, Franklin, Jefferson, Hamilton, Lafayette, Liberty, Manatee, and Sarasota Counties for Public Assistance.

Nassau and Union Counties for Individual Assistance and Public Assistance.

Duval County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18486 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4068–DR; Docket ID FEMA–2012–0002]

Florida; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4068–DR), dated July 3, 2012, and related determinations.

DATES: *Effective Date:* July 12, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 3, 2012.

Hillsborough and Taylor Counties for Individual Assistance. Manatee County for Individual Assistance (already designated for Public Assistance).

Collier, Lee, Levy, Madison, Putnam, Santa Rosa, and Taylor Counties for Public Assistance.

Bradford and Duval Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially

Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18492 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4068–DR; Docket ID FEMA–2012–0002]

Florida; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4068–DR), dated July 3, 2012, and related determinations.

DATES: *Effective Date:* July 17, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 3, 2012.

Gilchrist and Polk Counties for Individual Assistance.

Citrus, Lafayette, and Sarasota Counties for Individual Assistance (already designated for Public Assistance).

Pinellas County for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–18491 Filed 7–27–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–B–1259]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 29, 2012.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1259, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of

experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *www.fema.gov/pdf/media/factsheets/2010/srp_fs.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Community	Community map repository address
City of Dubuque, Iowa	
Maps Available for Inspection Online at: *http://www.starr-team.com/starr/RegionalWorkspaces/RegionVII/DubuqueCountyIowa/Preliminary%20Maps/Forms/AllItems.aspx*	
City of Dubuque	City Hall, 50 West 13th Street, Dubuque, IA 52001.
Boyd County, Kentucky, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.bakeraecom.com/index.php/kentucky/boyd/*	
City of Ashland	Department of Planning and Community Development, 1700 Greenup Avenue, Room 208, Ashland, KY 41101.
City of Catlettsburg	City Hall, 216 26th Street, Catlettsburg, KY 41129.
Unincorporated Areas of Boyd County	Boyd County Courthouse, 2800 Louisa Street. Catlettsburg, KY 41129.
Hampden County, Massachusetts (All Jurisdictions)	
Maps Available for Inspection Online at: *http://www.starr-team.com/starr/RegionalWorkspaces/RegionI/HampdenCountyMA/Preliminary%20Maps/Forms/AllItems.aspx*	
City of Chicopee	City Hall Annex, 274 Front Street, 4th Floor, Chicopee, MA 01013.
Town of Blandford	Town Hall, 1 Russell Stage Road, Blandford, MA 01008.
Town of Granville	Town Hall, 707 Main Road, Granville, MA 01034.
Town of Montgomery	Town Hall, 161 Main Road, Montgomery, MA 01085.
Town of Russell	Town Hall, 65 Main Street, Russell, MA 01071.
Town of Tolland	Town Hall, 241 West Granville Road, Tolland, MA 01034.
Lee County, Texas, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.riskmap6.com*	
City of Giddings	City Hall, 118 East Richmond Street, Giddings, TX 78942.
Town of Lexington	City Hall, 604 Wheatley Street, Lexington, TX 78947.
Unincorporated Areas of Lee County	Lee County Courthouse, 200 South Main Street, Room 107, Giddings, TX 78942.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Sandra K. Knight,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–18531 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–B–1261]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new

buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 29, 2012.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1261, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *www.fema.gov/pdf/media/factsheets/2010/srp_fs.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Community	Community map repository address
Manatee County, Florida, and Incorporated Areas	
Maps Available for Inspection Online at: *http:www.bakeraecom.com/index.php/florida/manatee/*	
City of Anna Maria	City Hall, 10005 Gulf Drive, Anna Maria, FL 34216.
City of Bradenton	City Hall, 101 Old Main Street West, Bradenton, FL 34205.
City of Palmetto	City Hall, 516 8th Avenue West, Palmetto, FL 34221.
Unincorporated Areas of Manatee County	Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205.
Ravalli County, Montana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.bakeraecom.com/index.php/montana/ravalli/*	
City of Hamilton	202 South 3rd Street, Hamilton, MT 59840.
City of Stevensville	206 Buck Street, Stevensville, MT 59870.
Town of Darby	101 East Tanner Avenue, Darby, MT 59829.
Unincorporated Areas of Ravalli County	215 South 4th Avenue, Suite F, Hamilton, MT 59840.
Mecklenburg County, North Carolina, and Incorporated Areas	
Maps Availble for Inspection Online at: *http://mapserver.mecklenburgcountync.gov/fmr/*	
City of Charlotte	City Hall, 600 East 4th Street, Charlotte, NC 28202.
Town of Matthews	Town Hall, 232 Matthews Station Street, Matthews, NC 28105.
Town of Mint Hill	Town Hall, 7151 Matthews-Mint Hill Road, Mint Hill, NC 28277.
Town of Pineville	Town Hall, 200 Dover Street, Pineville, NC 28134.
Unincorporated Areas of Mecklenburg County	Mecklenburg County Government Center, 600 East 4th Street, Charlotte, NC 28202.
Union County, North Carolina, and Incorporated Areas	
Maps Availble for Inspection Online at: *http://www.ncfloodmaps.com*	
Town of Indian Trail	Administrative Services, 130 Blythe Drive, Indian Trail, NC 28079.

Community	Community map repository address
Town of Stallings	Town Hall, 315 Stallings Road, Stallings, NC 28104.
Town of Weddington	Town Hall, 1924 Weddington Road, Weddington, NC 28104.
Unincorporated Areas of Union County	Union County Office, 500 North Main Street, Monroe, NC 28112.
Village of Marvin	Village Hall, 10004 New Town Road, Marvin, NC 28173.
Town of Springfield, South Carolina	
Maps Availble for Inspection Online at: *http://www.dnr.sc.gov/water/flood/comaps.html*	
Town of Springfield	Town Hall, 1505 Georgia Street, Springfield, SC 29146.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: July 12, 2012.

Sandra K. Knight,

Deputy Associate Administrator for Mitigation,Department of Homeland Security,Federal Emergency Management Agency.

[FR Doc. 2012–18529 Filed 7–27–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5603–N–50]

Continuum of Care Homeless Assistance Grant Application—Technical Submission

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Information to be used to obtain more detailed technical information not contained in the original Continuum of Care Homeless Assistance Grant Application.

DATES: *Comments Due Date:* August 29, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2506–0183) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov*. or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Continuum of Care Homeless Assistance Grant Application—Technical Submission.

OMB Approval Number: 2506–0183.

Form Numbers: HUD–40090–3a., HUD–40090–3b.

Description of the Need for the Information and Its Proposed

Information to be used to obtain more detailed technical information not contained in the original Continuum of Care Homeless Assistance Grant Application.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	500	1		9.04		4,520

Total Estimated Burden Hours: 4,520.

Status: Reinstatement with change of a previously approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 25, 2012.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2012–18526 Filed 7–27–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5603–N–54]

Notice of Submission of Proposed Information Collection to OMB Mortgage's Certificate of Fees and Escrow and Surety Bond Against Defects Due to Defective Material and/or Faulty Workmanship

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The information collection is used by Mortgagees to ensure that fees are within acceptable limits and the

required escrows will be collected. HUD determines the reasonableness of the fees and uses the information in calculating the financial requirement for closing.

DATES: *Comments Due Date: August 29, 2012.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502–0468) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov.* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice Also Lists the Following Information

Title of Proposal: Mortgagee's Certificate of Fees and Escrow and Surety Bond Against Defects Due to Defective Material and/or Faulty Workman.

OMB Approval Number: 2502–0468.

Form Numbers: HUD 2434, HUD 3259.

Description of the Need for the Information and Its Proposed

The information collection is used by Mortgagees to ensure that fees are within acceptable limits and the required escrows will be collected. HUD determines the reasonableness of the fees and uses the information in calculating the financial requirement for closing.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	1,000	2		0.525		1,050

Total Estimated Burden Hours: 1,050.

Status: Revision of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended

Dated: July 25, 2012.

Colette Pollard,

Department Reports Management Officer. Office of the Chief Information Officer.

[FR Doc. 2012–18544 Filed 7–27–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5603–N–52]

Rental Assistance Demonstration (RAD) Application Form

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The Rental Assistance Demonstration allows Public Housing and Moderate Rehabilitation (Mod Rehab) properties to convert to long-term Section 8 rental assistance contracts; and Rent Supplement (Rent Supp), Rental Assistance Payment (RAP), and Mod Rehab properties, upon contract expiration or termination, to convert tenant protection vouchers (TPVs) to project-based vouchers (PBVs). Participation in the initiative will be voluntary. Public Housing Agencies and Mod Rehab owners interested in participating in the Demonstration are required to submit applications to HUD. HUD intends through the conversion process, to assure the physical and financial sustainability of properties and enable owners to leverage private financing to address immediate and long-term capital needs, improve operations, and implement energy efficiency improvements. The RAD applications are Excel based and will be interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

DATES: *Comments Due Date: August 29, 2012.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–Pending) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov*. or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Rental Assistance Demonstration (RAD) Application Form.

OMB Approval Number: 2577–Pending.

Form Numbers: HUD 5260, HUD 5261.

Description of the Need for the Information and Its Proposed Use

The Rental Assistance Demonstration allows Public Housing and Moderate Rehabilitation (Mod Rehab) properties to convert to long-term Section 8 rental assistance contracts; and Rent Supplement (Rent Supp), Rental Assistance Payment (RAP), and Mod Rehab properties, upon contract expiration or termination, to convert tenant protection vouchers (TPVs) to project-based vouchers (PBVs). Participation in the initiative will be voluntary. Public Housing Agencies and Mod Rehab owners interested in participating in the Demonstration are required to submit applications to HUD. HUD intends through the conversion process, to assure the physical and financial sustainability of properties and enable owners to leverage private financing to address immediate and long-term capital needs, improve operations, and implement energy efficiency improvements. The RAD applications are Excel based and will be interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

	Number of respondents	Annual responses	×	Hours per burden	=	Burden hours
Reporting Burden	8,855	1		2		17,710

Total Estimated Burden Hours: 17,710.

Status: New collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended

Dated: July 25, 2012.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2012–18538 Filed 7–27–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5603–N–51]

FY 2012 Notice of Funding Availability (NOFA) for Rural Capacity Building Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The Narratives associated with Rural Capacity Building program will allow CPD to accurately assess the experience, expertise, and overall capacity of national organizations with expertise in rural housing, including experience working with rural housing organizations, local governments, and Indian tribes. HUD requires information in order to ensure the eligibility of Rural Capacity Building program applicants and proposals, to rate and rank applications, and to select applicants for grant awards. The Rural Capacity Building NOFA requires applicants to submit specific forms and narrative responses.

DATES: Comments Due Date: August 29, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2506–Pending) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov*. or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: FY 2012 Notice of Funding Availability (NOFA) for Rural Capacity Building Program.

OMB Approval Number: 2506–Pending.

Form Numbers: SF–424, HUD, 424–CB, HUD 424–CBW, SF LLL.

Description of the Need for the Information and Its Proposed

The Narratives associated with Rural Capacity Building program will allow CPD to accurately assess the experience, expertise, and overall capacity of national organizations with expertise in rural housing, including experience working with rural housing organizations, local governments, and Indian tribes. HUD requires information in order to ensure the eligibility of Rural Capacity Building program applicants and proposals, to rate and rank applications, and to select applicants for grant awards. The Rural Capacity Building NOFA requires applicants to submit specific forms and narrative responses.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	30	1		40		1200

Total Estimated Burden Hours: 1,200.
Status: New collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: July 25, 2012.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2012–18541 Filed 7–27–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5643–N–01]

Notice of Annual Factors for Determining Public Housing Agency Administrative Fees for the Section 8 Housing Choice Voucher and Moderate Rehabilitation Programs

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

ACTION: Notice.

SUMMARY: This Notice announces the monthly per unit fee amounts for use in determining the on-going administrative fee for housing agencies administering the rental voucher and moderate rehabilitation programs, including Single Room Occupancy during Calendar Year (CY) 2012.

DATES: *Effective Date:* January 1, 2012.

FOR FURTHER INFORMATION CONTACT: Miguel Fontanez, Director, Housing Voucher Financial Management Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4222, 451 Seventh Street SW., Washington, DC 20410–8000, telephone number 202–402–2934. (This is not a toll-free number). Hearing or speech impaired individuals may call TTY number 800–877–8337.

SUPPLEMENTARY INFORMATION:

A. Purpose and Substantive Description

This **Federal Register** Notice provides the Department's methodology to determine the Calendar Year 2012 administrative fees rates by area, which the Office of Housing Voucher Programs (OHVP) will utilize to compensate public housing agencies (PHAs) for administering the Housing Choice Voucher (HCV) program. PIH Notice 2012–9 entitled, Implementation of the Federal Fiscal Year (FY) 2012 Funding Provision for the Housing Choice Voucher Program, issued on February 8, 2012,[1] describes the settlement process for this compensation, which will be a result of the mandate enacted in the ''Consolidated and Furthering Continuing Appropriations Act, 2012'' (Pub. L. 112–55, approved November 18, 2011) (FY 2012 Appropriation Act).

B. Methodology History

Section 8 Administrative Fees are based on the higher of the FY 1993 Fair Market Rent (FMR) for a two-bedroom unit in a PHA's market area or the FY 1994 FMR for a two-bedroom unit, but not more than 103.5 percent of the FY 1993 FMR. This Fee Base is also subject to a $428 minimum and a $811 maximum. (The average FMR in 1993 was $555).

FMR areas (Fee Base areas) were updated in 2005 to new OMB metropolitan area definitions. Where a new metropolitan area is made up of more than one old metropolitan area, the fee base for the largest of the old areas in the new area was used.

Prior to 2005, the Quality Housing and Work Responsibility Act of 1998 (Pub. L. 105–276) (QHWRA) required renewals to be based on the per unit cost from a PHA's latest year-end settlement statement for 100 percent of expiring annual contribution contract (ACC) units. Since then, HUD has made changes to how it calculates the administrative fees for PHAs administering the Section 8 programs. These changes have been caused by budgetary mandates rather than research on what it actually costs to administer a well-run program.

When the voucher program was introduced, administrative fees were set at 6.5% of the two-bedroom FMR. Administrative Fees had three components, ongoing, preliminary, and hard-to-house fees. In FY 2003, a flat fee was implemented, which was calculated based on the amount each PHA was eligible to receive in CY 2003. This calculation used the Column A and Column B published rates to determine the fees. This change meant that PHAs would receive a set amount regardless of leasing. This methodology for calculating administrative fees was the basis for determining fee funding in 2004 through 2007.

The Consolidated Appropriations Act, 2008 (Pub. L. 110–161, approved December 26, 2007), changed the methodology again for calculating fees back to Section 8 (q) pre-QHWRA where fees are now based on the leasing reported in the Voucher Management System. This same methodology has been applied in each year since 2007 because Congress has continued to require that the same standard be used in the relevant appropriations acts.

The Fee Base numbers are updated annually using Bureau of Labor Statistics data on average local government wages at the State metropolitan and nonmetropolitan level. The Congress has changed the percentage of the fee base used to reimburse administrative costs three times since the current system was established. The following chart shows the history of admin fee rates for Column A and Column B.

Fiscal year	First 600 units (percent)	Additional units (percent)
1995 and 1996	8.2	7.79
1997	7.5	7
1998 and 1999	7.65	7
2000 through 2012	7.5	7

[1] PIH Notice 2012–9 is available online at: *http://portal.hud.gov/hudportal/HUD?src=/program_offices/public_indian_housing/publications/notices.*

In 1998 HUD, with OMB's approval, began to apply the State nonmetropolitan minimum FMR to metropolitan areas for fee determination purposes. Fees for PHA-owned units will be determined in the same manner as all other units.

Fees are updated with Bureau of Labor Statistics (BLS) local government wage change factors aggregated to the metropolitan/nonmetropolitan level. The Year-end 1993 is used as the base to account for the two-year lag between data availability and the year updating was to start (FY 1995).

C. FY 2012 Methodology

For CY 2012, in accordance with the FY 2012 Appropriations Act, administrative fees will be paid on the basis of units leased as of the first day of each month; this data will be extracted from the Voucher Management System (VMS) at the close of each reporting cycle.

Two fee rates are provided for each housing authority (HA). The first rate, Column A, applies to the first 7,200 unit months leased in CY 2012. The second rate, Column B, applies to all remaining unit months leased in CY 2012. In years prior to 2010, a Column C rate was also provided, which applied to all unit months leased in units owned by the HA. For CY 2012 there are no Column C administrative fee rates. Fees for leased HA-owned units will be earned in the same manner and at the same Column A and Column B rates as for all other leasing.

The fee rates calculated for CY 2012, using the standard procedure, in many cases resulted in rates lower than those provided for CY 2011. In those cases, the affected HAs are being held harmless at the CY 2011 rates.

The fee rates for each HA are those rates covering the areas in which each HA has the greatest proportion of its participants, based on PIC data. In some cases, HAs have participants in more than one fee area. If an HA so chooses, the HA may request that the Department establish a blended fee rate schedule that will consider proportionately all areas in which participants are located. Once a blended rate schedule is calculated, it will be used to determine the HA's fee eligibility for all months of CY 2012.

PHAs that operate over a large geographic area were permitted to request a higher administrative fee rate if eligible under the circumstances as described in the CY 2012 implementation notice, PIH Notice 2012–9. Additionally, PHAs serving multiple administrative fee areas were permitted, in lieu of the fee determined for their agency, to request a blended rate based on the actual location of their assisted units. These fee rates also apply to the Moderate Rehabilitation program and the 5-Year Mainstream Program.

Paperwork Reduction Act Statement

The information collection requirements contained in this document are pending approval by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and have been assigned OMB control number 2502–0348. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid control number.

Accordingly, the Department publishes the monthly per unit fee amount to be used for determining HA administrative fees under the Housing Choice Voucher and Moderate Rehabilitation programs as set forth on the Appendix to this notice.

Dated: July 6, 2012.

Deborah Hernandez,

General Deputy Assistant Secretary for Public and Indian Housing.

Appendix

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012

PHA No.	Column A rate	Column B rate
AK901	$84.45	$78.83
AL001	58.64	54.73
AL002	59.56	55.60
AL004	58.20	54.32
AL005	58.20	54.32
AL006	58.20	54.32
AL007	58.20	54.32
AL008	58.20	54.32
AL010	58.64	54.73
AL011	58.20	54.32
AL012	58.20	54.32
AL013	58.64	54.73
AL014	58.20	54.32
AL047	59.58	55.62
AL048	58.20	54.32
AL049	58.20	54.32
AL050	58.20	54.32
AL052	58.20	54.32
AL053	58.20	54.32
AL054	58.20	54.32
AL055	58.20	54.32
AL060	58.20	54.32
AL061	58.20	54.32
AL063	58.64	54.73
AL068	58.20	54.32
AL069	58.64	54.73
AL072	58.64	54.73
AL073	58.35	54.45

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
AL075	58.20	54.32
AL077	58.20	54.32
AL086	58.64	54.73
AL090	58.20	54.32
AL091	58.20	54.32
AL099	58.20	54.32
AL103	58.20	54.32
AL105	58.20	54.32
AL107	58.20	54.32
AL112	58.20	54.32
AL114	58.20	54.32
AL115	58.20	54.32
AL116	58.20	54.32
AL118	58.20	54.32
AL121	58.20	54.32
AL124	58.35	54.45
AL125	58.64	54.73
AL128	58.20	54.32
AL129	58.20	54.32
AL131	58.20	54.32
AL138	58.20	54.32
AL139	58.20	54.32
AL152	58.20	54.32
AL154	58.20	54.32
AL155	58.20	54.32
AL160	58.20	54.32
AL165	60.78	56.74
AL169	59.56	55.60
AL171	58.20	54.32
AL172	58.20	54.32
AL173	58.20	54.32
AL174	58.20	54.32
AL177	58.20	54.32
AL181	58.20	54.32
AL192	58.20	54.32
AL202	59.56	55.60
AR002	60.72	56.68
AR003	55.66	51.95
AR004	60.72	56.68
AR006	60.72	56.68
AR010	55.01	51.34
AR012	53.75	50.17
AR015	55.99	52.26
AR016	53.75	50.17
AR017	55.66	51.95
AR020	53.75	50.17
AR024	58.99	55.06
AR031	55.66	51.95
AR033	53.75	50.17
AR034	55.66	51.95
AR035	53.75	50.17
AR037	53.75	50.17
AR039	53.75	50.17
AR041	60.72	56.68
AR042	55.66	51.95
AR045	53.75	50.17
AR048	53.75	50.17
AR052	53.75	50.17
AR059	53.75	50.17
AR066	53.75	50.17
AR068	53.75	50.17
AR082	53.75	50.17
AR104	55.66	51.95
AR117	53.75	50.17
AR121	53.75	50.17
AR131	55.66	51.95

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
AR135	53.75	50.17
AR152	53.75	50.17
AR161	53.75	50.17
AR163	55.66	51.95
AR166	53.75	50.17
AR170	60.72	56.68
AR175	60.72	56.68
AR176	53.75	50.17
AR177	53.75	50.17
AR181	55.66	51.95
AR194	55.66	51.95
AR197	53.75	50.17
AR200	53.75	50.17
AR201	53.75	50.17
AR202	53.75	50.17
AR210	53.75	50.17
AR211	53.75	50.17
AR213	53.75	50.17
AR214	53.75	50.17
AR215	53.75	50.17
AR219	60.72	56.68
AR222	53.75	50.17
AR223	53.75	50.17
AR224	53.75	50.17
AR225	53.75	50.17
AR226	53.75	50.17
AR228	53.75	50.17
AR232	55.66	51.95
AR238	53.75	50.17
AR240	53.75	50.17
AR241	55.66	51.95
AR246	53.75	50.17
AR247	53.75	50.17
AR249	53.75	50.17
AR250	53.75	50.17
AR252	60.72	56.68
AR257	53.75	50.17
AR264	58.99	55.06
AR265	53.75	50.17
AR266	53.75	50.17
AZ001	65.82	61.42
AZ003	65.82	61.42
AZ004	65.07	60.72
AZ005	65.82	61.42
AZ006	71.96	67.17
AZ008	50.87	47.48
AZ009	65.82	61.42
AZ010	65.82	61.42
AZ013	73.12	68.25
AZ021	65.82	61.42
AZ023	53.60	50.02
AZ025	65.07	60.72
AZ028	65.82	61.42
AZ031	65.82	61.42
AZ032	65.82	61.42
AZ033	65.07	60.72
AZ034	51.79	48.34
AZ035	73.12	68.25
AZ037	51.79	48.34
AZ038	65.82	61.42
AZ041	71.96	67.17
AZ043	88.12	82.26
AZ045	52.71	49.20
AZ880	65.82	61.42
AZ901	71.96	67.17
CA001	106.74	99.64

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
CA002	106.74	99.64
CA003	106.74	99.64
CA004	106.74	99.64
CA006	74.38	69.41
CA007	81.07	75.66
CA008	81.35	75.93
CA009	85.16	79.49
CA010	106.74	99.64
CA011	106.74	99.64
CA014	106.74	99.64
CA019	85.16	79.49
CA021	104.24	97.27
CA022	85.16	79.49
CA023	69.89	65.24
CA024	77.79	72.61
CA026	78.33	73.10
CA027	85.16	79.49
CA028	74.38	69.41
CA030	69.36	64.75
CA031	106.74	99.64
CA032	106.74	99.64
CA033	91.97	85.82
CA035	106.74	99.64
CA039	77.40	72.24
CA041	92.67	86.49
CA043	71.49	66.71
CA044	81.07	75.66
CA048	61.34	57.25
CA052	106.74	99.64
CA053	67.13	62.66
CA055	92.67	86.49
CA056	106.74	99.64
CA058	106.74	99.64
CA059	106.74	99.64
CA060	106.74	99.64
CA061	72.55	67.72
CA062	106.74	99.64
CA063	95.44	89.07
CA064	92.41	86.25
CA065	92.67	86.49
CA066	92.67	86.49
CA067	106.74	99.64
CA068	106.74	99.64
CA069	74.38	69.41
CA070	66.40	61.97
CA071	106.74	99.64
CA072	106.74	99.64
CA073	92.67	86.49
CA074	106.74	99.64
CA075	106.74	99.64
CA076	104.24	97.27
CA077	95.44	89.07
CA079	106.74	99.64
CA082	106.74	99.64
CA084	78.19	72.98
CA085	104.11	97.18
CA086	74.74	69.75
CA088	104.11	97.18
CA092	106.74	99.64
CA093	106.74	99.64
CA094	106.74	99.64
CA096	74.38	69.41
CA102	106.74	99.64
CA103	106.74	99.64
CA104	106.74	99.64
CA105	106.74	99.64

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
CA106	74.38	69.41
CA107	61.34	57.25
CA108	95.44	89.07
CA110	106.74	99.64
CA111	106.74	99.64
CA114	106.74	99.64
CA116	95.44	89.07
CA117	106.74	99.64
CA118	106.74	99.64
CA119	106.74	99.64
CA120	106.74	99.64
CA121	106.74	99.64
CA122	84.47	78.84
CA123	106.74	99.64
CA125	92.67	86.49
CA126	106.74	99.64
CA128	81.07	75.66
CA131	92.67	86.49
CA132	95.44	89.07
CA135	106.74	99.64
CA136	106.74	99.64
CA137	106.74	99.64
CA143	77.40	72.24
CA144	72.55	67.72
CA145	106.74	99.64
CA146	89.10	83.15
CA149	81.07	75.66
CA151	81.07	75.66
CA155	95.44	89.07
CA913	79.48	74.18
CO001	67.55	63.05
CO002	62.40	58.23
CO005	67.67	63.16
CO016	76.65	71.54
CO019	67.55	63.05
CO024	57.92	54.06
CO028	63.02	58.82
CO031	57.92	54.06
CO034	72.64	67.80
CO035	62.63	58.47
CO036	67.55	63.05
CO040	89.45	83.49
CO041	72.64	67.80
CO043	67.67	63.16
CO045	57.92	54.06
CO048	67.55	63.05
CO049	67.55	63.05
CO050	67.55	63.05
CO051	79.02	73.75
CO052	67.55	63.05
CO057	67.55	63.05
CO058	67.55	63.05
CO061	76.65	71.54
CO065	57.92	54.06
CO070	76.65	71.54
CO071	63.02	58.82
CO072	67.55	63.05
CO079	67.67	63.16
CO081	76.73	71.62
CO087	89.45	83.49
CO090	62.63	58.47
CO095	85.53	79.83
CO100	63.02	58.82
CO101	57.92	54.06
CO103	72.64	67.80
CO105	63.02	58.82

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
CO888	62.40	58.23
CO889	76.65	71.54
CO901	67.55	63.05
CO911	67.55	63.05
CT001	85.06	79.39
CT002	91.17	85.10
CT003	80.17	74.82
CT004	88.37	82.48
CT005	80.17	74.82
CT006	72.15	67.34
CT007	91.17	85.10
CT008	80.17	74.82
CT009	80.17	74.82
CT010	65.37	61.01
CT011	88.37	82.48
CT013	80.17	74.82
CT015	85.06	79.39
CT017	85.06	79.39
CT018	78.70	73.45
CT019	91.17	85.10
CT020	91.17	85.10
CT022	78.70	73.45
CT023	80.17	74.82
CT024	65.37	61.01
CT025	70.47	65.77
CT026	80.17	74.82
CT027	85.06	79.39
CT028	80.17	74.82
CT029	88.37	82.48
CT030	85.06	79.39
CT031	70.47	65.77
CT032	80.17	74.82
CT033	80.17	74.82
CT036	80.17	74.82
CT038	80.17	74.82
CT039	80.17	74.82
CT040	80.17	74.82
CT041	80.17	74.82
CT042	88.37	82.48
CT047	72.15	67.34
CT048	80.17	74.82
CT049	80.17	74.82
CT051	80.17	74.82
CT052	85.06	79.39
CT053	80.17	74.82
CT058	65.37	61.01
CT061	65.37	61.01
CT063	88.37	82.48
CT067	88.37	82.48
CT068	80.17	74.82
CT901	89.51	83.55
DC001	101.63	94.86
DC880	101.63	94.86
DE001	77.32	72.17
DE002	73.26	68.37
DE003	77.32	72.17
DE005	77.32	72.17
DE901	73.26	68.37
FL001	65.90	61.51
FL002	69.57	64.92
FL003	69.57	64.92
FL004	72.66	67.81
FL005	94.40	88.12
FL007	69.74	65.09
FL008	76.35	71.26
FL009	73.72	68.80

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
FL010	88.39	82.50
FL011	57.90	54.04
FL013	96.54	90.12
FL015	61.92	57.78
FL016	72.66	67.81
FL017	94.40	88.12
FL018	56.15	52.41
FL019	67.07	62.62
FL020	67.07	62.62
FL021	73.72	68.80
FL022	69.74	65.09
FL023	76.35	71.26
FL024	69.74	65.09
FL025	67.07	62.62
FL026	57.90	54.04
FL028	88.39	82.50
FL030	69.74	65.09
FL031	56.15	52.41
FL032	57.01	53.20
FL033	72.66	67.81
FL034	69.57	64.92
FL035	56.15	52.41
FL037	65.90	61.51
FL041	74.11	69.17
FL045	74.11	69.17
FL046	56.15	52.41
FL047	73.14	68.27
FL049	56.15	52.41
FL053	57.01	53.20
FL057	56.15	52.41
FL060	71.22	66.48
FL062	69.57	64.92
FL063	62.51	58.35
FL066	94.40	88.12
FL068	94.40	88.12
FL069	56.15	52.41
FL070	62.51	58.35
FL071	57.90	54.04
FL072	69.74	65.09
FL073	61.92	57.78
FL075	69.57	64.92
FL079	88.39	82.50
FL080	73.72	68.80
FL081	88.39	82.50
FL083	73.72	68.80
FL089	69.57	64.92
FL092	57.01	53.20
FL093	72.66	67.81
FL096	56.15	52.41
FL098	65.90	61.51
FL102	56.15	52.41
FL104	69.57	64.92
FL105	76.35	71.26
FL106	72.66	67.81
FL107	57.90	54.04
FL109	56.15	52.41
FL110	56.15	52.41
FL111	76.35	71.26
FL113	69.74	65.09
FL116	88.39	82.50
FL117	56.15	52.41
FL119	73.72	68.80
FL123	70.85	66.12
FL128	73.14	68.27
FL132	73.84	68.94
FL136	88.39	82.50

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
FL137	69.57	64.92
FL139	57.90	54.04
FL140	61.92	57.78
FL141	76.11	71.04
FL143	57.90	54.04
FL144	96.54	90.12
FL145	94.40	88.12
FL147	56.15	52.41
FL201	72.66	67.81
FL202	56.15	52.41
FL880	73.72	68.80
FL881	94.40	88.12
FL888	69.57	64.92
GA001	58.70	54.79
GA002	57.63	53.79
GA004	58.20	54.32
GA006	74.94	69.93
GA007	57.63	53.79
GA009	57.63	53.79
GA010	74.94	69.93
GA011	74.94	69.93
GA023	57.63	53.79
GA062	57.63	53.79
GA078	74.94	69.93
GA095	74.94	69.93
GA116	74.94	69.93
GA188	74.94	69.93
GA228	74.94	69.93
GA232	74.94	69.93
GA237	74.94	69.93
GA264	74.94	69.93
GA266	74.94	69.93
GA285	57.63	53.79
GA901	74.94	69.93
GQ901	98.83	92.25
HI002	90.57	84.53
HI003	101.47	94.71
HI004	102.01	95.22
HI005	102.01	95.22
HI901	101.47	94.71
IA002	56.23	52.48
IA004	59.12	55.18
IA015	56.23	52.48
IA018	59.11	55.18
IA020	67.55	63.06
IA022	68.85	64.27
IA023	60.08	56.07
IA024	65.40	61.04
IA030	56.23	52.48
IA038	65.66	61.28
IA042	56.23	52.48
IA045	64.00	59.73
IA047	56.23	52.48
IA049	56.23	52.48
IA050	65.66	61.28
IA054	56.23	52.48
IA056	56.23	52.48
IA057	56.23	52.48
IA084	56.23	52.48
IA087	60.53	56.49
IA089	59.64	55.65
IA098	59.24	55.30
IA100	56.23	52.48
IA107	56.23	52.48
IA108	56.23	52.48
IA113	65.66	61.28

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
IA114	56.23	52.48
IA117	58.91	54.99
IA119	56.23	52.48
IA120	67.55	63.06
IA121	56.23	52.48
IA122	56.23	52.48
IA123	64.00	59.73
IA124	58.07	54.19
IA125	56.23	52.48
IA126	60.26	56.24
IA127	56.23	52.48
IA128	56.23	52.48
IA129	56.23	52.48
IA130	56.23	52.48
IA131	67.55	63.06
IA132	65.66	61.28
IA133	56.23	52.48
IA136	58.85	54.93
ID005	58.95	55.02
ID013	73.26	68.38
ID016	73.26	68.38
ID021	73.26	68.38
ID901	63.76	59.51
IL001	58.90	54.97
IL002	84.74	79.08
IL003	66.91	62.45
IL004	60.98	56.91
IL006	59.72	55.74
IL009	64.00	59.73
IL010	64.00	59.73
IL011	54.96	51.29
IL012	57.70	53.85
IL014	69.17	64.56
IL015	58.90	54.97
IL016	54.96	51.29
IL018	64.00	59.73
IL020	64.00	59.73
IL022	60.85	56.79
IL024	84.74	79.08
IL025	84.74	79.08
IL026	84.74	79.08
IL028	60.98	56.91
IL030	58.90	54.97
IL032	65.74	61.36
IL034	59.72	55.74
IL035	65.74	61.36
IL036	54.96	51.29
IL037	54.96	51.29
IL038	54.96	51.29
IL039	57.81	53.96
IL040	54.96	51.29
IL042	54.96	51.29
IL043	54.96	51.29
IL050	55.61	51.89
IL051	59.51	55.55
IL052	54.96	51.29
IL053	55.61	51.89
IL054	84.74	79.08
IL056	84.74	79.08
IL057	54.96	51.29
IL059	54.96	51.29
IL061	55.61	51.89
IL069	54.96	51.29
IL070	54.96	51.29
IL074	58.90	54.97
IL076	54.96	51.29

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
IL079	54.96	51.29
IL082	54.96	51.29
IL083	60.85	56.79
IL084	58.30	54.41
IL085	56.11	52.37
IL086	58.30	54.41
IL087	54.96	51.29
IL088	54.96	51.29
IL089	67.15	62.68
IL090	84.74	79.08
IL091	54.96	51.29
IL092	84.74	79.08
IL094	54.96	51.29
IL095	64.46	60.16
IL096	54.96	51.29
IL101	84.74	79.08
IL103	84.74	79.08
IL104	66.91	62.45
IL107	84.74	79.08
IL115	54.96	51.29
IL116	84.74	79.08
IL117	59.51	55.55
IL120	54.96	51.29
IL122	60.85	56.79
IL123	54.96	51.29
IL124	66.91	62.45
IL126	55.61	51.89
IL130	84.74	79.08
IL131	64.00	59.73
IL136	84.74	79.08
IL137	85.46	79.76
IL911	54.96	51.29
IN002	48.38	45.15
IN003	53.09	49.57
IN004	49.46	46.16
IN005	49.46	46.16
IN006	58.70	54.79
IN007	51.65	48.21
IN009	48.38	45.15
IN010	64.82	60.51
IN011	64.82	60.51
IN012	54.82	51.17
IN015	52.26	48.78
IN016	50.95	47.56
IN017	58.70	54.79
IN018	48.38	45.15
IN019	51.20	47.78
IN020	52.26	48.78
IN021	49.46	46.16
IN022	52.62	49.12
IN023	54.82	51.17
IN025	54.82	51.17
IN026	51.31	47.89
IN029	64.82	60.51
IN031	48.38	45.15
IN032	49.46	46.16
IN035	49.46	46.16
IN036	48.38	45.15
IN037	50.95	47.56
IN041	48.38	45.15
IN043	48.38	45.15
IN047	48.38	45.15
IN048	48.38	45.15
IN050	48.38	45.15
IN055	49.46	46.16
IN056	50.64	47.26

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
IN058	53.57	50.01
IN060	48.38	45.15
IN062	51.93	48.48
IN067	48.38	45.15
IN069	48.38	45.15
IN070	62.29	58.13
IN071	56.70	52.91
IN073	48.38	45.15
IN077	49.46	46.16
IN078	50.64	47.26
IN079	58.70	54.79
IN080	58.70	54.79
IN083	54.82	51.17
IN084	48.38	45.15
IN086	48.38	45.15
IN091	48.38	45.15
IN092	48.38	45.15
IN094	49.58	46.27
IN100	52.26	48.78
IN101	51.31	47.89
IN103	48.38	45.15
IN901	64.10	59.84
KS001	57.26	53.44
KS002	55.01	51.35
KS004	59.27	55.31
KS006	50.37	47.01
KS017	50.37	47.01
KS038	50.37	47.01
KS041	50.37	47.01
KS043	57.26	53.44
KS053	60.79	56.74
KS062	50.37	47.01
KS063	50.42	47.06
KS068	57.26	53.44
KS073	59.27	55.31
KS091	50.37	47.01
KS105	50.42	47.06
KS149	50.37	47.01
KS159	56.66	52.88
KS161	50.37	47.01
KS162	57.26	53.44
KS163	50.37	47.01
KS165	50.37	47.01
KS166	50.37	47.01
KS167	50.42	47.06
KS168	50.37	47.01
KS169	59.27	55.31
KS170	50.37	47.01
KY001	54.82	51.17
KY003	51.83	48.37
KY004	60.71	56.67
KY007	50.88	47.48
KY008	50.88	47.48
KY009	54.82	51.17
KY011	59.76	55.78
KY012	50.95	47.56
KY015	62.29	58.13
KY017	50.88	47.48
KY021	50.88	47.48
KY022	50.88	47.48
KY026	50.88	47.48
KY027	50.88	47.48
KY035	50.88	47.48
KY040	50.88	47.48
KY047	50.88	47.48
KY053	50.88	47.48

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
KY056	50.88	47.48
KY061	60.71	56.67
KY071	54.82	51.17
KY086	50.88	47.48
KY107	50.88	47.48
KY121	50.88	47.48
KY132	56.34	52.59
KY133	62.29	58.13
KY135	62.29	58.13
KY136	62.29	58.13
KY137	50.88	47.48
KY138	50.88	47.48
KY140	60.71	56.67
KY141	50.88	47.48
KY142	53.78	50.19
KY150	50.88	47.48
KY157	50.88	47.48
KY160	50.88	47.48
KY161	53.78	50.19
KY163	50.88	47.48
KY169	50.88	47.48
KY171	54.82	51.17
KY901	59.43	55.47
LA001	66.29	61.86
LA002	64.89	60.58
LA003	71.58	66.81
LA004	60.78	56.73
LA005	60.78	56.73
LA006	60.78	56.73
LA009	71.58	66.81
LA012	66.29	61.86
LA013	66.29	61.86
LA023	60.78	56.73
LA024	60.24	56.22
LA029	60.24	56.22
LA031	60.24	56.22
LA032	60.24	56.22
LA033	60.24	56.22
LA036	60.24	56.22
LA037	64.31	60.03
LA046	60.78	56.73
LA057	60.78	56.73
LA063	60.78	56.73
LA067	60.24	56.22
LA074	60.24	56.22
LA075	60.24	56.22
LA086	60.24	56.22
LA094	66.29	61.86
LA097	60.24	56.22
LA099	60.24	56.22
LA101	71.58	66.81
LA103	66.29	61.86
LA104	60.24	56.22
LA111	60.24	56.22
LA114	60.24	56.22
LA115	60.24	56.22
LA120	60.78	56.73
LA122	60.78	56.73
LA125	60.24	56.22
LA128	60.24	56.22
LA129	60.78	56.73
LA132	60.24	56.22
LA159	60.24	56.22
LA163	60.24	56.22
LA165	60.24	56.22
LA166	60.24	56.22

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
LA168	60.24	56.22
LA169	60.24	56.22
LA171	60.78	56.73
LA172	60.78	56.73
LA173	60.78	56.73
LA174	60.24	56.22
LA178	60.78	56.73
LA179	60.78	56.73
LA181	66.29	61.86
LA182	60.24	56.22
LA184	64.89	60.58
LA186	60.78	56.73
LA187	66.29	61.86
LA188	60.24	56.22
LA189	60.24	56.22
LA190	64.89	60.58
LA192	60.24	56.22
LA194	63.47	59.25
LA195	60.24	56.22
LA196	60.78	56.73
LA199	71.58	66.81
LA202	71.58	66.81
LA204	71.58	66.81
LA205	71.58	66.81
LA206	60.24	56.22
LA207	60.24	56.22
LA211	63.47	59.25
LA212	60.24	56.22
LA213	64.31	60.03
LA214	60.78	56.73
LA215	60.24	56.22
LA217	60.24	56.22
LA219	71.58	66.81
LA220	60.24	56.22
LA222	60.24	56.22
LA229	60.24	56.22
LA230	64.89	60.58
LA232	60.24	56.22
LA233	60.24	56.22
LA238	66.29	61.86
LA241	60.24	56.22
LA242	60.24	56.22
LA246	60.24	56.22
LA247	60.24	56.22
LA248	60.24	56.22
LA253	63.47	59.25
LA254	66.29	61.86
LA257	60.24	56.22
LA258	60.24	56.22
LA266	60.78	56.73
LA888	64.89	60.58
LA889	66.29	61.86
LA903	66.29	61.87
MA001	99.98	93.32
MA002	103.81	96.88
MA003	103.81	96.88
MA005	99.98	93.32
MA006	99.98	93.32
MA007	99.98	93.32
MA008	99.98	93.32
MA010	99.98	93.32
MA012	99.98	93.32
MA013	103.81	96.88
MA014	103.81	96.88
MA015	103.81	96.88
MA016	103.81	96.88

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MA017	103.81	96.88
MA018	99.98	93.32
MA019	103.81	96.88
MA020	103.81	96.88
MA022	103.81	96.88
MA023	103.81	96.88
MA024	99.98	93.32
MA025	103.81	96.88
MA026	99.98	93.32
MA027	103.81	96.88
MA028	103.81	96.88
MA029	99.98	93.32
MA031	103.81	96.88
MA032	103.81	96.88
MA033	103.81	96.88
MA034	99.98	93.32
MA035	99.98	93.32
MA036	103.81	96.88
MA037	99.98	93.32
MA039	99.98	93.32
MA040	103.81	96.88
MA041	99.98	93.32
MA042	103.81	96.88
MA043	99.98	93.32
MA044	103.81	96.88
MA045	103.81	96.88
MA046	104.05	97.12
MA047	104.05	97.12
MA048	103.81	96.88
MA050	99.98	93.32
MA051	99.98	93.32
MA053	103.81	96.88
MA054	103.81	96.88
MA055	103.81	96.88
MA056	103.81	96.88
MA057	103.81	96.88
MA059	103.81	96.88
MA060	99.98	93.32
MA061	103.81	96.88
MA063	103.81	96.88
MA065	103.81	96.88
MA066	99.98	93.32
MA067	103.81	96.88
MA069	103.81	96.88
MA070	103.81	96.88
MA071	103.81	96.88
MA072	103.81	96.88
MA073	103.81	96.88
MA074	103.81	96.88
MA075	103.81	96.88
MA076	99.98	93.32
MA077	99.98	93.32
MA078	99.98	93.32
MA079	103.81	96.88
MA080	99.98	93.32
MA081	99.98	93.32
MA082	99.98	93.32
MA084	99.98	93.32
MA085	99.98	93.32
MA086	99.98	93.32
MA087	99.98	93.32
MA088	99.98	93.32
MA089	103.81	96.88
MA090	103.81	96.88
MA091	103.81	96.88
MA092	103.81	96.88

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MA093	103.81	96.88
MA094	99.98	93.32
MA095	104.05	97.12
MA096	99.98	93.32
MA098	103.81	96.88
MA099	103.81	96.88
MA100	99.98	93.32
MA101	103.81	96.88
MA105	99.98	93.32
MA106	99.98	93.32
MA107	99.98	93.32
MA108	99.98	93.32
MA109	103.81	96.88
MA110	104.05	97.12
MA111	103.81	96.88
MA112	103.81	96.88
MA116	103.81	96.88
MA117	103.81	96.88
MA118	103.81	96.88
MA119	103.81	96.88
MA121	103.81	96.88
MA122	99.98	93.32
MA123	99.98	93.32
MA125	103.81	96.88
MA126	99.98	93.32
MA127	99.98	93.32
MA133	103.81	96.88
MA134	103.81	96.88
MA135	103.81	96.88
MA138	104.05	97.12
MA139	99.98	93.32
MA140	103.81	96.88
MA147	103.81	96.88
MA154	103.81	96.88
MA155	103.81	96.88
MA165	103.81	96.88
MA170	102.25	95.43
MA172	99.98	93.32
MA174	103.81	96.88
MA181	104.05	97.12
MA188	99.98	93.32
MA880	103.81	96.88
MA881	102.25	95.43
MA882	99.98	93.32
MA883	103.81	96.88
MA884	99.98	93.32
MA901	102.25	95.43
MD001	75.97	70.90
MD002	75.97	70.90
MD003	101.63	94.86
MD004	101.63	94.86
MD006	59.59	55.61
MD007	101.63	94.86
MD009	57.55	53.71
MD013	70.56	65.85
MD014	68.28	63.73
MD015	101.63	94.86
MD016	77.32	72.17
MD018	75.97	70.90
MD019	70.56	65.85
MD021	86.59	80.81
MD022	101.63	94.86
MD023	75.97	70.90
MD024	101.63	94.86
MD025	75.97	70.90
MD027	75.97	70.90

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MD028	59.59	55.61
MD029	77.32	72.17
MD032	75.97	70.90
MD033	75.97	70.90
MD034	75.97	70.90
MD901	101.63	94.86
ME001	57.28	53.46
ME002	57.28	53.46
ME003	91.54	85.44
ME004	57.28	53.46
ME005	65.51	61.13
ME006	70.00	65.32
ME007	65.51	61.13
ME008	60.22	56.20
ME009	66.49	62.07
ME011	80.53	75.16
ME015	91.54	85.44
ME018	66.49	62.07
ME019	73.37	68.46
ME020	91.54	85.44
ME021	66.49	62.07
ME025	57.28	53.46
ME027	58.80	54.89
ME028	80.53	75.16
ME030	60.22	56.20
ME031	80.53	75.16
ME901	91.32	85.24
MI001	63.46	59.23
MI003	63.46	59.23
MI005	63.46	59.23
MI006	54.26	50.65
MI008	63.46	59.23
MI009	54.62	50.98
MI010	55.31	51.63
MI019	50.19	46.84
MI020	50.19	46.84
MI023	50.19	46.84
MI026	75.61	70.57
MI027	63.46	59.23
MI030	50.19	46.84
MI031	59.90	55.91
MI032	55.31	51.63
MI035	57.19	53.39
MI036	50.19	46.84
MI037	63.46	59.23
MI038	54.84	51.19
MI039	63.46	59.23
MI040	63.46	59.23
MI044	63.46	59.23
MI045	63.46	59.23
MI047	50.19	46.84
MI048	63.46	59.23
MI049	50.19	46.84
MI050	50.19	46.84
MI051	63.46	59.23
MI052	63.46	59.23
MI055	63.46	59.23
MI058	60.84	56.79
MI059	63.46	59.23
MI060	53.83	50.23
MI061	54.17	50.56
MI063	50.19	46.84
MI064	75.61	70.57
MI066	59.90	55.91
MI070	53.83	50.23
MI073	59.90	55.91

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MI074	54.17	50.56
MI080	55.71	52.00
MI084	53.83	50.23
MI087	53.83	50.23
MI089	63.46	59.23
MI093	59.90	55.91
MI094	50.19	46.84
MI096	63.46	59.23
MI097	63.46	59.23
MI100	63.46	59.23
MI112	50.19	46.84
MI115	59.90	55.91
MI117	50.40	47.03
MI119	50.19	46.84
MI120	55.31	51.63
MI121	54.17	50.56
MI132	50.19	46.84
MI139	63.46	59.23
MI157	63.46	59.23
MI160	63.46	59.23
MI165	63.46	59.23
MI167	60.84	56.79
MI168	60.84	56.79
MI178	50.19	46.84
MI186	50.19	46.84
MI188	63.46	59.23
MI194	60.84	56.79
MI198	59.90	55.91
MI880	60.84	56.79
MI901	63.46	59.23
MN001	76.62	71.51
MN002	76.62	71.51
MN003	56.67	52.90
MN006	52.63	49.12
MN007	56.67	52.90
MN008	51.91	48.44
MN009	51.91	48.44
MN010	76.62	71.51
MN017	62.41	58.25
MN018	51.91	48.44
MN021	59.66	55.69
MN032	51.91	48.44
MN034	51.91	48.44
MN037	51.91	48.44
MN038	58.38	54.48
MN045	59.66	55.69
MN049	51.91	48.44
MN051	54.46	50.82
MN063	56.92	53.12
MN067	76.62	71.51
MN073	56.67	52.90
MN077	56.63	52.86
MN085	51.91	48.44
MN090	51.91	48.44
MN101	51.91	48.44
MN107	51.91	48.44
MN128	51.91	48.44
MN144	76.62	71.51
MN147	76.62	71.51
MN151	63.44	59.22
MN152	76.62	71.51
MN153	51.91	48.44
MN154	51.91	48.44
MN158	58.72	54.81
MN161	54.46	50.82
MN163	76.62	71.51

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MN164	62.41	58.25
MN166	51.91	48.44
MN167	56.92	53.12
MN168	54.46	50.82
MN169	51.91	48.44
MN170	76.62	71.51
MN171	53.97	50.37
MN172	58.38	54.48
MN173	51.91	48.44
MN174	51.91	48.44
MN176	51.91	48.44
MN177	51.91	48.44
MN178	54.46	50.82
MN179	51.91	48.44
MN180	51.91	48.44
MN182	51.91	48.44
MN184	76.62	71.51
MN186	51.91	48.44
MN188	51.91	48.44
MN190	51.91	48.44
MN191	51.91	48.44
MN192	51.91	48.44
MN193	58.32	54.44
MN197	62.92	58.74
MN200	51.91	48.44
MN203	54.46	50.82
MN212	76.62	71.51
MN216	76.62	71.51
MN219	56.92	53.12
MN220	56.63	52.86
MN801	76.62	71.51
MN802	76.62	71.51
MN803	76.62	71.51
MO001	58.90	54.97
MO002	57.26	53.44
MO003	55.97	52.24
MO004	58.90	54.97
MO006	58.90	54.97
MO007	55.97	52.24
MO008	55.97	52.24
MO009	55.97	52.24
MO010	55.97	52.24
MO014	55.97	52.24
MO016	55.97	52.24
MO017	57.26	53.44
MO030	57.26	53.44
MO037	55.97	52.24
MO040	55.97	52.24
MO053	57.26	53.44
MO058	55.97	52.24
MO060	55.97	52.24
MO065	55.97	52.24
MO070	57.26	53.44
MO072	55.97	52.24
MO074	55.97	52.24
MO076	55.97	52.24
MO080	55.97	52.24
MO107	55.97	52.24
MO111	55.97	52.24
MO129	55.97	52.24
MO133	55.97	52.24
MO145	55.97	52.24
MO149	55.97	52.24
MO188	55.97	52.24
MO190	55.97	52.24
MO192	55.97	52.24

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
MO193	57.26	53.44
MO196	56.66	52.88
MO197	57.26	53.44
MO198	55.97	52.24
MO199	58.90	54.97
MO200	55.97	52.24
MO203	55.97	52.24
MO204	56.66	52.88
MO205	58.90	54.97
MO206	58.29	54.39
MO207	55.97	52.24
MO208	55.97	52.24
MO209	55.97	52.24
MO210	57.26	53.44
MO212	55.97	52.24
MO213	57.26	53.44
MO215	55.97	52.24
MO216	55.97	52.24
MO217	55.97	52.24
MO219	57.26	53.44
MO227	58.90	54.97
MO880	57.26	53.44
MS004	57.65	53.81
MS005	59.19	55.24
MS006	57.65	53.81
MS016	58.99	55.06
MS019	57.65	53.81
MS030	57.65	53.81
MS040	59.19	55.24
MS057	57.65	53.81
MS058	69.84	65.18
MS095	57.65	53.81
MS103	69.84	65.18
MS107	57.65	53.81
MS109	59.19	55.24
MS128	57.65	53.81
MS301	59.19	55.24
MT001	73.06	68.19
MT002	64.68	60.38
MT003	60.72	56.66
MT004	70.60	65.89
MT006	57.20	53.39
MT015	61.97	57.83
MT033	65.76	61.37
MT036	61.97	57.83
MT901	73.06	68.19
NC001	56.33	52.57
NC002	67.29	62.80
NC003	61.71	57.59
NC004	55.31	51.62
NC006	58.29	54.41
NC007	56.33	52.57
NC008	61.71	57.59
NC009	57.26	53.43
NC011	58.29	54.41
NC012	58.29	54.41
NC013	67.29	62.80
NC014	55.31	51.62
NC015	56.33	52.57
NC018	55.31	51.62
NC019	56.33	52.57
NC020	55.31	51.62
NC021	67.29	62.80
NC022	56.33	52.57
NC025	55.31	51.62
NC032	56.33	52.57

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
NC035	55.82	52.10
NC039	57.24	53.43
NC043	55.31	51.62
NC050	56.33	52.57
NC056	59.34	55.40
NC057	61.71	57.59
NC059	58.29	54.41
NC065	61.71	57.59
NC070	60.60	56.55
NC071	57.24	53.43
NC072	60.34	56.32
NC075	55.31	51.62
NC077	55.31	51.62
NC081	58.29	54.41
NC087	56.33	52.57
NC089	55.31	51.62
NC098	56.33	52.57
NC102	60.60	56.55
NC104	67.29	62.80
NC118	55.31	51.62
NC120	67.29	62.80
NC134	60.60	56.55
NC137	56.33	52.57
NC138	55.31	51.62
NC139	55.31	51.62
NC140	56.33	52.57
NC141	55.31	51.62
NC144	56.33	52.57
NC145	68.93	64.33
NC146	55.31	51.62
NC147	56.33	52.57
NC149	55.31	51.62
NC150	55.31	51.62
NC151	55.31	51.62
NC152	56.33	52.57
NC154	55.31	51.62
NC155	67.29	62.80
NC158	55.31	51.62
NC159	59.34	55.40
NC160	55.31	51.62
NC161	55.31	51.62
NC163	56.33	52.57
NC164	67.29	62.80
NC165	55.31	51.62
NC166	58.29	54.41
NC167	67.20	62.72
NC173	56.33	52.57
NC175	56.33	52.57
NC901	55.31	51.62
ND001	62.41	58.25
ND002	55.99	52.26
ND003	55.99	52.26
ND009	55.99	52.26
ND010	62.55	58.37
ND011	55.99	52.26
ND012	59.66	55.69
ND013	55.99	52.26
ND014	62.41	58.25
ND015	55.99	52.26
ND016	55.99	52.26
ND017	55.99	52.26
ND019	55.99	52.26
ND021	62.55	58.37
ND022	55.99	52.26
ND024	55.99	52.26
ND025	55.99	52.26

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
ND026	55.99	52.26
ND028	55.99	52.26
ND030	55.99	52.26
ND031	55.99	52.26
ND035	55.99	52.26
ND036	55.99	52.26
ND037	55.99	52.26
ND038	55.99	52.26
ND039	55.99	52.26
ND040	55.99	52.26
ND044	55.99	52.26
ND049	55.99	52.26
ND052	55.99	52.26
ND054	55.99	52.26
ND055	55.99	52.26
ND057	55.99	52.26
ND070	55.99	52.26
NE001	60.08	56.07
NE002	59.29	55.34
NE003	57.52	53.68
NE004	57.52	53.68
NE010	57.52	53.68
NE041	57.52	53.68
NE078	57.52	53.68
NE083	57.52	53.68
NE094	57.52	53.68
NE100	57.52	53.68
NE104	57.52	53.68
NE114	57.52	53.68
NE120	57.52	53.68
NE123	57.52	53.68
NE141	57.52	53.68
NE143	57.52	53.68
NE150	57.52	53.68
NE153	60.08	56.07
NE157	57.52	53.68
NE174	60.08	56.07
NE175	59.11	55.18
NE179	57.52	53.68
NE180	58.85	54.93
NE181	57.52	53.68
NE182	57.52	53.68
NH001	80.86	75.46
NH002	85.90	80.17
NH003	83.72	78.15
NH004	83.72	78.15
NH005	94.85	88.52
NH006	83.72	78.15
NH007	74.71	69.73
NH008	83.72	78.15
NH009	77.13	71.98
NH010	88.64	82.73
NH011	67.99	63.47
NH012	72.43	67.60
NH013	83.72	78.15
NH014	83.72	78.15
NH015	67.99	63.47
NH016	67.99	63.47
NH022	99.98	93.32
NH888	85.90	80.17
NH901	102.25	95.43
NJ002	100.02	93.33
NJ003	100.02	93.33
NJ004	85.36	79.67
NJ006	102.42	95.60
NJ007	100.27	93.58

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
NJ008	100.27	93.58
NJ009	85.36	79.67
NJ010	77.32	72.17
NJ011	102.42	95.60
NJ012	85.36	79.67
NJ013	102.42	95.60
NJ014	84.57	78.95
NJ015	85.36	79.67
NJ021	102.42	95.60
NJ022	102.42	95.60
NJ023	100.02	93.33
NJ025	100.02	93.33
NJ026	85.36	79.67
NJ030	85.36	79.67
NJ032	100.02	93.33
NJ033	102.42	95.60
NJ035	102.42	95.60
NJ036	85.36	79.67
NJ037	100.02	93.33
NJ039	100.02	93.33
NJ042	102.42	95.60
NJ043	102.42	95.60
NJ044	102.42	95.60
NJ046	100.27	93.58
NJ047	102.42	95.60
NJ048	100.27	93.58
NJ049	81.31	75.88
NJ050	100.02	93.33
NJ051	77.32	72.17
NJ052	100.02	93.33
NJ054	100.27	93.58
NJ055	102.42	95.60
NJ056	100.27	93.58
NJ058	77.32	72.17
NJ059	84.57	78.95
NJ060	100.27	93.58
NJ061	81.31	75.88
NJ063	81.31	75.88
NJ065	100.27	93.58
NJ066	100.02	93.33
NJ067	102.42	95.60
NJ068	100.02	93.33
NJ070	102.42	95.60
NJ071	102.42	95.60
NJ073	77.32	72.17
NJ074	77.32	72.17
NJ075	102.42	95.60
NJ077	85.36	79.67
NJ081	100.27	93.58
NJ083	85.36	79.67
NJ084	102.42	95.60
NJ086	100.02	93.33
NJ088	100.02	93.33
NJ089	102.42	95.60
NJ090	102.42	95.60
NJ091	102.42	95.60
NJ092	100.02	93.33
NJ095	100.27	93.58
NJ097	102.42	95.60
NJ099	100.02	93.33
NJ102	100.02	93.33
NJ105	100.02	93.33
NJ106	102.42	95.60
NJ108	100.02	93.33
NJ109	100.02	93.33
NJ110	102.42	95.60

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
NJ112	102.42	95.60
NJ113	100.02	93.33
NJ114	102.42	95.60
NJ115	77.32	72.17
NJ118	77.32	72.17
NJ204	77.32	72.17
NJ212	98.26	91.71
NJ214	100.27	93.58
NJ215	77.32	72.17
NJ880	100.27	93.58
NJ881	83.04	77.50
NJ882	97.29	90.79
NJ912	100.02	93.33
NM001	71.91	67.12
NM002	54.41	50.79
NM003	57.07	53.27
NM006	70.31	65.62
NM009	85.10	79.42
NM020	55.06	51.38
NM030	54.41	50.79
NM033	54.41	50.79
NM035	71.91	67.12
NM038	58.02	54.16
NM039	54.41	50.79
NM050	85.10	79.42
NM057	71.91	67.12
NM061	54.41	50.79
NM062	57.07	53.27
NM063	55.06	51.38
NM066	70.77	66.04
NM067	54.41	50.79
NM069	71.91	67.12
NM070	71.91	67.12
NM077	55.06	51.38
NV001	75.86	70.81
NV014	87.57	81.74
NV018	87.57	81.74
NV905	76.49	71.39
NY001	64.33	60.05
NY002	60.13	56.13
NY003	100.14	93.47
NY005	87.05	81.24
NY006	58.89	54.98
NY009	69.91	65.25
NY012	69.91	65.25
NY015	69.91	65.25
NY016	61.00	56.94
NY017	53.63	50.06
NY018	56.85	53.06
NY019	58.89	54.98
NY020	69.91	65.25
NY021	61.92	57.79
NY022	69.91	65.25
NY023	100.14	93.47
NY025	69.91	65.25
NY027	64.33	60.05
NY028	69.91	65.25
NY033	69.91	65.25
NY034	58.89	54.98
NY035	100.14	93.47
NY039	56.16	52.42
NY041	73.60	68.69
NY044	73.60	68.69
NY045	78.73	73.48
NY048	50.87	47.48
NY049	89.47	83.51

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
NY050	100.14	93.47
NY051	89.47	83.51
NY054	68.76	64.18
NY055	100.14	93.47
NY057	100.14	93.47
NY059	58.89	54.98
NY060	65.16	60.81
NY061	58.73	54.81
NY062	89.47	83.51
NY065	59.49	55.53
NY066	59.95	55.96
NY067	56.75	52.96
NY068	55.60	51.88
NY070	60.13	56.13
NY071	66.48	62.04
NY073	66.19	61.78
NY077	100.14	93.47
NY079	66.19	61.78
NY084	87.05	81.24
NY085	100.14	93.47
NY086	100.14	93.47
NY087	54.67	51.02
NY088	100.14	93.47
NY089	73.60	68.69
NY091	60.13	56.13
NY094	100.14	93.47
NY098	65.16	60.81
NY102	64.33	60.05
NY103	78.73	73.48
NY107	64.33	60.05
NY109	58.89	54.98
NY110	87.05	81.24
NY111	100.14	93.47
NY113	100.14	93.47
NY114	87.05	81.24
NY115	100.14	93.47
NY116	100.14	93.47
NY117	100.14	93.47
NY120	100.14	93.47
NY121	100.14	93.47
NY123	100.14	93.47
NY125	89.47	83.51
NY127	100.14	93.47
NY128	100.14	93.47
NY130	100.14	93.47
NY132	100.14	93.47
NY134	89.47	83.51
NY137	89.47	83.51
NY138	87.05	81.24
NY141	100.14	93.47
NY146	100.14	93.47
NY147	100.14	93.47
NY148	87.05	81.24
NY149	100.14	93.47
NY151	100.14	93.47
NY152	100.14	93.47
NY154	100.14	93.47
NY155	100.14	93.47
NY158	89.47	83.51
NY159	100.14	93.47
NY160	87.05	81.24
NY165	100.14	93.47
NY176	100.14	93.47
NY402	62.12	57.97
NY403	50.64	47.26
NY404	60.13	56.13

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
NY405	60.13	56.13
NY406	73.60	68.69
NY408	69.91	65.25
NY409	60.13	56.13
NY413	65.16	60.81
NY416	69.91	65.25
NY417	58.89	54.98
NY421	69.91	65.25
NY422	69.91	65.25
NY424	69.91	65.25
NY427	69.91	65.25
NY428	69.91	65.25
NY430	69.91	65.25
NY431	69.91	65.25
NY432	62.12	57.97
NY433	50.87	47.48
NY437	61.00	56.94
NY443	58.89	54.98
NY447	69.91	65.25
NY449	60.13	56.13
NY501	69.91	65.25
NY503	69.91	65.25
NY504	64.33	60.05
NY505	61.00	56.94
NY512	69.91	65.25
NY513	69.91	65.25
NY516	69.91	65.25
NY517	54.67	51.02
NY519	69.91	65.25
NY521	64.33	60.05
NY522	54.67	51.02
NY527	64.33	60.05
NY529	78.73	73.48
NY530	65.16	60.81
NY532	69.91	65.25
NY534	58.89	54.98
NY535	69.91	65.25
NY538	69.91	65.25
NY541	55.60	51.88
NY542	58.89	54.98
NY552	58.89	54.98
NY557	69.91	65.25
NY561	69.91	65.25
NY562	69.91	65.25
NY564	69.91	65.25
NY568	89.47	83.51
NY630	69.91	65.25
NY888	100.14	93.47
NY889	53.63	50.06
NY891	100.14	93.47
NY892	100.14	93.47
NY893	100.14	93.47
NY894	100.14	93.47
NY904	100.14	93.47
OH001	61.01	56.94
OH002	55.41	51.71
OH003	64.33	60.03
OH004	62.29	58.13
OH005	56.82	53.03
OH006	63.94	59.67
OH007	63.27	59.06
OH008	55.41	51.71
OH009	53.78	50.19
OH010	53.78	50.19
OH012	64.33	60.03
OH014	55.78	52.07

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
OH015	62.29	58.13
OH016	54.51	50.88
OH018	54.51	50.88
OH019	53.78	50.19
OH020	53.78	50.19
OH021	56.82	53.03
OH022	56.82	53.03
OH024	53.78	50.19
OH025	64.33	60.03
OH026	54.67	51.01
OH027	64.33	60.03
OH028	56.80	53.02
OH029	63.46	59.22
OH030	53.78	50.19
OH031	63.27	59.06
OH032	53.78	50.19
OH033	53.78	50.19
OH034	53.78	50.19
OH035	53.78	50.19
OH036	54.03	50.43
OH037	53.78	50.19
OH038	62.29	58.13
OH039	53.78	50.19
OH040	53.78	50.19
OH041	53.78	50.19
OH042	64.33	60.03
OH043	61.01	56.94
OH044	55.41	51.71
OH045	53.78	50.19
OH046	53.78	50.19
OH047	53.78	50.19
OH049	62.29	58.13
OH050	53.78	50.19
OH053	53.78	50.19
OH054	56.04	52.30
OH056	53.78	50.19
OH058	53.78	50.19
OH059	61.01	56.94
OH060	53.78	50.19
OH061	55.02	51.35
OH062	56.82	53.03
OH063	53.78	50.19
OH065	62.29	58.13
OH066	53.78	50.19
OH067	53.78	50.19
OH069	53.78	50.19
OH070	61.01	56.94
OH071	63.94	59.67
OH072	53.78	50.19
OH073	64.33	60.03
OH074	55.29	51.60
OH075	53.78	50.19
OH076	53.78	50.19
OH077	53.78	50.19
OH078	53.78	50.19
OH079	61.01	56.94
OH080	54.65	51.00
OH081	54.51	50.88
OH082	53.91	50.31
OH083	61.01	56.94
OH085	63.94	59.67
OH086	53.78	50.19
OH880	64.33	60.03
OH882	64.33	60.03
OK002	55.96	52.23
OK005	54.43	50.80

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
OK006	53.21	49.66
OK024	53.21	49.66
OK027	53.21	49.66
OK032	53.21	49.66
OK033	54.43	50.80
OK044	53.21	49.66
OK062	53.21	49.66
OK067	53.21	49.66
OK073	54.43	50.80
OK095	54.70	51.05
OK096	53.21	49.66
OK099	53.21	49.66
OK111	53.21	49.66
OK118	53.21	49.66
OK139	55.96	52.23
OK142	54.43	50.80
OK146	53.21	49.66
OK148	54.70	51.05
OK150	55.96	52.23
OK901	55.96	52.23
OR001	67.64	63.12
OR002	67.64	63.12
OR003	71.00	66.28
OR005	66.08	61.68
OR006	77.73	72.55
OR007	67.93	63.41
OR008	72.62	67.78
OR011	72.62	67.78
OR014	72.62	67.78
OR015	77.22	72.07
OR016	67.64	63.12
OR017	64.85	60.53
OR019	69.30	64.67
OR020	71.00	66.28
OR022	67.64	63.12
OR026	71.87	67.08
OR027	64.85	60.53
OR028	67.64	63.12
OR031	71.00	66.28
OR032	67.93	63.41
OR034	74.67	69.69
PA001	53.96	50.36
PA002	77.32	72.17
PA003	52.31	48.82
PA004	65.85	61.45
PA005	53.96	50.36
PA006	53.96	50.36
PA007	77.32	72.17
PA008	67.39	62.90
PA009	64.22	59.93
PA010	53.96	50.36
PA011	65.85	61.45
PA012	77.32	72.17
PA013	65.51	61.14
PA014	53.96	50.36
PA015	53.96	50.36
PA016	60.01	56.01
PA017	53.96	50.36
PA018	53.96	50.36
PA019	55.38	51.68
PA020	60.80	56.74
PA021	55.38	51.68
PA022	61.86	57.73
PA023	77.32	72.17
PA024	65.85	61.45
PA026	55.10	51.42
PA027	52.22	48.73
PA028	70.92	66.20
PA029	56.41	52.65
PA030	52.31	48.82
PA031	57.02	53.22
PA032	55.58	51.86
PA033	55.10	51.42
PA034	59.42	55.45
PA035	67.39	62.90
PA036	68.45	63.89
PA037	60.01	56.01
PA038	52.31	48.82
PA039	63.39	59.16
PA041	54.97	51.30
PA042	52.31	48.82
PA043	52.31	48.82
PA044	52.31	48.82
PA045	55.58	51.86
PA046	77.32	72.17
PA047	52.31	48.82
PA048	64.57	60.27
PA049	54.38	50.74
PA050	53.64	50.07
PA051	77.32	72.17
PA052	67.39	62.90
PA053	55.58	51.86
PA054	54.38	50.74
PA055	55.58	51.86
PA056	53.18	49.62
PA057	52.31	48.82
PA058	55.10	51.42
PA059	53.18	49.62
PA060	55.58	51.86
PA061	55.58	51.86
PA063	55.58	51.86
PA064	53.64	50.07
PA065	55.58	51.86
PA066	65.51	61.14
PA067	65.85	61.45
PA068	53.64	50.07
PA069	57.02	53.22
PA071	64.22	59.93
PA073	52.31	48.82
PA074	53.64	50.07
PA075	67.39	62.90
PA076	65.85	61.45
PA077	54.38	50.74
PA078	85.36	79.68
PA079	55.10	51.42
PA080	54.38	50.74
PA081	65.85	61.45
PA082	62.89	58.70
PA083	53.29	49.74
PA085	52.22	48.73
PA086	53.18	49.62
PA087	65.51	61.14
PA088	73.41	68.51
PA089	53.18	49.62
PA090	68.45	63.89
PA091	63.02	58.81
PA092	53.77	50.18
PA889	77.32	72.17
RI001	99.98	93.32
RI002	99.98	93.32
RI003	99.98	93.32
RI004	99.98	93.32
RI005	99.07	92.46
RI006	99.98	93.32
RI007	99.98	93.32
RI008	90.17	84.16
RI009	99.98	93.32
RI010	99.98	93.32
RI011	99.98	93.32
RI012	99.98	93.32
RI013	99.07	92.46
RI014	99.98	93.32
RI015	99.98	93.32
RI016	99.98	93.32
RI017	99.98	93.32
RI018	99.98	93.32
RI019	99.98	93.32
RI020	99.98	93.32
RI022	99.98	93.32
RI024	99.98	93.32
RI026	99.98	93.32
RI027	99.98	93.32
RI028	99.98	93.32
RI029	99.98	93.32
RI901	99.98	93.32
RQ006	76.17	71.09
RQ007	70.87	66.15
RQ008	76.17	71.09
RQ009	70.87	66.15
RQ010	70.87	66.15
RQ011	76.17	71.09
RQ012	70.87	66.15
RQ013	76.17	71.09
RQ014	76.17	71.09
RQ015	76.17	71.09
RQ016	76.17	71.09
RQ017	70.87	66.15
RQ018	70.87	66.15
RQ019	76.17	71.09
RQ020	77.83	72.64
RQ021	76.17	71.09
RQ022	76.17	71.09
RQ023	76.17	71.09
RQ024	76.17	71.09
RQ025	76.17	71.09
RQ026	70.87	66.15
RQ027	76.17	71.09
RQ028	76.17	71.09
RQ029	70.87	66.15
RQ030	70.87	66.15
RQ031	70.87	66.15
RQ032	76.17	71.09
RQ033	70.87	66.15
RQ034	76.17	71.09
RQ035	70.87	66.15
RQ036	76.17	71.09
RQ037	70.87	66.15
RQ038	76.17	71.09
RQ039	77.83	72.64
RQ040	77.83	72.64
RQ041	70.87	66.15
RQ042	70.87	66.15
RQ043	70.87	66.15
RQ044	76.17	71.09
RQ045	76.17	71.09
RQ046	70.87	66.15
RQ047	76.17	71.09
RQ048	70.87	66.15

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
RQ049	76.17	71.09
RQ050	76.17	71.09
RQ052	70.87	66.15
RQ053	76.17	71.09
RQ054	76.17	71.09
RQ055	70.87	66.15
RQ056	76.17	71.09
RQ057	70.87	66.15
RQ058	70.87	66.15
RQ059	70.87	66.15
RQ060	70.87	66.15
RQ061	70.87	66.15
RQ062	70.87	66.15
RQ063	76.17	71.09
RQ064	76.17	71.09
RQ065	70.87	66.15
RQ066	70.87	66.15
RQ067	70.87	66.15
RQ068	70.87	66.15
RQ069	70.87	66.15
RQ070	76.17	71.09
RQ071	70.87	66.15
RQ072	76.17	71.09
RQ073	70.87	66.15
RQ074	70.87	66.15
RQ075	76.17	71.09
RQ076	70.87	66.15
RQ077	76.17	71.09
RQ080	70.87	66.15
RQ081	76.17	71.09
RQ082	76.17	71.09
RQ083	76.17	71.09
RQ901	76.17	71.09
RQ911	76.17	71.09
SC001	62.10	57.97
SC002	62.78	58.59
SC003	58.70	54.79
SC004	58.70	54.79
SC005	58.70	54.79
SC007	58.70	54.79
SC008	62.78	58.59
SC015	58.70	54.79
SC016	58.70	54.79
SC018	58.70	54.79
SC019	58.70	54.79
SC020	58.70	54.79
SC021	58.70	54.79
SC022	61.71	57.59
SC023	58.70	54.79
SC024	62.10	57.97
SC025	58.70	54.79
SC026	59.91	55.90
SC027	58.70	54.79
SC028	58.70	54.79
SC029	58.70	54.79
SC030	58.70	54.79
SC031	58.70	54.79
SC032	58.70	54.79
SC033	58.70	54.79
SC034	58.70	54.79
SC035	58.70	54.79
SC036	61.71	57.59
SC037	58.70	54.79
SC046	61.71	57.59
SC056	62.10	57.97
SC057	62.10	57.97

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
SC059	58.70	54.79
SC911	62.78	58.59
SD010	59.04	55.10
SD011	55.19	51.51
SD014	55.19	51.51
SD016	59.04	55.10
SD021	55.19	51.51
SD026	55.19	51.51
SD034	55.19	51.51
SD035	59.97	55.97
SD036	55.19	51.51
SD037	55.19	51.51
SD038	55.19	51.51
SD039	59.04	55.10
SD043	55.19	51.51
SD045	55.28	51.60
SD047	55.19	51.51
SD048	55.19	51.51
SD055	55.19	51.51
SD056	55.19	51.51
SD057	55.19	51.51
SD058	55.19	51.51
SD059	55.19	51.51
TN001	58.99	55.06
TN002	54.65	51.01
TN003	55.03	51.37
TN004	58.74	54.82
TN005	65.38	61.02
TN006	54.65	51.01
TN007	54.65	51.01
TN011	52.97	49.44
TN012	54.50	50.88
TN013	52.97	49.44
TN015	52.97	49.44
TN016	52.97	49.44
TN020	65.38	61.02
TN024	52.97	49.44
TN026	52.97	49.44
TN038	54.65	51.01
TN042	52.97	49.44
TN054	54.65	51.01
TN062	52.97	49.44
TN065	55.03	51.37
TN066	54.65	51.01
TN076	54.65	51.01
TN079	65.38	61.02
TN088	55.03	51.37
TN095	58.99	55.06
TN113	55.03	51.37
TN117	58.74	54.82
TN903	64.76	60.44
TQ901	99.98	93.32
TX001	72.84	67.99
TX003	61.88	57.75
TX004	69.59	64.95
TX005	66.07	61.67
TX006	64.03	59.77
TX007	56.77	52.99
TX008	65.29	60.92
TX009	74.69	69.72
TX010	55.99	52.26
TX011	55.99	52.26
TX012	66.07	61.67
TX014	55.99	52.26
TX016	53.03	49.50
TX017	66.07	61.67

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
TX018	55.99	52.26
TX019	53.03	49.50
TX021	53.03	49.50
TX023	63.98	59.70
TX024	74.69	69.72
TX025	56.77	52.99
TX028	56.13	52.38
TX029	56.13	52.38
TX031	72.84	67.99
TX032	66.07	61.67
TX033	53.03	49.50
TX034	63.98	59.70
TX035	53.16	49.61
TX037	63.98	59.70
TX039	53.03	49.50
TX042	53.03	49.50
TX044	53.03	49.50
TX046	56.13	52.38
TX048	53.03	49.50
TX049	53.03	49.50
TX051	56.13	52.38
TX053	53.03	49.50
TX062	56.13	52.38
TX064	56.13	52.38
TX065	56.77	52.99
TX072	53.03	49.50
TX073	56.13	52.38
TX075	53.03	49.50
TX079	55.99	52.26
TX081	53.03	49.50
TX085	77.58	72.40
TX087	72.84	67.99
TX095	74.69	69.72
TX096	53.03	49.50
TX105	53.03	49.50
TX111	57.30	53.48
TX114	53.03	49.50
TX128	74.69	69.72
TX134	53.03	49.50
TX137	55.99	52.26
TX147	53.03	49.50
TX152	53.03	49.50
TX158	55.99	52.26
TX163	65.29	60.92
TX164	65.29	60.92
TX173	56.77	52.99
TX174	65.29	60.92
TX175	53.03	49.50
TX177	56.13	52.38
TX178	53.03	49.50
TX183	53.03	49.50
TX189	53.03	49.50
TX193	64.03	59.77
TX197	55.99	52.26
TX201	53.03	49.50
TX202	56.13	52.38
TX206	56.77	52.99
TX208	55.99	52.26
TX210	55.99	52.26
TX217	53.03	49.50
TX224	56.13	52.38
TX232	55.99	52.26
TX236	55.99	52.26
TX242	53.03	49.50
TX251	53.03	49.50
TX257	55.99	52.26

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
TX259	72.84	67.99
TX263	53.03	49.50
TX264	72.84	67.99
TX266	72.84	67.99
TX272	53.03	49.50
TX284	53.03	49.50
TX291	69.59	64.95
TX298	53.03	49.50
TX300	53.03	49.50
TX302	65.29	60.92
TX303	64.03	59.77
TX309	53.03	49.50
TX313	65.29	60.92
TX318	53.03	49.50
TX322	72.84	67.99
TX326	53.03	49.50
TX327	55.99	52.26
TX330	53.03	49.50
TX332	53.03	49.50
TX335	53.03	49.50
TX341	62.79	58.60
TX343	64.03	59.77
TX349	69.59	64.95
TX350	64.03	59.77
TX358	53.03	49.50
TX367	72.84	67.99
TX372	63.46	59.23
TX376	53.03	49.50
TX377	72.84	67.99
TX378	53.16	49.61
TX381	53.03	49.50
TX391	53.03	49.50
TX392	74.69	69.72
TX395	55.99	52.26
TX396	53.03	49.50
TX397	53.03	49.50
TX408	53.03	49.50
TX421	53.03	49.50
TX428	53.03	49.50
TX431	69.59	64.95
TX432	61.88	57.75
TX433	69.59	64.95
TX434	74.69	69.72
TX435	74.69	69.72
TX436	74.69	69.72
TX437	74.69	69.72
TX439	61.88	57.75
TX440	66.07	61.67
TX441	66.07	61.67
TX444	55.99	52.26
TX445	56.13	52.38
TX447	56.13	52.38
TX448	56.13	52.38
TX449	53.03	49.50
TX452	64.03	59.77
TX454	53.03	49.50
TX455	71.95	67.15
TX456	63.84	59.58
TX457	59.47	55.51
TX458	55.99	52.26
TX459	62.79	58.60
TX461	56.42	52.67
TX469	66.07	61.67
TX470	55.99	52.26
TX472	55.99	52.26
TX480	72.84	67.99

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
TX481	55.65	51.94
TX482	55.99	52.26
TX483	66.07	61.67
TX484	71.35	66.59
TX485	53.03	49.50
TX486	53.91	50.31
TX488	53.03	49.50
TX489	74.69	69.72
TX493	74.69	69.72
TX495	69.59	64.95
TX497	56.13	52.38
TX498	57.30	53.48
TX499	55.65	51.94
TX500	53.03	49.50
TX505	66.07	61.67
TX509	56.77	52.99
TX511	53.03	49.50
TX512	63.59	59.35
TX514	55.99	52.26
TX516	53.03	49.50
TX519	53.03	49.50
TX522	74.69	69.72
TX523	57.30	53.48
TX526	74.83	69.84
TX530	66.07	61.67
TX533	74.69	69.72
TX534	71.95	67.15
TX535	53.03	49.50
TX537	53.03	49.50
TX542	55.99	52.26
TX546	55.99	52.26
TX559	74.69	69.72
TX560	66.07	61.67
TX564	53.03	49.50
TX901	74.24	69.30
UT002	62.18	58.03
UT003	62.18	58.03
UT004	62.18	58.03
UT006	67.63	63.12
UT007	62.18	58.03
UT009	62.18	58.03
UT011	62.18	58.03
UT014	76.93	71.80
UT015	76.93	71.80
UT016	76.93	71.80
UT020	62.18	58.03
UT021	67.04	62.58
UT022	62.18	58.03
UT025	62.18	58.03
UT026	62.18	58.03
UT028	76.93	71.80
UT029	76.93	71.80
UT030	62.18	58.03
UT031	67.63	63.12
VA001	68.93	64.33
VA002	54.65	51.01
VA003	68.93	64.33
VA004	101.63	94.86
VA005	62.53	58.35
VA006	68.93	64.33
VA007	62.53	58.35
VA010	53.64	50.06
VA011	55.03	51.35
VA012	68.93	64.33
VA013	55.64	51.93
VA014	55.64	51.93

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
VA015	50.83	47.44
VA016	69.91	65.25
VA017	68.93	64.33
VA018	50.83	47.44
VA019	101.63	94.86
VA020	62.53	58.35
VA021	50.83	47.44
VA022	50.96	47.55
VA023	50.96	47.55
VA024	50.83	47.44
VA025	68.93	64.33
VA028	101.63	94.86
VA030	50.83	47.44
VA031	54.65	51.01
VA032	54.65	51.01
VA034	50.83	47.44
VA035	101.63	94.86
VA036	69.91	65.25
VA037	50.96	47.55
VA038	50.83	47.44
VA039	68.93	64.33
VA040	50.83	47.44
VA041	68.93	64.33
VA042	54.65	51.01
VA043	55.03	51.35
VA044	62.53	58.35
VA045	51.07	47.66
VA046	101.63	94.86
VA880	69.91	65.25
VA901	65.01	60.67
VQ901	84.56	78.93
VT001	82.66	77.15
VT002	71.69	66.91
VT003	74.15	69.21
VT004	73.42	68.52
VT005	68.73	64.15
VT006	82.66	77.15
VT008	68.73	64.15
VT009	69.47	64.84
VT011	82.66	77.15
VT901	82.66	77.15
WA001	84.94	79.26
WA002	84.94	79.26
WA003	75.03	70.02
WA004	71.56	66.78
WA005	72.13	67.33
WA006	84.94	79.26
WA007	59.58	55.60
WA008	67.64	63.12
WA011	84.94	79.26
WA012	65.53	61.15
WA013	66.40	61.97
WA014	55.18	51.50
WA017	58.95	55.02
WA018	71.56	66.78
WA019	57.83	53.98
WA020	57.83	53.98
WA021	65.53	61.15
WA024	84.08	78.45
WA025	80.64	75.25
WA036	75.03	70.02
WA039	84.94	79.26
WA042	68.13	63.58
WA049	77.51	72.33
WA054	72.13	67.33
WA055	65.25	60.91

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
WA057	71.17	66.42
WA061	73.72	68.81
WA064	67.09	62.61
WA069	55.18	51.50
WA071	60.47	56.43
WI001	56.67	52.90
WI002	60.23	56.22
WI003	67.04	62.57
WI006	57.63	53.79
WI011	49.52	46.22
WI019	48.72	45.47
WI020	76.62	71.51
WI031	49.57	46.27
WI039	48.72	45.47
WI043	50.72	47.34
WI045	48.72	45.47
WI047	49.91	46.59
WI048	48.72	45.47
WI050	48.72	45.47
WI060	76.62	71.51
WI064	55.89	52.17
WI065	50.72	47.34
WI068	49.52	46.22
WI069	49.52	46.22
WI070	48.72	45.47
WI083	60.23	56.22
WI085	48.72	45.47
WI091	48.72	45.47
WI096	48.72	45.47
WI127	48.72	45.47
WI131	48.72	45.47
WI142	60.23	56.22
WI160	48.72	45.47
WI166	48.72	45.47
WI183	55.03	51.35
WI186	50.49	47.12
WI193	48.72	45.47
WI195	62.29	58.13
WI201	60.23	56.22
WI203	55.89	52.17
WI204	49.52	46.22
WI205	48.72	45.47
WI206	48.72	45.47
WI207	48.72	45.47
WI208	48.72	45.47
WI213	50.72	47.34
WI214	67.04	62.57
WI218	60.23	56.22
WI219	55.89	52.17
WI221	48.72	45.47
WI222	48.72	45.47
WI230	48.72	45.47
WI231	48.72	45.47
WI233	48.72	45.47
WI237	49.63	46.32
WI241	48.72	45.47
WI242	48.72	45.47
WI244	53.49	49.92
WI245	48.72	45.47
WI246	50.94	47.54
WI248	48.72	45.47
WI256	48.72	45.47
WI259	60.23	56.22
WI261	60.23	56.22
WI262	48.72	45.47
WI263	48.72	45.47

ADMINISTRATIVE FEES FOR THE SECTION 8 HOUSING CHOICE VOUCHER AND MODERATE REHABILITATION PROGRAMS FOR CALENDAR YEAR 2012—Continued

PHA No.	Column A rate	Column B rate
WI901	59.67	55.70
WV001	64.06	59.78
WV002	53.95	50.36
WV003	53.78	50.19
WV004	53.78	50.19
WV005	53.78	50.19
WV006	53.39	49.82
WV009	53.95	50.36
WV010	57.55	53.71
WV013	49.82	46.50
WV014	53.78	50.19
WV015	49.82	46.50
WV016	55.78	52.07
WV017	49.82	46.50
WV018	49.82	46.50
WV027	50.86	47.47
WV034	49.82	46.50
WV035	50.86	47.47
WV037	53.15	49.61
WV039	49.82	46.50
WV042	64.06	59.78
WV045	49.82	46.50
WV046	49.82	46.50
WY002	75.92	70.86
WY003	61.83	57.71
WY004	91.47	85.38
WY013	61.83	57.71

[FR Doc. 2012–18581 Filed 7–27–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CR–10734; 2200–3210–665]

60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. To comply with the Paperwork Reduction Act of 1995 and as a part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to comment on this IC. We may not conduct or sponsor and a person is not required to respond to a collection unless it displays a currently valid OMB control number.

DATES: Please submit your comment on or before September 28, 2012.

ADDRESSES: Please send your comments on the proposed information collection to Madonna Baucum, Information Collection Clearance Officer, National Park Service, 1849 C Street NW., Mailstop 2605 (Rm. 1242), Washington, DC 20240 (mail); via fax at 202/371–6741, or via email to *madonna_baucum@nps.gov.* Please reference Information Collection ''1024–New, National Historic Landmark Nomination Process'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Patricia Henry, Historian, National Historic Landmark Program, 1849 C Street NW., Washington, DC 20240. You may send an email to *patty_henry@nps.gov* or contact her by telephone at (202/354–2216) or via fax at (202/371–2229).

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this information collection is to assist the National Park Service (NPS) in managing the National Historic Landmarks (NHL) program. The information requested will allow the NPS to evaluate properties nominated as NHLs and provide documentation for the proposed designation.

NHLs are nationally significant historic places designated by the Secretary of the Interior because they possess exceptional value or quality in illustrating or interpreting the heritage of the United States and they have significance to all citizens of our nation. The Historic Sites Act of 1935 charged the Department of the Interior with the responsibility for designating nationally significant historic buildings, structures, sites, and objects and promoting their preservation for the inspiration and benefit of the people of the United States. The NPS administers the NHL Program for the Secretary of the Interior.

All NHLs are also listed in the National Register of Historic Places, the official Federal list of districts, sites, buildings, structures, and objects significant in American history, architecture, archeology, engineering, and culture. Thus, NHLs must also be considered in the planning for Federal or Federally assisted projects, and NHL designation provides for eligibility for Federal rehabilitation tax incentives. Designation as a NHL provides formal recognition of a property's national significance in history, architecture, engineering, or archeology based on national standards. The designation places no obligations on private property owners, and there are no restrictions on the use, treatment, transfer, or disposition of private property.

Nominations for the designation of NHLs come from private individuals

and organizations, local governments, State Historic Preservation Officers, Federal Preservation Officers for properties owned or controlled by the United States Government, and Tribal Historic Preservation Officers and American Indian tribes for properties on tribal lands. Regulations at 36 CFR 65 establish the criteria and guidelines for designating National Historic Landmarks. The request to OMB to approve this existing information collection in use without approval will include one form, the National Historic Landmark Nomination Form, which is used to nominate properties and provide documentation for the proposed designation.

Nomination forms will be submitted to the National Historic Landmarks staff in the Washington, DC and regional offices. These offices determine if the property may or may not meet the NHL criteria or if more information is needed to make a determination. Once a nomination is considered complete by the NPS staff, it will be peer reviewed by leading scholars through a blind peer review process. The Landmarks Committee of the National Park System Advisory Board will review all nominations prior to referring those properties to the Advisory Board that they believe meet the NHL criteria. The Advisory Board will review the properties and the Landmarks Committee's recommendations to make their own recommendations to the Secretary of the Interior who has the ultimate authority to designate National Historic Landmarks.

II. Data

OMB Control Number: 1024–New.

Title: National Historic Landmark Nomination Process.

Form(s): National Historic Landmark Nomination Form.

Type of Request: Existing collection in use without approval.

Automated Data Collection: No.

Will the Information Be Collected Electronically? Yes.

Description of Respondents: Private individuals; state, tribal, and local governments; businesses; educational institutions; and nonprofit organizations.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency of Collection: On Occasion.

Description of Need: The purpose of this information collection is to provide documentation in order to consider properties for designation as National Historic Landmarks.

III. Comments

We invite comments concerning this IC on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- 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.

Please note that the comments submitted in response to this notice are a matter of public record. 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: July 24, 2012.

Madonna L. Baucum,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2012–18476 Filed 7–27–12; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CR–10633; 2200–3210–665]

Information Collection Activities: National Historic Landmarks (NHL) Condition Survey

AGENCY: National Park Service (NPS), Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) will ask the Office of Management and Budget (OMB) to approve the Information Collection (IC) described below. This collection will consist of a survey instrument. As required by the Paperwork Reduction Act of 1995, and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC.

DATES: To ensure that your comments on this IC are considered, we must receive them on or before September 28, 2012.

ADDRESSES: Please send your comments to Phadrea Ponds, Information Collections Coordinator, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525 (mail); or *phadrea_ponds@nps.gov* (email). Please reference Information Collection 1024–NEW, National *Historic Landmarks (NHL) Condition Survey* in the subject line.

FOR FURTHER INFORMATION CONTACT: Barbara Wyatt, Historian, National Historic Landmarks Program, 1201 Eye St. NW., Washington, DC 20005. You may send an email to *barbara_wyatt@nps.gov* (email) or 202–371–2229 (fax).

SUPPLEMENTARY INFORMATION:

I. Abstract

National Historic Landmarks (NHL) are nationally significant historic places designated by the Secretary of the Interior because they possess exceptional value or quality in illustrating or interpreting the heritage of the United States. Today, 2,501 historic places bear this national distinction. Working with citizens throughout the nation, the National Historic Landmarks Program draws upon the expertise of National Park Service staff who work to nominate new landmarks and provide assistance to stewards of existing landmarks. Nominations are submitted by property owners and property stewards to the National Park Service. They are reviewed by qualified subject experts prior to their review by the NHL Advisory Board.

The NPS and NHL staff is required by The Historic Sites Act to collect information regarding the condition of designated landmarks. A questionnaire will be designed and used to collect information from owners or other stewards so the condition of NHLs can be monitored over time. The regional offices of NPS assist in the collection of the condition data. Regional NPS staff contributed to the design of the questionnaire that is the subject of this request.

II. Data

OMB Control Number: 1024—New.

Title: National Historic Landmarks (NHL) Condition Survey.

Type of Request: Existing collection in use without an OMB Control Number.

Description of Respondents: State, tribal, and local governments; businesses; nonprofit organizations; and individuals.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Estimated Number of Responses: 1,625.

Annual Burden Hours: 271 hours. We estimate an average of 10 minutes per response.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We have not identified any ''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 and current expiration date.

III. Request for Comments

We invite comments concerning this IC on: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) how to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: July 23, 2012.

Madonna L. Baucum,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2012–18474 Filed 7–27–12; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Notice of Availability of the Proposed Notice of Sale for Outer Continental Shelf (OCS) Oil and Gas Lease Sale 229 in the Western Planning Area (WPA) in the Gulf of Mexico; Correction

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice; correction.

SUMMARY: The Bureau of Ocean Energy Management published a notice that appeared for Public Inspection on July 23, 2012 and published in the **Federal Register** July 24, 2012. It contained a typographical mistake. This document corrects the error.

FOR FURTHER INFORMATION CONTACT: Donna Dixon, Leasing Division Chief, *Donna.Dixon@boem.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–No. 142, published July 24, 2012, at 77 FR 43355, there was a typographical error. The second sentence of the **SUMMARY** section is corrected to read: ''This sale will be the first under the Proposed Final OCS Oil and Gas Leasing Program for 2012–2017.'' All other portions of the Notice remain unchanged.

Dated: July 24, 2012.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2012–18443 Filed 7–27–12; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Docket No. 2904]

Certain Wireless Consumer Electronics Devices and Components Thereof; Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled Certain Wireless Consumer Electronics Devices and Components Thereof, DN 2904; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Technology Properties Limited LLC, Phoenix Digital Solutions LLC and Patriot Scientific Corporation on July 24, 2012. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless consumer electronics devices and components thereof. The complaint names as respondents Acer, Inc. of Taiwan; Acer America Corporation of CA; Amazon.com, Inc. of WA; Barnes & Noble, Inc. of NY; Garmin Ltd. of Switzerland; Garmin International, Inc. of KS; Garmin USA, Inc. of KS; HTC Corporation of Taiwan; HTC America of WA; Huawei Technologies Co., Ltd. of China; Huawei North America of TX; Kyocera Corporation of Japan; Kyocera Communications, Inc. of CA; LG Electronics, Inc. of Korea; LG Electronics U.S.A., Inc. of NJ; Nintendo Co., Ltd. of Japan; Nintendo of America, Inc. of WA; Novatel Wireless, Inc. of CA; Samsung Electronics Co., Ltd. of Korea; Samsung Electronics America, Inc. of NJ; Sierra Wireless, Inc. of Canada, Sierra Wireless America, Inc. of CA; ZTE Corporation of China; and ZTE (USA) Inc. of TX.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the

United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 2904'') in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: July 25, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–18469 Filed 7–27–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–12–021]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 2, 2012 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

Matters To Be Considered

1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701–TA–442–443 and 731–TA–1095–1097 (Review) (Certain Lined Paper School Supplies from China, India, and Indonesia). The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before August 14, 2012.

5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: July 25, 2012.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2012–18604 Filed 7–26–12; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–12–020]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 31, 2012 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

Matters To Be Considered

1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Vote in Inv. No. 731–TA–344 (Third Review)(Tapered Roller Bearings From China). The Commission is currently scheduled to transmit its determination and Commissioners'' opinions to the Secretary of Commerce on or before August 16, 2012.

5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: July 24, 2012.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2012–18564 Filed 7–26–12; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Water and Clean Air Acts

Notice is hereby given that on July 24, 2012, a proposed Consent Decree in *United States, et al.* v. *Shenango Incorporated,* Civil Action No. 2:12–cv–01029–GLL was lodged with the United States District Court for the Western District of Pennsylvania.

Shenango Incorporated (''Shenango'') is a company located in the greater Pittsburgh area which owns and operates a single battery containing 56 coke ovens in which it converts coal to coke. The Consent Decree obligates Shenango to implement a program of ceramic welding to address opacity violations at the coke ovens and combustion stack at the facility, and to adhere to various protocols for inspection, maintenance, and operation of the coke ovens. The settlement

further obligates Shenango to install certain interim measures at its wastewater treatment plant and, after issuance of a new and revised National Pollutant Discharge Elimination System (''NPDES'') permit, to install biological treatment in the wastewater treatment plant. In addition, Shenango will pay a civil penalty of $1,750,000 to resolve its violations of the Clean Air Act and the Clean Water Act. The Allegheny County Health Department (''ACHD'') and the Pennsylvania Department of Environmental Protection (''PADEP'') are co-plaintiffs with the United States.

The Consent Decree resolves civil claims for violations alleged in a Complaint filed concurrently with the Consent Decree. In the Complaint, Plaintiffs allege that Shenango violated regulations of ACHD, which are incorporated into the Pennsylvania State Implementation Plan (''SIP''), because Shenango had visible emissions in excess of those allowed under the ACHD regulations, from charging, from the door areas, from offtake piping, from pushing, and at the combustion stack. In addition, Plaintiffs allege that Shenango violated the limits on flaring, mixing or combustion of coke oven gas. Under the Clean Water Act, Plaintiffs allege that Shenango violated the effluent limitations in the NPDES Permit issued to it, that Shenango also discharged polluted stormwater without authorization into the Ohio River, and that Shenango failed to properly operate and maintain its wastewater treatment plant in violation of the terms of its NPDES permit.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States et al.* v. *Shenango Incorporated,* D.J. Ref. 90–5–2–3–1099/3.

During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, to *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or emailing a request to ''Consent Decree Copy''(*EESCDCopy.ENRD@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–5271. If requesting a copy from the Consent Decree Library by mail, please enclose a check in the amount of $ 15.75 for the Consent Decree and $100.00 for the Appendices thereto (25 cents per page reproduction cost) payable to the U.S. Treasury or, if requesting by email or fax, forward a check in that amount to the Consent Decree Library at the address given above.

Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2012–18434 Filed 7–27–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *American Bottom Conservancy* v. *Jackson,* Civil Action No. 3:12–cv–00296–GPM–SCW, was lodged with the United States District Court for the Southern District of Illinois on July 23, 2012.

This proposed Consent Decree concerns a complaint filed by American Bottom Conservancy (''ABC'') against Lisa P. Jackson, in her official capacity as Administrator of the Environmental Protection Agency (''EPA''), pursuant to Section 304(a)(2) of the Clean Air Act (''CAA''), 42 U.S.C. § 7604(a)(2), to obtain injunctive relief to require EPA to respond to an administrative petition filed by ABC challenging an air pollution permit issued by the Illinois Environmental Protection Agency for the U.S. Steel Corporation's Granite City Works facility, Permit No. 96030056. The proposed Consent Decree resolves these allegations by requiring EPA to act on the administrative petition on or before December 3, 2012.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Perry M. Rosen, Trial Attorney, United States Department of Justice, Environment and Natural Resources Division, P.O. Box 7611, Washington, DC 20044 and refer to *ABC* v. *Jackson,* DJ # 90–5–2–4–19402.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Southern District of Illinois, 750 Missouri Avenue, East St. Louis, Illinois 62201. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/Consent_Decrees.html.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment & Natural Resources Division.

[FR Doc. 2012–18406 Filed 7–27–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (BJA) Docket No. 1597]

Meeting of the Department of Justice National Motor Vehicle Title Information System Federal Advisory Committee

AGENCY: Office of Justice Programs (OJP), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of Department of Justice's (DOJ's) National Motor Vehicle Title Information System (NMVTIS) Federal Advisory Committee to discuss various issues relating to the operation and implementation of NMVTIS.

DATES: The meeting will take place on Tuesday, September 11, 2012, from 8:30 a.m. to 4:30 p.m. et.

ADDRESSES: The meeting will take place at the Office of Justice Programs (OJP), 810 7th Street NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Todd Brighton, Designated Federal Employee (DFE), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531; Phone: (202) 616–3879 [**Note:** this is not a toll-free number]; Email: *Todd.Brighton@usdoj.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Members of the public who wish to attend this meeting must register with Mr. Brighton at the above address at least seven (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. Please bring photo identification and allow extra time prior to the meeting. Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFE.

Anyone requiring special accommodations should notify Mr. Brighton at least seven (7) days in advance of the meeting.

Purpose

The NMVTIS Federal Advisory Committee will provide input and recommendations to the Office of Justice Programs (OJP) regarding the operations and administration of NMVTIS. The primary duty of the NMVTIS Federal Advisory Committee is to advise the Bureau of Justice Assistance (BJA) Director on NMVTIS-related issues, including but not limited to: Implementation of a system that is self-sustainable with user fees; options for alternative revenue-generating opportunities; determining ways to enhance the technological capabilities of the system to increase its flexibility; and options for reducing the economic burden on current and future reporting entities and users of the system.

Todd Brighton,

NMVTIS Enforcement Coordinator, Bureau of Justice Assistance, Office of Justice Programs.

[FR Doc. 2012–18556 Filed 7–27–12; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—National Institute of Corrections Inaugural Virtual Conference: Event Planning and Delivery

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is soliciting proposals from organizations, companies, or agencies to enter into a cooperative agreement for a 9-month project period for the design, scheduling, promotion, production, and delivery of an NIC Virtual Conference entitled ''Handcuff Key to Door Key: A Systems Approach to Re-Entry.''

DATES: Applications must be received by 4:00 p.m. EST on Wednesday, August 8, 2012.

ADDRESSES: Applicants are encouraged to submit their proposals electronically via *http://www.grants.gov.* Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street NW., Room 5002, Washington, DC 20534. If submitted in hard copy, there must be an original and three unbound copies of the full proposal. The original should have the applicant's signature in blue ink. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date. Faxed applications will not be accepted.

FOR FURTHER INFORMATION CONTACT: A copy of this announcement can be downloaded from the NIC Web site at *www.nicic.gov.* All technical or programmatic questions concerning this announcement should be directed to Bernie Iszler, Correctional Program Specialist, National Institute of Corrections. She can be reached by calling 303–338–6618 or by email at *biszler@bop.gov.* All questions, answers, and additional information on this solicitation will be posted on NIC's Web site at *www.nicic.gov* for public review (the names of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation. Only questions received by 12:00 p.m. (EDT) on August 3, 2012 will be posted on the NIC Web site.

SUPPLEMENTARY INFORMATION:

Background: The National Institute of Corrections has been providing technical assistance, training, and information to the corrections field since 1974 by using a variety of delivery strategies, including networks, Web sites, and other outreach tools. As information technology has advanced, NIC has adopted the use of synchronous and asynchronous learning platforms, electronic networks, e-newsletters, and soon-to-be-added NIC mobile applications (e.g., smart phone apps). The Inaugural Virtual Conference is another step NIC is taking in using new technologies to deliver services to the field as effectively and efficiently as possible. The National Institute of Corrections target date for hosting its Inaugural Virtual Conference is April 2013. Titled ''Handcuff Key to Door Key: A Systems Approach to Re-Entry,'' the conference will cater to criminal justice and corrections professionals, service providers, and stakeholders in the field of corrections. NIC staff and corrections subject matter experts will be providing the content for the virtual conference. NIC is seeking to produce a half-day virtual conference (approximately 5 hours in length) that will include (1) a fully branded convention center with a video greeting; (2) Virtual exhibit hall with scheduled live staff interaction (staff from all NIC divisions); (3) Auditorium with live and/or prerecorded keynote speakers and other presenters; (4) Resource center with downloadable content including white papers, NIC documents, and links in formats including but not limited to .pdf, .doc, .ppt, and .wmv; (5) Communications center with networking opportunities, scheduled discussions, group chat, and forums; and (6) Workshops with live and prerecorded presentations.

Scope of Work: The goals and tasks of this work will include (1) a program manager, a team of event facilitators, and support personnel to manage the virtual conference through design, scheduling, promotion, and delivery; (2) In-studio and/or onsite production staff to create and capture video greetings and workshop sessions; (3) Technical and streaming expertise in delivering content; (4) Event scheduling expertise; (5) Expertise in best practices and communication tips for presenters; (6) Chat-based and phone-based technical support for the event. Proposals will outline in a project plan a detailed chart and description of a project management structure and team roles, a task plan that addresses the planning phase with specific deliverables, delivery phase with specific deliverables, and post conference phase with specific deliverables. In all phases of the project planning, development, and delivery, NIC involvement and approval benchmarks will be included in the overarching project plan.

The deliverables for this project include (1) a fully branded convention center with a video greeting; (2) Virtual exhibit hall with scheduled live staff interaction (staff from all NIC divisions); (3) Auditorium with live and/or prerecorded keynote speakers and other presenters; (4) Resource center with downloadable content including NIC documents and links in formats including .pdf, .doc, .ppt, and wmv; (5) Communications center with networking opportunities, scheduled discussions, group chat, and forums; (6) Workshops with live and prerecorded presentations; (7) Post-conference reports outlining lessons learned (both technical and programmatic); and (8) Registration of attendees and metrics of attendees (e.g., number of hours of attendance per attendee).

Specific Requirements: Requirements include event platform product and technical expertise in virtual conference event planning, scheduling, promotion, and delivery.

Document Requirements: Documents or other media produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's writer/editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. The awardee must follow the guidelines listed herein, as well as

follow (1) the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements* and (2) NIC recommendations for producing media using plain language, which can be found at *www.nicici.gov/plainlanguage.*

All final documents and other media submitted under this project may be posted on the NIC Web site and must meet the Federal Government's requirement for accessibility (e.g., 508 PDFs or HTML files). The awardee must provide descriptive text interpreting all graphics, photos, graphs, and/or multimedia that will be included with or distributed alongside the materials and must provide transcripts for all applicable audio/visual works.

Application Requirements: Applications should be concisely written, typed double spaced and reference the project by the ''NIC Opportunity Number'' and title in this announcement. The package must include a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (e.g., July 1 through June 30); a program narrative not to exceed 30 pages in response to the statement of work; and a budget narrative explaining projected costs. Applicants may submit a description of the project team's qualifications and expertise relevant to the project but should not attach lengthy resumes. Large attachments to the proposal describing the organization are discouraged.

The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements available at *http://nicic.gov/Downloads/General/certif-frm.pdf.* Failure to supply all required forms with the application package will result in disqualification of the application from consideration.

Authority: Pub. L. 93–415.

Funds Available: NIC is seeking the applicant's best ideas regarding accomplishment of the scope of work and the related costs for achieving the goals of this solicitation. Funds may be used only for the activities that are linked to the desired outcome of the project.

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual, or team with expertise in the described areas.

Review Considerations: Applications received under this announcement will be subject to the NIC review process. Proposals that fail to provide sufficient information to have them evaluated under the criteria below may be judged non-responsive and disqualified. The criteria for the evaluation of each application will be as follows: Programmatic (40%)

Are all of the goals and project tasks adequately discussed? Is there a clear statement of how each task will be accomplished, including major sub-tasks, the strategies to be employed, required staffing, and other required resources? Are there any innovative approaches, techniques, or design aspects proposed that will enhance the project? Organizational (35%)

Does the proposed project staff possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to achieve all five project tasks? Are the proposed project management and staffing plans realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If the applicant proposes consultants and/or partnerships, is there a reasonable justification for their inclusion in the project and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: http://www.bpn.gov/ccr. A CCR Handbook and worksheet can also be reviewed at the Web site.

Number of Awards: One.

NIC Opportunity Number: 12AC07. This number should appear as a reference line in the cover letter, where indicated on Standard Form 424, and outside of the envelope in which the application is sent.

Catalog of Federal Domestic Assistance Number: 16.601.

Executive Order 12372: This project is not subject to the provisions of Executive Order 12372.

Jimmy L. Cosby,

Acting Director, National Institute of Corrections.

[FR Doc. 2012–18465 Filed 7–27–12; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request: Site Visit Data Collection Request for American Recovery and Reinvestment Act Funded Grants; Job Training Evaluations

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''Site Visit Data Collection Request for American Recovery and Reinvestment Act funded Grants; Job Training Evaluations,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before August 29, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235,

725 17th Street NW., Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The ETA seeks approval to collect site visit data from organizations that received grants issued under the American Recovery and Reinvestment Act: Pathways Out of Poverty (POP), Energy Training Partnership (ETP), State Energy Sector Partnership (SESP), and Health Care and Other High Growth and Emerging Industries Training grant initiative. POP, ETP, and SESP are all Green Jobs training programs. The overall aim of these evaluations is to determine the extent to which enrollees achieve increases in employment, earnings, and career advancement because of their participation in the training provided and to identify promising best practices and strategies for replication.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0486. The current approval is scheduled to expire on July 31, 2012; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on April 20, 2012 (77 FR 23764).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0486. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Site Visit Data Collection Request for American Recovery and Reinvestment Act funded Grants; Job Training Evaluations.

OMB Control Number: 1205–0486.

Affected Public: Individuals or Households and Private Sector—Not-for-profit institutions.

Total Estimated Number of Respondents: 84.

Total Estimated Number of Responses: 84.

Total Estimated Annual Burden Hours: 126.

Total Estimated Annual Other Costs Burden: $0.

Dated: July 24, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–18499 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

162nd Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 162nd open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on August 28–30, 2012.

The three-day meeting will take place in C5521 Room 4, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. The meeting will run from 9:00 a.m. to approximately 5:30 p.m. on August 28 and 29 and from 8:30 a.m. to approximately 4:30 p.m. on August 30, with a one hour break for lunch each day. The purpose of the open meeting is for Advisory Council members to hear testimony from invited witnesses and to receive an update from the Employee Benefits Security Administration (EBSA).

The Advisory Council is studying the following issues: (1) Managing Disability Risks in an Environment of Individual Responsibility; (2) Current Challenges and Best Practices Concerning Beneficiary Designations in Retirement and Life Insurance Plans; and (3) Examining Income Replacement During Retirement Years in a Defined Contribution Plan System. The schedule for testimony and discussion of these issues generally will be one issue per day in the order noted above. Descriptions of these topics are available on the Advisory Council page of the EBSA web site, at *www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html*. The EBSA update is scheduled for the afternoon of August 29, subject to change.

Organizations or members of the public wishing to submit a written statement may do so by submitting 30 copies on or before August 14 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N–5623, 200 Constitution Avenue NW., Washington, DC 20210. Statements also may be submitted as email attachments in text or pdf format transmitted to *good.larry@dol.gov.* It is requested that statements not be included in the body of an email. Statements deemed relevant by the Advisory Council and received on or before August 14 will be included in the record of the meeting and made available in the EBSA Public Disclosure Room, along with witness statements. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Written statements submitted by invited witnesses will be posted on the Advisory Council page of the EBSA web site, without change, and can be retrieved by most Internet search engines.

Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary by email or telephone (202) 693–8668. Oral presentations will be limited to ten minutes, time permitting, but an extended statement may be submitted for the record. Individuals with

disabilities who need special accommodations should contact the Executive Secretary by August 21.

Signed at Washington, DC, this 23rd day of July 2012.

Michael L. Davis,

Deputy Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2012–18407 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,482]

Quad/Graphics Inc.,Including On-Site Leased Workers From Staff Mart and A.I.D.,Jonesboro, AR; Amended Certification Regarding EligibilityTo Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 21, 2012, applicable to workers of Quad/Graphics Inc., Jonesboro, Arkansas. The Department's notice of determination was published in the **Federal Register** on July 10, 2012 (77 FR 40641).

At the request of a state workforce office, the Department reviewed the certification for workers of the subject firm. The workers were engaged in activities related to the production of printed material such as magazines and catalogues.

The company reports that workers leased from Staff Mart and A.I.D. were employed on-site at the Jonesboro, Arkansas location of Quad/Graphics, Inc. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Staff Mart and A.I.D. working on-site at the Jonesboro, Arkansas location of Quad/Graphics, Inc.

The amended notice applicable to TA–W–81,482 is hereby issued as follows:

All workers of Staff Mart and A.I.D., reporting to Quad/Graphics, Inc., Jonesboro Arkansas, who became totally or partially separated from employment on or after April 5, 2011 through June 21, 2014, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 19th day of July 2012.

Elliott S. Kushner,

Certifying Officer, Office ofTrade Adjustment Assistance.

[FR Doc. 2012–18413 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,919]

RG Steel Sparrows Point LLC,Formerly Known as Severstal Sparrows Point LLC,a Subsidiary of RG Steel LLC,Including On-Site Leased Workers From Echelon Service Company, Sun Associated Industries, Inc., MPI Consultants LLC, Alliance Engineering, Inc., Washington Group International, Javan & Walter, Inc., Kinetic Technical Resources Co., Innovative Practical Approach, Inc., CPSI, Accounts International, Adecco, Aerotek, Booth Consulting, Crown Security, Eastern Automation, EDS(HP), Teksystems, and URS Corporation,Sparrows Point, MD; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 9, 2011, applicable to workers and former workers of Severstal International, Sparrows Point, Maryland. The workers are engaged in activities related to the production of rolled steel. On June 22, 2012, the Department issued a Notice of Amended Certification applicable to the subject firm to reflect the change in name due to a change in ownership.

Subsequent to the issuance of the amendment, the Department received new information regarding on-site leased workers at the Sparrows Point, Maryland facility. As a result, the Department reviewed the certification for workers of the subject firm.

New information shows that Accounts International, Adecco, Aerotek, Booth Consulting, Crown Security, Eastern Automation, EDS(HP), TekSystems, and URS Corporation are under the operational control of RG Steel Sparrows Point LLC, Sparrows Point, Maryland.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of the subject firm, including on-site leased workers, who were adversely affected by increased company imports of flat rolled steel.

The amended notice applicable to TA–W–74,919 is hereby issued as follows:

All workers of RG Steel Sparrows Point LLC, formerly known as Severstal Sparrows Point LLC, a subsidiary of RG Steel LLC, including on-site leased workers from Echelon Service Company, Sun Associated Industries, Inc., MPI Consultants LLC, Alliance Engineering, Inc., Washington Group International, Javan & Walter, Inc., Kinetic Technical Resources Co., Innovative Practical Approach, Inc., CPSI, Accounts International, Adecco, Aerotek, Booth Consulting, Crown Security, Eastern Automation, EDS(HP), TekSystems, and URS Corporation, Sparrows Point, Maryland who became totally or partially separated from who became totally or partially separated from employment on or after November 22, 2009 through February 9, 2013, and all workers in the group threatened with total or partial separation from employment on February 9, 2011 through February 9, 2013, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC, this 18th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office ofTrade Adjustment Assistance.

[FR Doc. 2012–18411 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,546]

Lawson Software, Inc., Including Workers Whose Unemployment Insurance (UI) Wages Were Reported Through Lawson Software Americas, Inc. and Infor, Inc., St. Paul, MN; Including Off-Site Workers From Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin Reporting to St. Paul, MN; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 29, 2012, applicable to workers of Lawson Software, Inc., including workers whose unemployment insurance (UI) wages were reported through Lawson Software Americas, Inc. and Infor, Inc., and including remote workers working from home throughout the United States reporting to St. Paul, Minnesota. The Department's notice of determination was published in the **Federal Register** on July 18, 2012 (77 FR 42336).

The Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of software.

New information shows that worker separations occurred involving employees under the control of the subject firm working off-site specifically working in the following states: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin. The employees support Lawson Software, Inc., including workers whose unemployment insurance (UI) wages were reported through Lawson Software Americas, Inc. and Infor, Inc., St. Paul, Minnesota engaged in activities related to the production of software.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by a shift in production of software.

Based on these findings, the Department is amending this certification to include employees of the subject firm's St. Paul, Minnesota facility working off-site in Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.

The amended notice applicable to TA–W–81,546 is hereby issued as follows:

All workers of Lawson Software, Inc., including workers whose unemployment insurance (UI) wages were reported through Lawson Software Americas, Inc. and Infor, Inc., St. Paul, Minnesota, including off-site workers from Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin reporting to St. Paul, Minnesota who became totally or partially separated from employment on or after April 26, 2011 through June 29, 2014, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 19th day of July 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18410 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,097]

Kimberly-Clark Worldwide, Inc.,a Subsidiary of Kimberly-Clark Corporation,Everett Mill,Including On-Site Leased Workers From Injury Free, Incorporated, Ventilation Power Cleaning, Inc., Covenant Security Services, Healthforce, UNISEVE Corporation, Jacobs Engineering, STAFFLOGIX Corporation, and Swift Trucking,Everett, WA; Amended Certification Regarding EligibilityTo Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on December 16, 2011, applicable to workers of Kimberly-Clark Worldwide, Inc., a subsidiary of Kimberly-Clark Corporation, Everett Mill, including on-site leased workers from Injury Free, Incorporated, Ventilation Power Cleaning, Inc., Covenant Security Services, Healthforce, UNISEVE Corporation, and Jacobs Engineering, Everett, Washington. The Department issued an amended certification on January 25, 2012 to include on-site leased workers from STAFFLOGIX Corporation. The subject firm produces tissue products and wood pulp.

Following the allegation that workers of Swift Trucking are part of the subject worker group, the Department reviewed the certification for workers of the subject firm.

The company reports that workers leased from Swift Trucking were employed on-site at the Everett, Washington location of Kimberly-Clark Worldwide, Inc., a subsidiary of Kimberly-Clark Corporation, Everett Mill. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Swift Trucking working on-site at the Everett, Washington location of the subject firm.

The amended notice applicable to TA–W–81,097 is hereby issued as follows:

All workers of Kimberly-Clark Worldwide, Inc., a subsidiary of Kimberly-Clark Corporation, Everett Mill, including on-site leased workers from Injury Free,

Incorporated, Ventilation Power Cleaning, Inc., Covenant Security Services, Healthforce, UNISEVE Corporation, Jacobs Engineering, STAFFLOGIX Corporation, and Swift Trucking, Everett, Washington, who became totally or partially separated from employment on or after February 13, 2012, through December 16, 2013, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 18th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18412 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–80,510]

Suntron Corporation, Including On-Site Leased Workers From Manpower, Nesco, TPI and Robert Half, Sugarland, TX; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor (Department) issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on November 17, 2011, applicable to workers and former workers of Suntron Corporation, including on-site leased workers from Manpower, Sugarland, Texas. The Department's Notice of determination was published in the **Federal Register** on December 6, 2012 (Vol. 76, No. 234 FR 76186).

At the request of a state workforce official, the Department reviewed the certification for workers of the subject firm. The workers were engaged in activities related to the production of circuit boards.

The company reports that workers leased from NESCO, TPI, and Robert Half were employed on-site at the Sugarland, Texas location of Suntron Corporation. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from NESCO, TPI, and Robert Half working on-site at the Sugarland, Texas location of the subject firm.

The amended notice applicable to TA–W–80,510 is hereby issued as follows:

All workers of Suntron Corporation, including on-site leased workers from Manpower, NESCO, TPI, and Robert Half, Sugar Land, Texas, who became totally or partially separated from employment on or after October 12, 2010, through November 17, 2013, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 16th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18419 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding EligibilityTo Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *July 9, 2012 through July 13, 2012.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and

a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,566	European Touch, E Touch Holding Company, Argus Technical	Milwaukee, WI	May 1, 2011.
81,628	MX Solar USA LLC	Somerset, NJ	May 17, 2011.
81,685	Gardner Denver, Thomas Products Division	Sheboygan, WI	September 24, 2011.
81,688	OSRAM Sylvania, Inc., Consumer Lighting Division, Superior Technical Resources.	St. Marys, PA	October 2, 2011.
81,688A	W&W and Sons Contractors, Inc., OSRAM Sylvania, General Lighting, fka Consumer Lighting Division.	St. Marys, PA	June 5, 2011.
81,763	Intelicoat Technologies Image Products S. Hadley, LLC	South Hadley, MA	June 27, 2011.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,520	T-Mobile USA, Inc., Call Center	Allentown, PA	April 17, 2011.
81,520A	T-Mobile USA, Inc., Call Center	Fort Lauderdale, FL	April 17, 2011.
81,520B	T-Mobile USA, Inc., Call Center	Frisco, TX	April 17, 2011.
81,520C	T-Mobile USA, Inc., Call Center	Brownsville, TX	April 17, 2011.
81,520D	T-Mobile USA, Inc., Call Center	Lenexa, KS	April 17, 2011.
81,520E	T-Mobile USA, Inc., Call Center	Thornton, CO	April 17, 2011.
81,520F	T-Mobile USA, Inc., Call Center	Redmond, OR	April 17, 2011.
81,647	Sealed Air Corporation, Premier Recruitment Group	Rochester, NY	May 18, 2011.
81,681	Diebold Incorporated, Information Technology and Finanical Shared Services.	North Canton, OH	April 2, 2012.
81,686	Brookfield Global Relocation Services, Client Accounting Division, Accountemps and Quad.	Fort Washington, PA	June 5, 2011.
81,730	Market Track, LLC, Market Track Holdings, LLC, Data Entry Group.	Chicago, IL	June 15, 2011.
81,733	Air System Components, Inc., Tomkins Industries, DmDickanson Personnel.	El Paso, TX	October 24, 2011.
81,733A	RM Personnel and Select Services, Tomkins Industries, Working on Site at Air System Components.	El Paso, TX	June 13, 2011.
81,734	Ericsson, Inc., Network Operations Center, Convergenz, LLC and APEX Systems, Inc.	Albuquerque, NM	June 20, 2011.
81,743	Emerson Power Transmission, Emerson Electric Co.	Ithaca, NY	May 14, 2012.

TA–W No.	Subject firm	Location	Impact date
81,745	North Sails Nevada, LLC, 2379 Heybourne Road and 2549 Business Parkway, Aerotek, etc..	Minden, NV	June 22, 2011.
81,746	Lattice Semiconductor Corporation, Legal Compliance Department.	Hillsboro, OR	June 22, 2011.
81,746A	Lattice Semiconductor Corporation, Consumer Design Function ..	San Jose, CA	June 22, 2011.
81,746B	Lattice Semiconductor Corporation, Research and Development Function.	Hillsboro, OR	April 13, 2012.
81,746C	Lattice Semiconductor Corporation, Sales-Customer Service Function.	Hillsboro, OR	June 22, 2011.
81,757	Pro-Dex Astromec, Inc., Pro-Dex, Inc., Westaff Carson City	Carson City, NV	June 25, 2011.
81,760	EPIC Technologies, LLC	Norwalk, OH	December 23, 2011.
81,766	Sensata Technologies, Inc., Power Controls Business	Cambridge, MD	May 26, 2012.
81,766A	Experis Manpower Group, Sensata Techologies, Power Controls Business.	Cambridge, MD	June 29, 2011.
81,769	Federal-Mogul Corporation, Vehicle Safey and Protection Division, Kelly Services and AES Staffing.	Winchester, VA	June 29, 2011.
81,770	Hartford Financial Services Group, Inc., Operations/Consumer/NQ Manuel Rating Division.	Southington, CT	June 29, 2011.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,661	Oryx Advanced Materials, Benchmark Specialized Production Staffing.	Fremont, CA	April 25, 2011.
81,713	Siemens Baltimore Facility, Customer Services Division, Metallurgical Services, Mark F. Winstead.	Sparrows Point, MD	June 12, 2011.

The following certifications have been issued. The requirements of Section 222(c) (downstream producer for a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,693	Schlei Dray Line, Inc	Manitowoc, WI	May 29, 2011.

The following certifications have been issued. The requirements of Section 222(f) (firms identified by the International Trade Commission) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,640	Kaiser Aluminum, Kaiser Aluminum Corporation	Los Angeles, CA	May 19, 2010.
81,642	C.R. Laurence Company, Inc	Los Angeles, CA	May 19, 2010.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,720	Federal-Mogul Corporation, Global Aftermarket Division, Home-Based Workers Reporting to this Location.	Southfield, MI	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued in cases where these petitions were not filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to

the date of the petition cannot be covered under a certification of a petition under Section 223(b), and therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA–W No.	Subject firm	Location	Impact date
81,781	CDI Engineering Corporation	Virginia Beach, VA.	

I hereby certify that the aforementioned determinations were issued during the period of *July 9, 2012 through July 13, 2012.* These determinations are available on the Department's Web site tradeact/taa/taa search form.cfm under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Dated: July 18, 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18415 Filed 7–27–12; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 9, 2012.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 9, 2012.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 20th day of July 2012.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[19 TAA petitions instituted between 7/9/12 and 7/13/12]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
81784	SCHAWK Retail Marketing (Workers)	Chicago, IL	07/09/12	07/06/12
81785	DTE Energy (State/One-Stop)	Sparrows Point, MD	07/09/12	07/06/12
81786	AE Polysilicon Corporation (Company)	Fairless Hills, PA	07/10/12	06/26/12
81787	CSR Technology, Inc. (State/One-Stop)	Sunnyvale, CA	07/10/12	07/09/12
81788	ConAgra Foods, Inc. (State/One-Stop)	Batesville, AR	07/10/12	07/09/12
81789	Easy Gardener Products, Inc. (Company)	Batesburg, Sc	07/10/12	07/09/12
81790	Wellpoint, (Anthem BC/BS) (Workers)	Worthington, OH	07/10/12	06/29/12
81791	Regal Beloit Corp.—FASCO (Company)	Eldon, MO	07/11/12	07/09/12
81792	Solo W–2, Inc. (Company)	Salem, OR	07/11/12	07/10/12
81793	Altairnano, Inc. (Company)	Reno, NV	07/11/12	07/10/12
81794	Decision One (Inc. Tulsa, OK & OKC, OK) (State/One-Stop).	Devon, PA	07/12/12	07/11/12
81795	American Furniture Manufacturing, Inc. (Company)	Ecru, MS	07/12/12	07/12/12
81796	Adams Globalization, a Division of Transperfect, IDTP Department (Workers).	Austin, TX	07/12/12	07/09/12
81797	International Business Machines (IBM) (State/One-Stop)	Endicott, NY	07/13/12	07/12/12
81798	CoreLogic (Workers)	Des Moines, IA	07/13/12	07/12/12
81799	Dun & Bradstreet (Workers)	Center Valley, PA	07/13/12	07/12/12
81800	Raytheon (State/One-Stop)	El Segundo, CA	07/13/12	07/12/12
81801	Schott Solar (State/One-Stop)	Albuquerque, NM	07/13/12	07/12/12
81802	Southeast Poultry, Inc. (State/One-Stop)	Rogers, AR	07/13/12	07/12/12

[FR Doc. 2012–18414 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–80,308; TA–W–80,308A]

Notice of Investigation Regarding Termination of Certification

TA–W–80,308, Roseburg Forest Products, Composite Panel Division, Including On-Site Leased Workers of Robert Half, Orangeburg, SC;
TA–W–80,308A, Roseburg Forest Products, Composite Panel Division, Including On-Site Leased Workers of Robert Half, Russellville, SC.

On its own motion, the Department of Labor (Department) has initiated an investigation regarding the possible termination of certification regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of Roseburg Forest Products, Composite Panel Division, Orangeburg, South Carolina and Russellville, South Carolina (hereafter collectively referred to as the subject firm). The certification was issued on August 12, 2011. The Department's Notice of determination was published in the **Federal Register** on September 2, 2011 (76 FR 54796).

The certification was based on the Department's findings that aggregate industry imports of articles like or directly competitive with softwood and hardwood lumber products produced by the subject firm had contributed importantly to worker separations at the subject firm.

Subsequent to the issuance of the certification, the Department received new information that the aggregate industry imports analyzed by the Department are not specific to the subset of the industry in which the subject firm is situated.

Based on a careful review of new information and previously submitted information, the Department has reason to believe that the total or partial separations at the subject firm are no longer attributable to the conditions specified in Section 222 of the Trade Act of 1974, as amended, and 29 CFR 90(b). Consequently, the Department is conducting an investigation pursuant to 29 CFR 90.17.

Conclusion

After careful review, I conclude that the evidence is of sufficient weight to justify the investigation regarding the termination of certification regarding workers' eligibility to apply for Trade Adjustment Assistance applicable to workers and former workers of Roseburg Forest Products, Composite Panel Division, Orangeburg, South Carolina (TA–W–80,308) and Roseburg Forest Products, Composite Panel Division, Russellville, South Carolina (TA–W–80,308A).

Signed at Washington, DC, this 17th day of July, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18421 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,264]

Phillips-Van Heusen Corporation, IZOD Dress Furnishings Division, New York, NY; Notice of Negative Determination on Reconsideration

On May 21, 2012, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Phillips-Van Heusen Corporation, IZOD Women's Wholesale Division, New York, New York. The Department's Notice of determination was published in the **Federal Register** on April 19, 2012 (77 FR 23511).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The initial Trade Adjustment Assistance (TAA) investigation resulted in a negative determination based on the findings that with respect to Section 222(a)(2)(A)(ii) of the Act, imports of services like or directly competitive with the design, sourcing, and sales services supplied by Phillips-Van Heusen Corporation, IZOD Women's Wholesale Division, New York, New York has not increased.

In the request for reconsideration, the worker on whose behalf the New York State Department of Labor filed the initial TAA petition claimed that the worker group in the original investigation (workers of Phillips-Van Heusen Corporation, IZOD Women's Wholesale Division, New York, New York) was incorrect, that the subject workers are part of the ''Color Department'' of the ''Men's Dress Shirt Division'' at Phillips-Van Heusen Corporation, New York, New York, and that the separated workers were affected by a shift in the supply of color approval services to China.

Information obtained during the reconsideration investigation confirmed that Phillips-Van Heusen Corporation, Izod Dress Furnishings Division, New York, New York is the correct subject of the TAA investigation.

The reconsideration investigation revealed that, with respect to Section 222(a) and Section 222(b) of the Act, Criterion (1) has not been met. The investigation revealed that a significant number or proportion of the workers in Phillips-Van Heusen Corporation, Izod Dress Furnishings Division, New York, New York, have not become totally or partially separated, nor are they threatened to become totally or partially separated.

Significant number or proportion of the workers means at least three workers in a firm (or appropriate subdivision of the firm) with a work force of fewer than fifty workers or, in a firm (or appropriate subdivision of the firm) with a work force of fifty or more workers, at least five percent of the workers or fifty workers (whichever is less). 29 CFR 90.2

Therefore, after careful review of the request for reconsideration, the Department determines that 29 CFR 90.18(c) has not been met.

Conclusion

After careful review, I determine that the requirements of Section 222 of the Act, 19 U.S.C. 2272, have not been met and, therefore, deny the petition for group eligibility of Phillips-Van Heusen Corporation, Izod Dress Furnishings Division, New York, New York, to apply for adjustment assistance, in accordance with Section 223 of the Act, 19 U.S.C. 2273.

Signed in Washington, DC, on this 16th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18417 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,287]

American Woodmark Corporation, Moorefield, WV; Notice of Negative Determination on Reconsideration

On May 21, 2012, the Department of Labor (Department) issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of American Woodmark Corporation, Moorefield, West Virginia (subject firm). The Department's Notice was published in the**Federal Register** on June 6, 2012 (77 FR 33491). The workers are engaged in employment related to the production of kitchen and bath cabinetry products.

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The initial investigation resulted in a negative determination based on the findings that worker separations were not attributable to increased imports of kitchen and bath cabinetry, or articles like or directly competitive, by the subject firm or its declining customers. Further, worker separations were not attributable to a shift of production of kitchen and bath cabinetry, or articles like or directly competitive, to a foreign country, or a foreign acquisition of these products by the workers' firm.

In the request for reconsideration, petitioners alleged that workers at the subject firm were impacted by increased import competition of kitchen and bath cabinetry products or like or directly competitive articles.

During the reconsideration investigation, the Department reviewed and confirmed information collected during the initial investigation and collected additional information from the subject firm.

The reconsideration investigation findings confirmed that the subject firm and its major customers did not import articles like or directly competitive with kitchen and bath cabinetry products in the period under investigation. Additionally, the reconsideration investigation findings confirmed that the subject firm did not shift the production of kitchen and bath cabinetry products, or like or directly competitive articles, to a foreign country or acquire the production of such articles from a foreign country.

After careful review of the request for reconsideration, previously-submitted information, and information obtained during the reconsideration investigation, the Department determines that 29 CFR 90.18(c) has not been met.

Conclusion

After careful review, I determine that the requirements of Section 222 of the Act, 19 U.S.C. 272, have not been met and, therefore, deny the petition for group eligibility of to apply for adjustment assistance, in accordance with Section 223 of the Act, 19 U.S.C. 2273.

Signed in Washington, DC, on this 13th day of July, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18418 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,448]

General Dynamics Itronix Corporation; A Subsidiary of General Dynamics Corporation, Including Remote Workers Reporting to Sunrise, FL; Notice of Revised Determination on Reconsideration

On June 22, 2012, the Department of Labor issued a Notice of Affirmative Determination Regarding Application for Reconsideration applicable to workers and former workers of General Dynamics Itronix Corporation, a subsidiary of General Dynamics Corporation, Sunrise, Florida (subject firm). The workers' firm is engaged in activities related to the supply of program management services for rugged laptop computers and rugged mobile devices. The worker group includes remote workers reporting to Sunrise, Florida.

Based on information provided during the reconsideration investigation, the Department determines that worker separations at the subject firm are related to increased imports of articles which are produced using services supplied by the subject firm.

Section 222(a)(1) has been met because a significant number or proportion of the workers in General Dynamics Itronix Corporation, Sunrise, Florida have become totally or partially separated, or are threatened to become totally or partially separated.

Section 222(a)(2)(A)(i) has been met because the sales and/or production by General Dynamics Itronix Corporation, Sunrise, Florida have decreased absolutely.

Section 222(a)(2)(A)(ii) has been met because company imports of articles like or directly competitive with those which are/were produced by using the services supplied by workers of General Dynamics Itronix Corporation, Sunrise, Florida have increased during the relevant period.

Finally, Section 222(a)(2)(A)(iii) has been met because increased company imports contributed importantly to the worker group separations and sales/production declines at General Dynamics Itronix Corporation, Sunrise, Florida.

Conclusion

After careful review of the additional facts obtained on reconsideration, I determine that workers of General Dynamics Itronix Corporation, a subsidiary of General Dynamics Corporation, including remote workers reporting to, Sunrise, Florida, who are/were engaged in employment related to the supply of program management services for rugged laptop computers and rugged mobile devices, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

All workers of General Dynamics Itronix Corporation, a subsidiary of General Dynamics Corporation, including remote workers reporting to, Sunrise, Florida, who became totally or partially separated from employment on or after March 23, 2011, through two years from the date of certification, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 16th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18420 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,066]

ConocoPhillips Company, Trainer Refinery, Including On-Site Leased Workers From Shrack, Young, and Associates, Inc., and Project Control Associates, Trainer, PA; Notice of Revised Determination on Reconsideration

On April 30, 2012, the Department of Labor issued a Notice of Affirmative Determination Regarding Application for Reconsideration applicable to workers and former workers of ConocoPhillips Company, Trainer Refinery, Trainer, Pennsylvania (subject firm). The subject firm is engaged in activities related to the production of gasoline, distillate, and heavy oil. The subject worker group includes on-site leased workers from Shrack, Young, and Associates, Inc. and Project Control Services.

Based on information obtained during the reconsideration investigation, the Department determines that increased imports of articles like or directly competitive with gasoline, distillate, and heavy oil contributed importantly to workers' separations.

Section 222(a)(1) has been met because a significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated.

Section 222(a)(2)(A)(i) has been met because the sales and/or production of gasoline, distillate, and heavy oil by ConocoPhillips Company, Trainer Refinery, Trainer, Pennsylvania have decreased absolutely.

Section 222(a)(2)(A)(ii) has been met because imports by ConocoPhillips Company of articles like or directly competitive with those produced by ConocoPhillips Company, Trainer Refinery, Trainer, Pennsylvania, have increased during the relevant period.

Finally, Section 222(a)(2)(A)(iii) has been met because the increased imports contributed importantly to the worker group separations and sales/production declines at ConocoPhillips Company, Trainer Refinery, Trainer, Pennsylvania.

Conclusion

After careful review of the additional facts obtained on reconsideration, I determine that workers of ConocoPhillips Company, Trainer Refinery, Trainer, Pennsylvania, who were engaged in employment related to the production of gasoline, distillate, and heavy oil, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

All workers of ConocoPhillips Company, Trainer Refinery, including on-site leased workers from Shrack, Young, and Associates, Inc. and Project Control Services, Trainer, Pennsylvania Pennsylvania, who became totally or partially separated from employment on or after February 13 2010, through two years from the date of this certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 16th day of July 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–18416 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Brookwood-Sago Mine Safety Grants

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Solicitation for Grant Applications (SGA).

Announcement Type: New.
Funding Opportunity Number: SGA 12–3BS.

Catalog of Federal Domestic Assistance (CFDA) Number: 17.603

SUMMARY: The U.S. Department of Labor, Mine Safety and Health Administration (MSHA), is making $1,250,000 available in grant funds for educational and training programs to help identify, avoid, and prevent unsafe working conditions in and around mines. The focus of these grants for the Fiscal Year (FY) 2012 will be on training and training materials for mine emergency preparedness and mine emergency prevention for all underground mines. Applicants for the grants may be States and nonprofit (private or public) entities.

The number of grants awarded will be determined by MSHA's evaluation of grant applications. The amount of each individual grant will be at least $50,000.00. The maximum amount for a 12-month period of performance is $250,000. MSHA may award both annual and renewal (two-year) grants. This notice contains all of the information needed to apply for grant funding, including those eligible grantees awarded a 2011 renewal grant.

DATES: The closing date for applications will be August 31, 2012, (no later than 11:59 p.m. EDST). MSHA will award grants on or before September 30, 2012.

ADDRESSES: Applications for grants submitted under this competition must be submitted electronically using the Government-wide site at *http://www.grants.gov*. If applying online poses a hardship to any applicant, the MSHA Directorate of Educational Policy and Development will provide assistance to help applicants submit online.

FOR FURTHER INFORMATION CONTACT: Any questions regarding this solicitation for grant applications (SGA 12–3BS) should be directed to Robert Glatter at *glatter.robert@dol.gov* or at 202–693–9570 (this is not a toll-free number) or the Grant Officer, Valoree Lilley, at *lilley.valoree@dol.gov* or at 202–693–9831 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: This solicitation provides background information and the requirements for projects funded under the solicitation. This solicitation consists of nine parts:

- Part I provides background information on the Brookwood-Sago grants.
- Part II describes the size and nature of the anticipated awards.
- Part III describes the qualifications of an eligible applicant.
- Part IV provides information on the application and submission process for FY 2012 annual and renewal grants.
- Part V explains the review process and rating criteria that will be used to evaluate the FY 2012 applications.
- Part VI provides information for FY 2011 renewal grantees to apply for FY 2012 funding.
- Part VII provides award administration information.
- Part VIII contains MSHA contact information.
- Part IX addresses Office of Management and Budget information collection requirements.

I. Funding Opportunity Description

A. Overview of the Brookwood-Sago Mine Safety Grant Program

Responding to several coal mine disasters, Congress enacted the Mine Improvement and New Emergency Response Act of 2006 (MINER Act). When Congress passed the MINER Act, it expected that requirements for new and advanced technology, e.g., fire-resistant lifelines and increased breathable air availability in escapeways

would increase safety in mines. The MINER Act also required that every underground coal mine have persons trained in emergency response. Congress emphasized its commitment to training for mine emergencies when it strengthened the requirements for the training of mine rescue teams. Recent events demonstrate that training is the key for proper and safe emergency response and that all miners working underground should be trained in emergency response.

Under Section 14 of the MINER Act, the Secretary of Labor (Secretary) is required to establish a competitive grant program called the ''Brookwood-Sago Mine Safety Grants'' (Brookwood-Sago grants). This program provides funding of education and training programs to better identify, avoid, and prevent unsafe working conditions in and around mines. This program will use grant funds to establish and implement education and training programs or to create training materials and programs. The MINER Act requires the Secretary to give priority to mine safety demonstrations and pilot projects with broad applicability. It also mandates that the Secretary emphasize programs and materials that target miners in smaller mines, including training mine operators and miners on new MSHA standards, high-risk activities, and other identified safety priorities.

B. Grant Structures

MSHA funds the Brookwood-Sago grants annually for 12 months of performance through two types of grants. For the first type, ''annual grants,'' MSHA requires an applicant to compete each year for the available funds. For the second type, ''renewal grants,'' MSHA awards a grant eligible for two separate years of funding with two separate 12-month performance periods.

For renewal grants, the awardees' eligibility for the second year of funding in FY 2013 is contingent on certain conditions being met. MSHA will award funding for the second year of performance based on the following requirements:

1. The first-year grant topics are still a priority with MSHA for training under the Brookwood-Sago grants;

2. Funds are available for the Brookwood-Sago grant program; and

3. The grantee has demonstrated acceptable performance under the first year of the grant.

If MSHA funds the second year of renewal grants, it will advise, in the FY 2013 Brookwood-Sago SGA, those grantees eligible for renewal grants of the documentation necessary to obtain their second year of funding. If a renewal grantee chooses not to pursue the second year of funding, the grantee may still compete for a new Brookwood-Sago grant in FY 2013. MSHA would not penalize an eligible renewal grantee for not applying for its second year of funding under the renewal grant and would permit the grantee to compete for another annual or renewal Brookwood-Sago grant.

C. Educational and Training Program Priorities

MSHA priorities for the FY 2012 funding of the annual Brookwood-Sago grants will focus on training or training materials for mine emergency preparedness and mine emergency prevention for all underground mines. MSHA expects Brookwood-Sago annual grantees to develop training materials or to develop and provide mine safety training or educational programs, recruit mine operators and miners for the training, and conduct and evaluate the training.

For the renewal grants, MSHA's priorities will focus on training for mine emergency preparedness and mine emergency prevention for all underground mines. Except for creating very innovative educational material or equipment, MSHA expects that renewal grants will focus primarily on training mine operators and miners. A renewal grant may include a request for creating educational materials or equipment, but the purpose of these grants is to provide training for as many mine operators and miners as possible. MSHA also expects grantees with renewal grants to recruit mine operators and miners for the training, conduct training, and evaluate the grant program on mine emergency preparedness or mine emergency prevention.

For both annual and renewal grant programs, grantees are also expected to conduct follow-up evaluations with the people who received training in their programs to measure how the training promotes the Secretary's goal of ensuring a safe and healthy workplace. The evaluation will focus on determining how effective their training was in either reducing hazards, improving skills for the selected training topics, or in improving the conditions in mines. Grantees must also cooperate fully with MSHA evaluators of their programs.

II. Award Information

A. Award Amount for FY 2012

MSHA is providing $1,250,000 to award new FY 2012 annual and renewal grants and to fund the second year of eligible FY 2011 renewal grants. The number of grants awarded will be determined by MSHA's evaluation of grant applications. The amount of each individual grant will be no less than $50,000.00 for a 12-month performance period; and the maximum award for a 12-month performance period is $250,000. Applicants requesting less than $50,000 or more than $250,000 for a 12-month performance period will not be considered for funding.

B. Extension of Period of Performance

For annual awards, MSHA may approve a request for a one time no-cost extension to grantees for an additional period of up to 12 months from the expiration date of the annual award based on the success of the project and other relevant factors. See 29 CFR 95.25(e)(2). At the end of the second year of funding for a renewal grant, MSHA may approve a request for a no-cost extension for an additional period of performance of up to 12 months based on the success of the project and other relevant factors.

III. Eligibility Information

A. Eligible Applicants

Applicants for the grants may be States and nonprofit (private or public) entities. Eligible entities may apply for funding independently or in partnership with other eligible organizations. For partnerships, a lead organization must be identified.

Applicants other than States and State-supported or local government-supported institutions of higher education will be required to submit evidence of nonprofit status, preferably from the Internal Revenue Service (IRS). A nonprofit entity as described in 26 U.S.C. 501(c)(4), which engages in lobbying activities, is not eligible for a grant award. See 2 U.S.C. 1611.

B. Cost-Sharing or Matching

Cost-sharing or matching of funds is not required for eligibility.

C. Other Eligibility Requirements

1. Dun and Bradstreet Number (DUNS)

Under 2 CFR 25.200, every applicant for a Federal funding opportunity is required to include a DUNS number with its application. The DUNS number is a nine-digit identification number that uniquely identifies business entities. An applicant's DUNS number is to be entered into Block 8 of Standard Form (SF) 424. There is no charge for obtaining a DUNS number. To obtain a DUNS number, call 1–866–705–5711 or access the following Web site: *http://*

fedgov.dnb.com/webform/displayHomePage.do.

After receiving a DUNS number, all grant applicants must also register as a vendor with the Central Contractor Registration (CCR) through the Web site at *http://www.ccr.gov.* 2 CFR 25.200. Grant applicants must create a user account and then complete and submit the online registration. Once you have submitted the registration, it will take three to five business days to process. The applicant will receive an email notice that the registration is active.

2. Legal Rules Pertaining to Inherently Religious Activities by Organizations That Receive Federal Financial Assistance

The Government generally is prohibited from providing direct Federal financial assistance for inherently religious activities. See 29 CFR Part 2, Subpart D. Grants under this solicitation may not be used for religious instruction, worship, prayer, proselytizing, or other inherently religious activities. Neutral, non-religious criteria that neither favor nor disfavor religion will be employed in the selection of grant recipients and must be employed by grantees in the selection of contractors and subcontractors.

3. Non-Compliant Applications

Applications for new FY 2012 annual and renewal grants that are lacking any of the required elements or do not follow the format prescribed in IV.B will not be reviewed.

4. Late Applications

Applications received after the deadline will not be reviewed unless it is determined to be in the best interest of the Government.

IV. Application and Submission Information for New FY 2012 Annual and Renewal Grants

A. Application Forms

This announcement includes all information and links needed to apply for this funding opportunity. (The information regarding the second-year funding of the FY 2011 renewal grants is located in Part VI.) The full application is available through the Grants.gov Web site *http://www.grants.gov/* under ''Apply for Grants''. The Catalog of Federal Domestic Assistance (CFDA) number needed to locate the appropriate application for this opportunity is 17.603. If an applicant has problems downloading the application package from Grants.gov, contact Grants.gov Contact Center at 1–800–518–4726 or by email at *support@grants.gov.*

The full application package is also available on-line at *www.msha.gov:* Select ''Education & Training,'' click on ''Courses,'' select ''Brookwood-Sago Mine Safety Grants,'' then select ''SGA 12–3BS.'' This Web site also includes all forms and all regulations that are referenced in this SGA. Applicants, however, must apply for this funding opportunity through the Grants.gov Web site.

B. Content and Form of the FY 2012 Application

Each grant application must address mine emergency preparedness or mine emergency prevention for underground mines. The applicant must identify that an application is for an annual or a renewal grant. Applicants must submit a separate application for each topic and each type of grant. The application must consist of three separate and distinct sections. The three required sections are:

- Section 1—Project Forms and Financial Plan (No page limit).
- Section 2—Executive Summary (Not to exceed two pages).
- Section 3—Technical Proposal (Not to exceed 12 pages). Illustrative material can be submitted as an attachment.

The following are mandatory requirements for each section.

1. Project Forms and Financial Plan

This section contains the forms and budget section of the application. The Project Financial Plan will not count against the application page limits. A person with authority to bind the applicant must sign the grant application and forms. Applications submitted electronically through Grants.gov do not need to be signed manually; electronic signatures will be accepted.

(a) Completed SF–424, ''Application for Federal Assistance.'' This form is part of the application package on Grants.gov and is also available at *www.msha.gov.* The SF–424 must identify the applicant clearly and be signed by an individual with authority to enter into a grant agreement. Upon confirmation of an award, the individual signing the SF–424 on behalf of the applicant shall be considered the representative of the applicant.

(b) Completed SF–424A, ''Budget Information for Non-Construction Programs.'' The project budget should demonstrate clearly that the total amount and distribution of funds is sufficient to cover the cost of all major project activities identified by the applicant in its proposal, and must comply with the Federal cost principles and the administrative requirements set forth in this SGA. (Copies of all regulations that are referenced in this SGA are available on-line at *http://www.msha.gov.* Select ''Education & Training,'' click on ''Courses,'' then select ''Brookwood-Sago Mine Safety Grants.'')

For renewal grant applications, applicants must include all the renewal grants information on the SF–424 forms. For example, if the applicant is applying for a renewal grant, the total amount of the grant might be $100,000, and each year's funding could be $50,000. When filling out the SF–424 Application for Federal Assistance form, the proposed project start date in Item No. 17 for renewal grants is 9/30/2012, and the end date is 9/29/2014. The estimated funding in Item No. 18 would be $100,000. On the SF–424A Budget Information for Non-Construction Programs, the applicant would list a total of $50,000 for the first-year funding and $50,000 for the second-year funding.

(c) Budget Narrative. The applicant must provide a concise narrative explaining the request for funds. The budget narrative should separately attribute the Federal funds to each of the activities specified in the technical proposal and it should discuss precisely how any administrative costs support the project goals. Administrative costs may not exceed 15% of the total grant budget. Indirect cost charges must be supported with a copy of an approved Indirect Cost Rate Agreement.

If applicable, the applicant must provide a statement about its program income.

The amount of Federal funding requested for the entire period of performance must be shown on the SF–424 and SF–424A forms.

(d) Completed SF–424B, ''Assurances for Non-Construction Programs.'' Each applicant for these grants must certify compliance with a list of assurances. This form is part of the application package on *http://www.Grants.gov* and also is available at *http://www.msha.gov.*

(e) Supplemental Certification Regarding Lobbying Activities Form. If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the making of a grant or cooperative agreement, the applicant shall complete and submit SF–LLL, ''Disclosure Form to Report Lobbying,'' in accordance with

its instructions. This form is part of the application package on *http://www.Grants.gov* and is also available at *http://www.msha.gov.* Select ''Education & Training,'' click on ''Courses,'' then select ''Brookwood-Sago Mine Safety Grants.''

(f) Non-profit status. Applicants must provide evidence of non-profit status, preferably from the IRS, if applicable.

(g) Accounting System Certification. An organization that receives less than $1 million annually in Federal grants must attach a certification stating that the organization (directly or through a designated qualified entity) has a functioning accounting system that meets the criteria below. The certification should attest that the organization's accounting system provides for the following:

(1) Accurate, current and complete disclosure of the financial results of each Federally sponsored project.

(2) Records that identify adequately the source and application of funds for Federally sponsored activities.

(3) Effective control over and accountability for all funds, property, and other assets.

(4) Comparison of outlays with budget amounts.

(5) Written procedures to minimize the time elapsing between transfers of funds.

(6) Written procedures for determining the reasonableness, allocability, and allowability of cost.

(7) Accounting records, including cost accounting records that are supported by source documentation.

(h) Attachments. The application may include attachments such as resumes of key personnel or position descriptions, exhibits, information on prior government grants, and signed letters of commitment to the project.

2. Executive Summary

The executive summary is a short one-to-two page abstract that succinctly summarizes the proposed project. MSHA will publish, as submitted, all grantees' executive summaries on the DOL Web site. The executive summary must include the following information:

(a) Applicant. Provide the organization's full legal name and address.

(b) Funding requested. List how much Federal funding is being requested. If requesting a renewal grant, include the total for the two years of funding and list each year's requested funding levels.

(c) Grant Topic. List the grant topic and the location and number of mine operators and miners that the organization has selected to train or describe the training materials or equipment to be created with these funds.

(d) Program Structure. Identify the type of grant: An annual or a renewal grant.

(e) Summary of the Proposed Project. Write a brief summary of the proposed project. This summary must identify the key points of the proposal, including an introduction describing the project activities and the expected results. If requesting a renewal grant, also provide a summary of the key points of the second-year's activities and expected outcomes.

3. Technical Proposal

The technical proposal must demonstrate the applicant's capabilities to plan and implement a project or create educational materials or equipment to meet the objectives of this solicitation. MSHA's focus for these grants is on training mine operators and miners and developing training materials for mine emergency preparedness or mine emergency prevention for underground mines. MSHA has two program goals, described below, that will be considered indicators of the success of the program as a whole. The following table explains the types of data grantees must provide and their relationship with the Agency's program goals and performance measures for the Brookwood-Sago grants.

MSHA's program goals	MSHA's performance measures	DATA grantee provides each reporting period
1. Agency creates more effective training to ensure workplaces are safe.	Increase overall number of trainers trained.	Number of training events. Number of trainers trained.
	Increase the number of mine operators and miners trained.	Number of mine operators and miners trained. Number of course days of training provided to industry.
	Provide quality training with clearly stated goals and objectives for improving safety.	Pre- and post-assessment results of trainees. Course evaluations of trainer and training materials. A description of the extent to which others replicate (i.e., adopt or adapt) or institutionalize and continue the training or educational programs after grant funding ends.
2. Agency creates training materials to provide more effective training to ensure workplaces are safe.	Increase number of quality educational materials developed.	Pre- and post-assessment results of the training materials.
	Provide quality training materials with clearly stated goals and objectives for improving safety.	Evaluation of training materials to include the target audience, statement of goals and objectives, learning level, instructions for using, additional material requirements, secondary purposes, adult learning principles and usability in the mine training environment.
	Develop training materials that are reproducible or adaptable.	A description of the extent to which others will replicate (i.e., adopt or adapt) the funded training materials.

The technical proposal narrative is not to exceed 12 single-sided, double-spaced pages, using 12-point font, and must contain the following sections: Program Design, Overall Qualifications of the Applicant, and Output and Evaluation. Any pages over the 12-page limit will not be reviewed. Attachments to the technical proposal are not counted toward the 12-page limit. Major sections and sub-sections of the proposal should be divided and clearly identified. And as required in Section VII subpart I ''Transparency,'' a grantee's final technical proposal will be posted as is on MSHA's Web site unless MSHA receives a version redacting any proprietary, confidential business, or personally identifiable information by October 19, 2012.

MSHA will review and rate the technical proposal in accordance with the selection criteria specified in Part V.

(a) Program Design

(1) Statement of Problem/Need for Funds. Applicants must identify a clear and specific need for proposed activities. They must identify whether they are providing a training program or creating training materials or both. They also must identify whether their application is for an annual or a renewal Brookwood-Sago grant. Applicants also must identify the number of individuals expected to benefit from their training and education program; this should

include identifying the type of underground mines, the geographic locations, and the number of mine operators and miners. Applicants must also identify other Federal funds they receive for similar activities.

(2) Quality of the Project Design. MSHA requires that each applicant include a 12-month workplan that correlates with the grant project period that will begin September 30, 2012, and end September 29, 2013. Renewal grant applicants must also include a second 12-month workplan covering the period from September 30, 2013, and ending September 29, 2014. An outline of specific items required in the workplan follows.

(i) Plan Overview. Describe the plan for grant activities and the anticipated results. The plan should describe such things as the development of training materials, the training content, recruiting of trainees, where or how training will take place, and the anticipated benefits to mine operators and miners receiving the training.

(ii) Activities. Break the plan down into activities or tasks. For each activity, explain what will be done, who will do it, when it will be done, and the anticipated results of the activity. For training, discuss the subjects to be taught, the length of the training sessions, type of training (e.g., Mine Emergency Response Development exercise), and training locations (e.g., classroom, worksites). Describe how the applicant will recruit mine operators and miners for the training. (**Note:** Any commercially developed training materials the applicant proposes to use in its training must undergo an MSHA review before being used.)

(iii) Quarterly Projections. For training and other quantifiable activities, estimate the quantities involved using the table located in Part IV.B.3 for data required to meet the grant goals. For example, estimate how many classes will be conducted and how many mine operators and miners will be trained each quarter of the grant (grant quarters match calendar quarters, i.e., January to March, April to June; but the first quarter is the date of award to December 31, 2012). Also, provide the training number totals for the full year. Quarterly projections are used to measure the actual performance against the plan. Applicants planning to conduct a train-the-trainer program should estimate the number of individuals to be trained during the grant period by those who received the train-the-trainer training. These second-tier training numbers should be included only if the organization is planning to follow up with the trainers to obtain this data during the grant period.

(iv) Materials. Describe each educational material, including any piece of equipment (e.g., mine simulator) to be produced under the grant. Provide a timetable for developing and producing the material. The timetable must include provisions for an MSHA review of draft and camera-ready products or evaluation of equipment. MSHA must review and approve training materials or equipment for technical accuracy and suitability of content before use in the grant program. Whether or not an applicant's project is to develop training materials only, the applicant should provide an overall plan that includes time for MSHA to review any materials produced.

(b) Qualifications of the Applicant

(1) Applicant's Background. Describe the applicant, including its mission, and a description of its membership, if any. Provide an organizational chart (the chart may be included as a separate page which will not count toward the page limit). Identify the following:

(i) Project Director. The project director is the person who will be responsible for the day-to-day operation and administration of the program. Provide the name, title, street address and mailing address (if it is different from the organization's street address), telephone and fax numbers, and email address of the project director.

(ii) Certifying Representative. The certifying representative is the official in the organization who is authorized to enter into grant agreements. Provide the name, title, street address and mailing address (if it is different from the organization's street address), telephone and fax numbers, and email address of the certifying representative.

(2) Administrative and Program Capability. Briefly describe the organization's functions and activities, i.e., the applicant's management and internal controls. Relate this description of functions to the organizational chart. If the applicant has received any other government (Federal, State or local) grant funding, the application must have, as an attachment (which will not count towards the page limit), information regarding these previous grants. This information must include each organization for which the work was done and the dollar value of each grant. If the applicant does not have previous grant experience, it may partner with an organization that has grant experience to manage the grant. If the organization uses this approach, the management organization must be identified and its grant program experience discussed. Lack of past experience with Federal grants is not a determining factor, but an applicant should show a successful experience relevant to the opportunity offered in the application. Such experience could include staff members' experiences with other organizations.

(3) Program Experience. Describe the organization's experience conducting the proposed mine training program or other relevant experience. Include program specifics such as program title, numbers trained, and duration of training. If creating training materials, include the title of other materials developed. Nonprofit organizations, including community-based and faith-based organizations that do not have prior experience in mine safety may partner with an established mine safety organization to acquire safety expertise.

(4) Staff Experience. Describe the qualifications of the professional staff you will assign to the program. Attach resumes of staff already employed (resumes will not count towards the page limit). If some positions are vacant, include position descriptions and minimum hiring qualifications instead of resumes. Staff should have, at a minimum, mine safety experience, training experience, or experience working with the mining community.

(c) Outputs and Evaluations. There are two types of evaluations that must be conducted. First, describe the methods, approaches, or plans to evaluate the training sessions and/or training materials to meet the data requirements listed in the table above. Second, describe plans to assess the long-term effectiveness of the training materials and/or training conducted. The type of training given will determine whether the evaluation should include a process-related outcome or a result-related outcome or both. This will involve following up with an evaluation, or on-site review, if feasible, of miners trained. The evaluation should focus on what changes the trained miners made to abate hazards and improve workplace conditions, or to incorporate the training in the workplace, or both.

For training materials, include an evaluation from individuals trained on the clarity of the presentation, organization, and the quality of the information provided on the subject matter and whether they would continue to use the training materials. Include timetables for follow-up and for submitting a summary of the assessment results to MSHA.

For renewal grants, applicants must describe how the program will address the feedback from its or MSHA's

evaluations to improve its training program, materials (including equipment), or both during the second year.

C. Submission Date, Times, and Addresses

The closing date for receipt of applications under this announcement is August 31, 2012 (no later than 11:59 p.m. EDST). Grant applications must be submitted electronically through the Grants.gov Web site. The Grants.gov site provides all the information about submitting an application electronically through the site as well as the hours of operation. Interested parties can locate the downloadable application package by the CFDA number 17.603.

Applications received by Grants.gov are electronically date and time stamped. An application must be fully uploaded and submitted (and must be date and time stamped by the Grants.gov system) before the application deadline date. Once an interested party has submitted an application, Grants.gov will notify the interested party with an automatic notification of receipt that contains a Grants.gov tracking number. MSHA then will retrieve the application from Grants.gov and send a second notification to the interested party by email.

D. Intergovernmental Review

The Brookwood-Sago grants are not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' MSHA, however, reminds applicants that if they are not operating MSHA-approved State training grants, they should contact the State grantees and coordinate any training or educational program. Information about each state grant and the entity operating the state grant is provided online at: *http://www.msha.gov/TRAINING/STATES/STATES.asp.*

E. Funding Restrictions

MSHA will determine whether costs are allowable under the applicable Federal cost principles and other conditions contained in the grant award.

1. Allowable Costs

Grant funds may be spent on conducting training, conducting outreach and recruiting activities to increase the number of mine operators and miners participating in the program, developing educational materials, and on necessary expenses to support these activities. Allowable costs are determined by the applicable Federal cost principles identified in Part VII.B.

Program income earned during the award period shall be retained by the recipient, added to funds committed to the award, and used for the purposes and under the conditions applicable to the use of the grant funds.

2. Unallowable Costs

Grant funds may not be used for the following activities under this grant program:

(a) Any activity inconsistent with the goals and objectives of this SGA;

(b) Training on topics that are not targeted under this SGA;

(c) Purchasing any equipment unless pre-approved and in writing bythe MSHA grant officer;

(d) Administrative costs that exceed 15% of the total grant budget; and

(e) Any pre-award costs.

Unallowable costs also include any cost determined by MSHA as not allowed according to the applicable cost principles or other conditions in the grant.

V. Application Review Information for New FY 2012 Grants

A. Evaluation Criteria

MSHA will screen all applications to determine whether all required proposal elements are present and clearly identifiable. Those that do not comply with mandatory requirements will not be evaluated. The technical panels will review grant applications against the criteria listed below on the basis of 100 maximum points for annual grants and the annual portion of the renewal grants and 20 maximum points for the renewal portion of the grant applications.

MSHA will evaluate the applications for annual grants and the annual portion of the two-year applications using the first four categories below. From this group, MSHA will select applicants to receive one-year funding. From these selectees, MSHA will review those that applied for option year (renewal) grants against the criteria listed in category 5 on the basis of 20 maximum points. Please note that MSHA may offer an annual grant to applicants that may not be selected for renewal grants.

1. Program Design—40 Points Total

(a) Statement of Problem/Need for Funds (3 Points)

The proposed training and education program or training materials must address either mine emergency preparedness or mine emergency prevention.

(b) Quality of the Project Design (25 Points)

(1) The proposal to train mine operators and miners clearly estimates the number to be trained and clearly identifies the types of mine operators and miners to be trained.

(2) If the proposal contains a train-the-trainer program, the following information must be provided:

- What ongoing support the grantee will provide to new trainers;
- The number of individuals to be trained as trainers;
- The estimated number of courses to be conducted by the new trainers;
- The estimated number of students to be trained by these new trainers and a description of how the grantee will obtain data from the new trainers documenting their classes and student numbers if conducted during the grant period.

(3) The work plan activities and training are described.

- The planned activities and training are tailored to the needs and levels of the mine operators and miners to be trained. Any special constituency to be served through the grant program is described, e.g., smaller mines, limited English proficiency miners, etc. Organizations proposing to develop materials in languages other than English also will be required to provide an English version of the materials.
- If the proposal includes developing training materials, the work plan must include time during development for MSHA to review the educational materials for technical accuracy and suitability of content. If commercially developed training products will be used for a training program, applicants should also plan for MSHA to review the materials before using the products in their grant programs.
- The utility of the educational materials is described.
- The outreach or process to find mine operators, miners or trainees to receive the training is described.

(c) Replication (4 Points)

The potential for a project to serve a variety of mine operators, miners, or mine sites and/or the extent others may replicate the project.

(d) Innovativeness (3 Points)

The originality and uniqueness of the approach used.

(e) MSHA's Performance Goals (5 Points)

The extent the proposed project will contribute to MSHA's performance goals.

2. Budget—20 Points Total

(a) The Budget Presentation Is Clear and Detailed (15 Points)

- The budgeted costs are reasonable.

• No more than 15% of the total budget is for administrative costs.

• The budget complies with Federal cost principles (which can be found in the applicable Office of Management and Budget (OMB) Circulars and with MSHA budget requirements contained in the grant application instructions).

(b) The Application Demonstrates That the Applicant Has Strong Financial Management and Internal Control Systems (5 Points)

3. Overall Qualifications of the Applicant—25 Points Total

(a) Grant Experience (6 Points)

The applicant has administered, or will work with an organization that has administered, a number of different Federal or State grants. The applicant may demonstrate this experience by having project staff that has experience administering Federal or State grants.

(b) Mine Safety Training Experience (13 Points)

The applicant applying for the grant demonstrates experience with mine safety teaching or providing mine safety educational programs. Applicants that do not have prior experience in providing mine safety training to mine operators or miners may partner with an established mine safety organization to acquire mine safety expertise.

• Project staff has experience in mine safety, the specific topic chosen, or in training mine operators and miners.

• Project staff has experience in recruiting, training, and working with the population the organization proposes to serve.

• Applicant has experience in designing and developing mine safety training materials for a mining program.

• Applicant has experience in managing educational programs.

(c) Management (6 Points)

Applicant demonstrates internal control and management oversight of the project.

4. Outputs and Evaluations—15 Points Total

The proposal should include provisions for evaluating the organization's progress in accomplishing the grant work activities and accomplishments, evaluating training sessions, and evaluating the program's effectiveness and impact to determine if the safety training and services provided resulted in workplace change or improved workplace conditions. The proposal should include a plan to follow up with trainees to determine the impact the program has had in abating hazards and reducing miner injuries and illnesses.

5. Renewal Grants: Second-Year Request—20 Points Total

A renewal proposal must include a description of the project design and budget for the second-year funding. The applicant must also describe how it will obtain input and feedback from first-year training recipients and how it will improve its program based on its or MSHA evaluations.

B. Review and Selection Process for New FY 2012 Grants

A technical panel will rate each complete application against the criteria described in this SGA. One or more applicants may be selected as grantees on the basis of the initial application submission or a minimally acceptable number of points may be established. MSHA may request final revisions to the applications, and then evaluate the revised applications. MSHA may consider any information that comes to its attention in evaluating the applications.

The panel recommendations are advisory in nature. The Deputy Assistant Secretary of Labor for Mine Safety and Health will make a final selection determination based on what is most advantageous to the government, considering factors such as panel findings, geographic presence of the applicants or the areas to be served, Agency priorities, and the best value to the government, cost, and other factors. The Deputy Assistant Secretary's determination for award under this SGA is final.

C. Anticipated Announcement and Award Dates

Announcement of these awards is expected to occur by September 29, 2012. The grant agreement will be signed no later than September 30, 2012.

VI. FY 2011 Renewal Grantees' Process for FY 2012 Funding

A. General

In this section, MSHA is providing the eligible FY 2011 renewal grantees the procedures and required documentation that they must submit to receive their FY 2012 funding. MSHA will notify all renewal grantees of their eligibility. The grantees are reminded that they are not required to apply for the second year of funding. If they do not wish to apply for the second-year funding, the grantees may apply for a new grant under the FY 2012 annual and/or renewal grant program instead.

B. The Process and Required Documentation

1. Documentation

Using its current grant number, each grantee must provide:

(a) A revised SF–424 and SF–424A forms; and

(b) If necessary, a revised workplan.

2. Submission Date, Times, and Addresses

The closing date for receipt of applications under this announcement is August 31, 2012 (no later than 11:59 p.m. EDST). The renewal grantee must submit its application for FY 2012 funding electronically through the Grants.gov Web site.

C. Award Information

Announcement of these awards is expected to occur by

September 29, 2012. The amendment to the FY 2011 grant agreement will be signed no later than September 30, 2012.

VII. Award Administration Information

A. Award Process

Organizations selected as potential grant recipients will be notified by a representative of the Deputy Assistant Secretary, usually the Grant Officer or her staff. An applicant whose proposal is not selected will be notified in writing. The fact that an organization has been selected as a potential grant recipient does not necessarily constitute approval of the grant application as submitted (revisions may be required).

Before the actual grant award, MSHA may enter into negotiations with the potential grant recipient concerning such matters as program components (including the type of grant), staffing and funding levels, and administrative systems. If the negotiations do not result in an acceptable submittal, the Deputy Assistant Secretary reserves the right to terminate the negotiations and decline to fund the proposal.

B. Administrative and National Policy Requirements

All grantees will be subject to applicable Federal laws and regulations (including provisions of appropriations law) and applicable OMB Circulars. The grants awarded under this competitive grant program will be subject to the following administrative standards and provisions, if applicable:

• 29 CFR Part 2, subpart D, Equal Treatment for Religious Organizations.

• 29 CFR Parts 31, 32, 35 and 36, Nondiscrimination.

• 29 CFR Part 93, Restrictions on Lobbying.

- 29 CFR Part 94, Drug-free Workplace.
- 29 CFR Part 95, Uniform Grant Requirements for Nonprofit Organizations.
- 29 CFR Parts 96 and 99, Audits.
- 29 CFR Part 97, Uniform Grant Requirements for States.
- 29 CFR Part 98, Debarment and Suspension.
- 2 CFR Part 25, Universal Identifier and Central Contractor Registration.
- 2 CFR Part 170, Reporting Subawards.
- 2 CFR Part 175, Award Term for Trafficking in Persons.
- 2 CFR Part 220, Cost Principles for Educational Institutions.
- 2 CFR Part 225, Cost Principles for State and Local Governments.
- 2 CFR Part 230, Cost Principles for Other Nonprofit Organizations.
- Federal Acquisition Regulation (FAR) Subpart 31.2, Cost Principles for Commercial Organizations (codified at 48 CFR Subpart 31.2).

Administrative costs for these grants may not exceed 15%. Unless specifically approved, MSHA's acceptance of a proposal or MSHA's award of Federal funds to sponsor any program does not constitute a waiver of any grant requirement or procedure. For example, if an application identifies a specific sub-contractor to provide certain services, the MSHA award does not provide a basis to sole-source the procurement (to avoid competition).

C. Special Program Requirements

1. MSHA Review of Educational Materials

MSHA will review all grantee-produced educational and training materials for technical accuracy and suitability of content during development and before final publication. MSHA also will review training curricula and purchased training materials for technical accuracy and suitability of content before the materials are used. Grantees developing training materials must follow all copyright laws and provide written certification that their materials are free from copyright infringement.

When grantees produce training materials, they must provide copies of completed materials to MSHA before the end of the grant period. Completed materials should be submitted to MSHA in hard copy and in digital format (CD–ROM/DVD) for publication on the MSHA Web site. Two copies of the materials must be provided to MSHA. Acceptable formats for training materials include Microsoft XP Word, PDF, PowerPoint, and any other format agreed upon by MSHA.

2. License

As listed in 29 CFR 95.36, the Department of Labor reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for Federal purposes any work produced under a grant, and to authorize others to do so. Grantees must agree to provide the Department of Labor a paid-up, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use for Federal purposes all products developed, or for which ownership was purchased, under an award. Such products include, but are not limited to, curricula, training models, technical assistance products, and any related materials. Such uses include, but are not limited to, the right to modify and distribute such products worldwide by any means, electronic, or otherwise.

3. Acknowledgement on Printed Materials

All approved grant-funded materials developed by a grantee shall contain the following disclaimer: ''This material was produced under grant number XXXXX from the Mine Safety and Health Administration, U.S. Department of Labor. It does not necessarily reflect the views or policies of the U.S. Department of Labor, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.''

When issuing statements, press releases, request for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds must clearly state:

(a) The percentage of the total costs of the program or project that will be financed with Federal money;

(b) The dollar amount of Federal financial assistance for the project or program; and

(c) The percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

4. Use of U.S. Department of Labor (USDOL) and MSHA Logos

MSHA may allow the USDOL or the MSHA logo to be applied to the grant-funded material including posters, videos, pamphlets, research documents, national survey results, impact evaluations, best practice reports, and other publications. Before the DOL or MSHA logos are used on grant-funded materials, the grantees must consult with MSHA. In no event shall the USDOL or the MSHA logo be placed on any item until MSHA has given the grantee written permission to use either logo on the item.

5. Reporting

Grantees are required by Departmental regulations to submit financial and project reports, as described below, each quarter (grant quarters match calendar quarters, i.e., January to March, April to June).

(a) Financial Reports

All financial reports are due no later than 30 days after the end of the quarter and shall be submitted to MSHA electronically. Grantees will be contacted with instructions on how to submit reports.

(b) Technical Project Reports

After signing the agreement, the grantee shall submit technical project reports to MSHA no later than 30 days after the end of each quarter. Technical project reports provide both quantitative and qualitative information and a narrative assessment of performance for the preceding three-month period. See 29 CFR 95.51 and 29 CFR 97.40. This should include the current grant progress against the overall grant goals as provided in Part IV.B.3.

Between reporting dates, the grantee shall immediately inform MSHA of significant developments or problems affecting the organization's ability to accomplish the work. See 29 CFR 95.51(f) and 29 CFR 97.40(d).

(c) Final Reports

At the end of each 12-month performance period, each grantee must provide a final financial report, a summary of its technical project reports, and an evaluation report. These final reports are due no later than 90 days after the end of the 12-month performance period.

In addition to these requirements, in its second-year final technical report, renewal grantees must provide the total outputs for the two years, a list of best practices used, and any changes made as a result of evaluation feedback.

H. Freedom of Information

Any information submitted in response to this SGA will be subject to the provisions of the Freedom of Information Act, as appropriate.

I. Transparency in the Grant Process

DOL is committed to conducting a transparent grant award process and publicizing information about program outcomes. Posting awardees' grant applications on public Web sites is a means of promoting and sharing innovative ideas. Under this SGA, DOL

will publish the awardees' Executive Summaries, selected information from their SF–424s, and a version of awardees' Technical Proposals on the Department's Web site or similar location. None of the Attachments to the Technical Proposal provided with the applications will be published. The Technical Proposals and Executive Summaries will not be published until after the grants are awarded. In addition, information about grant progress and results may also be made publicly available.

DOL recognizes that grant applications sometimes contain information that an applicant may consider proprietary or business confidential information, or may contain personally identifiable information. Proprietary or business confidential information is information that is not usually disclosed outside your organization and disclosing this information is likely to cause you substantial competitive harm.

Personally identifiable information is any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.[1]

Executive Summaries will be published in the form originally submitted, without any redactions. Applicants should not include any proprietary or confidential business information or personally identifiable information in this summary. In the event that an applicant submits proprietary or confidential business information or personally identifiable information, DOL is not liable for the posting of this information contained in the Executive Summary. The submission of the grant application constitutes a waiver of the applicant's objection to the posting of any proprietary or confidential business information contained in the Executive Summary. Additionally, the applicant is responsible for obtaining all authorizations from relevant parties for publishing all personally identifiable information contained within the Executive Summary. In the event the Executive Summary contains proprietary or confidential business or personally identifiable information, the applicant is presumed to have obtained all necessary authorizations to provide this information and may be liable for any improper release of this information.

By submission of this grant application, the applicant agrees to indemnify and hold harmless the United States, the U.S. Department of Labor, its officers, employees, and agents against any liability or for any loss or damages arising from this application. By such submission of this grant application, the applicant further acknowledges having the authority to execute this release of liability.

In order to ensure that proprietary or confidential business information or personally identifiable information is properly protected from disclosure when DOL posts the winning Technical Proposals, applicants whose Technical Proposals will be posted will be asked to submit a second redacted version of their Technical Proposal, with any proprietary or confidential business information and personally identifiable information redacted. All non-public information about the applicant's staff or other individuals should be removed as well.

The Department will contact the applicants whose Technical Proposals will be published by letter or email, and provide further directions about how and when to submit the redacted version of the Technical Proposal.

Submission of a redacted version of the Technical Proposal will constitute permission by the applicant for DOL to make the redacted version publicly available. We will also assume that the applicant has obtained the agreement to the redacted version of the applicant's Technical Proposal. If an applicant fails to provide a redacted version of the Technical Proposal by October 19, 2012, DOL will publish the original Technical Proposal in full, after redacting only personally identifiable information. (Note that the original, unredacted version of the Technical Proposal will remain part of the complete application package, including an applicant's proprietary and confidential business information and any personally identifiable information.)

Applicants are encouraged to disclose as much of the grant application information as possible, and to redact only information that clearly is proprietary, confidential commercial/business information, or capable of identifying a person. The redaction of entire pages or sections of the Technical Proposal is not appropriate, and will not be allowed, unless the entire portion merits such protection. Should a dispute arise about whether redactions are appropriate, DOL will follow the procedures outlined in the Department's Freedom of Information Act (FOIA) regulations (29 CFR Part 70).

Redacted information in grant applications will be protected by DOL from public disclosure in accordance with federal law, including the Trade Secrets Act (18 U.S.C. 1905), FOIA, and the Privacy Act (5 U.S.C. 552a). If DOL receives a FOIA request for your application, the procedures in DOL's FOIA regulations for responding to requests for commercial/business information submitted to the government will be followed, as well as all FOIA exemptions and procedures. 29 CFR 70.26. Consequently, it is possible that application of FOIA rules may result in release of information in response to a FOIA request that an applicant redacted in its ''redacted copy.''

VIII. Agency Contacts

Any questions regarding this solicitation for grant applications (SGA 12–3BS) should be directed to Robert Glatter at *glatter.robert@dol.gov* or at 202–693–9570 (this is not a toll-free number) or the Grant Officer, Valoree Lilley at *lilley.valoree @dol.gov* or at 202–693–9831 (this is not a toll-free number). MSHA's Web page at *www.msha.gov* is a valuable source of background for this initiative.

IX. Office of Management and Budget Information Collection Requirements

This SGA requests information from applicants. This collection of information is approved under OMB Control No. 1225–0086 (expires November 30, 2012).

In accordance with the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. Public reporting burden for the grant application is estimated to average 20 hours per response, for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Each recipient who receives a grant award notice will be required to submit nine progress reports to MSHA. MSHA estimates that each report will take approximately two and half hours to prepare.

Send comments regarding the burden estimated or any other aspect of this collection of information, including suggestions for reducing this burden, to the OMB Desk Officer for MSHA, Office of Management and Budget, Room 10235, Washington, DC 20503 and MSHA, electronically to Robert Glatter

[1] OMB Memorandum 07–16 and 06–19. GAO Report 08–536, *Privacy: Alternatives Exist for Enhancing Protection of Personally Identifiable Information,* May 2008, *http://www.gao.gov/assets/280/275558.pdf.*

at *glatter.robert@dol.gov* or the Grant Officer, Valoree Lilley at *lilley.valoree @dol.gov* or by mail to Robert Glatter, Room 2148, 1100 Wilson Boulevard, Arlington, Virginia 22209.

This information is being collected for the purpose of awarding a grant. The information collected through this ''Solicitation for Grant Applications'' will be used by the Department of Labor to ensure that grants are awarded to the applicant best suited to perform the functions of the grant. Submission of this information is required in order for the applicant to be considered for award of this grant. Unless otherwise specifically noted in this announcement, information submitted in the respondent's application is not considered to be confidential.

Authority: 30 U.S.C. 965.

Dated: July 24, 2012.

Patricia W. Silvey,

Deputy Assistant Secretary for Operations, Mine Safety and Health.

[FR Doc. 2012–18436 Filed 7–27–12; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before August 29, 2012. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Management Services (ACNR) using one of the following means:

Mail: NARA (ACNR), 8601 Adelphi Road, College Park, MD 20740–6001.

Email: request.schedule@nara.gov.

FAX: 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, National Records Management Program (ACNR), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1799. Email: *request.schedule@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless specified otherwise. An item in a schedule is media neutral when the disposition instructions may be applied to records regardless of the medium in which the records are created and maintained. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is limited to a specific medium. (See 36 CFR 1225.12(e).)

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending

1. Department of Agriculture, Forest Service (N1–95–10–8, 32 items, 31 temporary items). Records related to agency programs such as waste prevention, recycling, safety and health, and road maintenance. Proposed for permanent retention are case files pertaining to Native American claims.

2. Department of Agriculture, Forest Service (N1–95–10–9, 84 items, 63 temporary items). Records related to various programs throughout the agency, including general correspondence, reports, case files, plans, and studies. Proposed for permanent retention are law enforcement reports and plans; boundary modification case files; land transfer, title, and status files; significant controlled correspondence; planned technology reports; aerial photographs; remote sensing data and imagery; maps; and channel and dam project design case files.

3. Department of the Army, Agency-wide (N1–AU–09–20, 1 item, 1 temporary item). Master files of an electronic system used to track equal opportunity complaints.

4. Department of the Army, Agency-wide (N1–AU–10–11, 1 item, 1 temporary item). Master files of an electronic information system containing force management data, including personnel and equipment requirements and authorizations.

5. Department of the Army, Agency-wide (N1–AU–10–38, 1 item, 1 temporary item). Master files of an electronic information system used to track real property planning criteria, including category codes, design criteria, and land use information.

6. Department of Defense, Office of the Secretary of Defense (N1–330–11–6, 44 items, 38 temporary items). Records relating to administrative functions of the Special Inspector General for Iraq Reconstruction, including office management files, record locators, reference publications, and routine budget and finance files. Proposed for permanent retention are publications, Congressional correspondence, policy files, organizational planning and structure files, press materials, budget justification files, legislative program files, and legal opinions.

7. Department of Homeland Security, U.S. Coast Guard (N1–26–12–1, 2 items, 1 temporary item). Routine search and rescue records which are not fully included in marine information tracking systems. Proposed for permanent retention are records of historically significant search and rescue case files.

8. Department of Homeland Security, U.S. Coast Guard (N1–26–12–3, 5 items, 5 temporary items). Records of the Coast Guard Exchange System scholarship committee, including files for accepted and rejected applicants and committee and conference files.

9. Department of the Interior, Bureau of Land Management, (N1–49–09–17, 5 items, 4 temporary items). Master files of an electronic information system used for wildfire management activities on public lands. Proposed for permanent retention are fire reports from the major Federal fire-fighting agencies.

10. Department of the Interior, Office of the Secretary (DAA–0048–2012–0002, 4 items, 1 permanent item). Records of the Office of Restoration and Damage Assessment, including administrative files, duplicate copies of consent decrees, and allocation records. Proposed for permanent retention are the designation records of the authorized official delegated to act on the behalf of the Secretary of the Interior, including official damage assessments, high level correspondence, final implementation orders of corrective actions, and all supporting documentation.

11. Department of Justice, Criminal Division (DAA–0060–2012–0007, 1 item, 1 temporary item). Master files of an electronic information system used to manage correspondence.

12. Department of Justice, United States Attorneys' Offices (N1–118–11–1, 6 items, 6 temporary items). Master files of electronic information systems providing administrative tracking of grand jury activity.

13. Department of the Navy, Agency-wide (DAA–0343–2012–0001, 6 items, 2 temporary items). Duplicate copies of engineering drawings and technical reports. Proposed for permanent retention are record copies of engineering drawings and technical reports.

14. Department of Transportation, National Highway Traffic Safety Administration (N1–416–05–4, 18 items, 15 temporary items). Records of the Office of the Chief Counsel, including routine litigation files, confidentiality requests, and administrative files. Proposed for permanent retention are legislative rulemaking and review files and significant litigation case files.

15. Department of the Treasury, Internal Revenue Service (N1–58–11–12, 4 items, 4 temporary items). Master files and system documentation of an electronic information system used to rank and score tax returns and identify improperly filed returns and appropriate treatments.

16. Department of the Treasury, Internal Revenue Service (N1–58–11–13, 14 items, 14 temporary items). Collection activity reports used for tracking and reporting purposes.

17. Department of the Treasury, Internal Revenue Service (N1–58–12–7, 4 items, 4 temporary items). Master files, inputs, outputs, and system documentation of an electronic information system used to allocate, bill, and collect fees from pharmaceutical companies for the Medicare Part B Trust Fund.

18. Department of the Treasury, Internal Revenue Service (N1–58–12–8, 5 items, 5 temporary items). Master files and system documentation of electronic information systems used to analyze and monitor excise tax compliance.

19. Department of the Treasury, Internal Revenue Service (N1–58–12–9, 2 items, 2 temporary items). Records documenting privacy protections for information systems, Web sites, and other automated systems that collect personally identifiable information.

20. Department of the Treasury, Internal Revenue Service (N1–58–12–11, 3 items, 3 temporary items). Master files and system documentation of an electronic information system used to track and send correspondence regarding Supplemental Group Ruling Information to exempt organizations.

21. Department of the Treasury, Internal Revenue Service (N1–58–12–12, 2 items, 2 temporary items). Records relating to forms used for the New Markets Tax Credit program that document taxpayers' equity investments and events requiring recapture of tax credit.

22. Department of the Treasury, Internal Revenue Service (N1–58–12–13, 1 item, 1 temporary item). Records including forms and letters used to alert exempt organizations of inadequate record keeping practices and legal requirements.

23. Department of the Treasury, Internal Revenue Service (N1–58–12–14, 2 items, 2 temporary items). Master files and system documentation of an electronic information system used to support strategic planning, budgeting, and performance management processes.

24. Department of the Treasury, Internal Revenue Service (N1–58–12–15, 1 item, 1 temporary item). Records including reports used to identify and track debit vouchers and accounting issues.

25. Consumer Financial Protection Bureau, Agency-wide (N1–587–12–2, 1 item, 1 temporary item). Master files of an electronic information system containing interstate land registration records.

26. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation (N1–431–09–2, 1 item, 1 temporary item). Master files of an electronic information system containing information on the structural integrity of reactor pressure vessels in licensed nuclear power plants.

Dated: July 23, 2012.

Paul M. Wester, Jr.,

Chief Records Officer for the U.S. Government.

[FR Doc. 2012–18482 Filed 7–27–12; 8:45 am]

BILLING CODE 7515–01–P

OFFICE OF NATIONAL DRUG CONTROL POLICY

Revised Meeting Notice: Leadership Meeting on Maternal, Fetal, and Infant Opioid Exposure and Neonatal Abstinence Syndrome

AGENCY: Office of National Drug Control Policy.

ACTION: Revised notice.

SUMMARY: An ONDCP Leadership Meeting on Maternal, Fetal and Infant

Opioid Exposure and Neonatal Abstinence Syndrome (NAS) will bring together leaders in the field of policy, opioid exposed infants, pain treatment during pregnancy, and addiction treatment during and after pregnancy. The meeting will be held on Thursday, August 30th 2012 in the Indian Treaty Room, Eisenhower Executive Office Building, 17th Street and Pennsylvania Avenue NW., Washington D.C, 20500 starting at 9:00 a.m. and concluding at 5:30 p.m. The overall objectives of the meeting are to review the state of science and policy and discuss the remaining challenges to the field concerning the upswing in maternal prescription drug abuse and dependence and resulting increases in opioid exposed babies with NAS and possibly other consequences. Misuse and abuse of, and dependence upon, prescription opioid drugs adversely affect the health of millions of Americans and their families.

The specific conference objectives are: (1) To share research findings concerning the NAS epidemic and its costs; (2) to begin a national discussion concerning promising and best practices for treating opioid exposed babies; (3) to raise awareness about opioid misuse and dependence during pregnancy and the need for women with drug use disorders to access treatment through family medicine and gynecological practitioners, and specialty treatment providers; (4) to discuss legal and policy issues related to opioid using pregnant women and mothers including barriers to accessing treatment; (5) to promote awareness among regulatory agencies and insurers concerning the risks and benefits of opioids to developing fetuses and the likelihood of neonatal abstinence syndrome resulting from long term opioid use during pregnancy; and (6) to raise awareness about risk prevention opportunities among practitioners and regulators. Members of the public who wish to attend this meeting should telephone ONDCP's Maternal, Fetal, and Infant Opioid Exposure and Neonatal Abstinence Syndrome telephone line at (202) 395–7454 to arrange building access no later than Friday, August 10, 2012. Seating for members of the public is limited and will be assigned on a first come, first served basis.

To Attend or For Further Information Contact: Cecelia Spitznas, Ph.D. at (202) 395–7454 or email *rsvp@ondcp.eop.gov*.

Dated: July 24, 2012.

Linda V. Priebe,

Deputy General Counsel.

[FR Doc. 2012–18488 Filed 7–27–12; 8:45 am]

BILLING CODE 3180–W1–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Railroad Retirement Board (RRB) is forwarding three Information Collection Requests (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collections of information to determine (1) the practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

1. *Title and purpose of information collection:* Employee Representative's Status and Compensation Reports; OMB 3220–0014.

Under Section 1(b)(1) of the Railroad Retirement Act (RRA), the term ''employee'' includes an individual who is an employee representative. As defined in Section 1(c) of the RRA, an employee representative is an officer or official representative of a railway labor organization other than a labor organization included in the term ''employer,'' as defined in the RRA, who before or after August 29, 1935, was in the service of an employer under the RRA and who is duly authorized and designated to represent employees in accordance with the Railway Labor Act, or, any individual who is regularly assigned to or regularly employed by such officer or official representative in connection with the duties of his or her office. The requirements relating to the application for employee representative status and the periodic reporting of the compensation resulting from such status is contained in 20 CFR part 209.10.

The RRB utilizes Forms DC–2a, *Employee Representative's Status Report,* and DC–2, *Employee Representative's Report of Compensation,* to obtain the information needed to determine employee representative status and to maintain a record of creditable service and compensation resulting from such status. Completion is required to obtain or retain a benefit. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (76 FR 40657 on July 10, 2012) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Employee Representative's Status and Compensation Reports.

OMB Control Number: 3220–0014.

Form(s) submitted: DC–2 and DC–2a.

Type of request: Revision of a currently approved collection of information.

Affected public: Private Sector; Businesses or other for-profits.

Abstract: Benefits are provided under the Railroad Retirement Act (RRA) for individuals who are employee representatives as defined in section 1 of the RRA. The collection obtains information regarding the status of such individuals and their compensation.

Changes proposed: The RRB proposes a minor editorial change to both Forms DC–2 and DC–2a.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
DC–2a	3	15	1
DC–2	65	30	33
Total	68	.....	34

2. *Title and Purpose of information collection:* Nonresident Questionnaire; OMB 3220–0145.Under Public Laws 98–21 and 98–76, benefits under the Railroad Retirement Act payable to annuitants living outside the United States may be subject to taxation under United States income tax laws. Whether the social security equivalent and non-social security equivalent portions of Tier I, Tier II, vested dual benefit, or supplemental annuity payments are subject to tax withholding, and whether the same or different rates are applied to each payment, depends on a beneficiary's citizenship and legal residence status, and whether exemption under a tax treaty between the United States and the country in which the beneficiary is a legal resident has been claimed. To effect the required tax withholding, the Railroad Retirement Board (RRB) needs to know a nonresident's citizenship and legal residence status.

To secure the required information, the RRB utilizes Form RRB–1001, *Nonresident Questionnaire,* as a supplement to an application as part of the initial application process, and as an independent vehicle for obtaining the needed information when an annuitant's residence or tax treaty status changes. Completion is voluntary. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (76 FR 40658 on July 10, 2012) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Nonresident Questionnaire.
OMB Control Number: 3220–0145.
Form(s) submitted: RRB–1001.
Type of request: Extension without change of a currently approved collection.
Affected public: Individuals or Households.
Abstract: Under the Railroad Retirement Act, the benefits payable to an annuitant living outside the United States may be subject to withholding under Public Laws 98–21 and 98–76. The form obtains the information needed to determine the amount to be withheld.
Changes proposed: The RRB proposes no changes to Form RRB–1001.
The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
RRB–1001	1,300	30	650

3. *Title and Purpose of information collection:* Statement of Claimant or Other Person; OMB 3220–0183

To support an application for an annuity under Section 2 of the Railroad Retirement Act (RRA) or for unemployment benefits under Section 2 of the Railroad Unemployment Insurance Act (RUIA), pertinent information and proofs must be furnished for the RRB to determine benefit entitlement. Circumstances may require an applicant or other person(s) having knowledge of facts relevant to the applicant's eligibility for an annuity or benefits to provide written statements supplementing or changing statements previously provided by the applicant. Under the railroad retirement program these statements may relate to a change in an annuity beginning date(s), date of marriage(s), birth(s), prior railroad or non-railroad employment, an applicant's request for reconsideration of an unfavorable RRB eligibility determination for an annuity or various other matters. The statements may also be used by the RRB to secure a variety of information needed to determine eligibility to unemployment and sickness benefits. Procedures related to providing information needed for RRA annuity or RUIA benefit eligibility determinations are prescribed in 20 CFR parts 217 and 320 respectively.

The RRB utilizes Form G–93, *Statement of Claimant or Other Person,* to obtain from applicants or other persons, the supplemental or corrective information needed to determine applicant eligibility for an RRA annuity or RUIA benefits. Completion is voluntary. One response is requested of each respondent.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (76 FR 40658 on July 10, 2012) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Statement of Claimant or Other Person.
OMB Control Number: 3220–0183.
Form(s) submitted: G–93.
Type of request: Extension without change of a currently approved collection.
Affected public: Individuals or Households.
Abstract: Under Section 2 of the Railroad Retirement Act and the Railroad Unemployment Insurance Act, pertinent information and proofs must be submitted by an applicant so that the Railroad Retirement Board can determine his or her entitlement to benefits. The collection obtains information supplementing or changing information previously provided by an applicant.
Changes proposed: The RRB proposes no revisions to Form G–93.
The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–93	900	15	225

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV*.

Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or *Charles.Mierzwa@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2012–18478 Filed 7–27–12; 8:45 am]

BILLING CODE 7905–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) the practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

Under Section 6 of the Railroad Retirement Act (RRA), lump-sum death benefits are payable to surviving widow(er)s, children, and certain other dependents. Lump-sum death benefits are payable after the death of a railroad employee *only* if there are no qualified survivors of the employee immediately eligible for annuities. With the exception of the residual death benefit, eligibility for survivor benefits depends on whether the deceased employee was ''insured'' under the RRA at the time of death. If the deceased employee was not insured, jurisdiction of any survivor benefits payable is transferred to the Social Security Administration and survivor benefits are paid by that agency instead of the RRB. The requirements for applying for benefits are prescribed in 20 CFR 217, 219, and 234.

The collection obtains the information required by the RRB to determine entitlement to and amount of the survivor death benefits applied for. To collect the information, the RRB uses Forms AA–11a, *Designation for Change of Beneficiary for Residual Lump-Sum;* AA–21, *Application for Lump-Sum Death Payment and Annuities Unpaid at Death;* AA–21cert, *Application Summary and Certification;* G–131, *Authorization of Payment and Release of All Claims to a Death Benefit or Accrued Annuity Payment;* and G–273a, *Funeral Director's Statement of Burial Charges.* One response is requested of each respondent. Completion is required to obtain benefits.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (76 FR 31898 on May 30, 2012) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Application for Survivor Death Benefits.

OMB Control Number: 3220–0031.

Form(s) submitted: AA–11a, AA–21cert, AA–21, G–131, G–273a.

Type of request: Extension without change of a currently approved collection.

Affected public: Individuals or Households.

Abstract: The collection obtains the information needed to pay death benefits and annuities due but unpaid at death under the Railroad Retirement Act. Benefits are paid to designated beneficiaries or to survivors in a priority designated law.

Changes proposed: The RRB proposes no changes to the forms in the collection.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
AA–11a	100	10	17
AA–21cert (with assistance)	4,500	20	1,500
AA–21 (without assistance)	300	40	200
G–131	600	5	50
G–273a	5,000	10	833
Total	10,500	.....	2,600

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.*

Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, 60611–2092 or *Charles.Mierzwa@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, email address: *OIRA_Submission@omb.eop.gov.*

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2012–18339 Filed 7–27–12; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form 11–K, OMB Control No. 3235–0082, SEC File No. 270–101.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management Budget for extension and approval.

Form 11–K (17 CFR 249.311) is the annual report designed for use by employee stock purchase, savings and similar plans to comply with the reporting requirements under Section 15(d) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') (15 U.S.C. 78o(d)). Section 15(d) establishes a periodic reporting obligation for every issuer of a class of securities registered under the Securities Act of 1933 (the ''Securities Act'') (15 U.S.C. 77a *et seq.*). Form 11–K provides employees of an issuer with financial information so that they can assess the performance of the investment vehicle or stock plan. Form 11–K takes approximately 30 burden hours per response and is filed by 2,000

respondents for total of 60,000 burden hours.

Written comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov*.

Dated: July 24, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–18395 Filed 7–27–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rules 17h–1T and 17h–2T, SEC File No. 270–359, OMB Control No. 3235–0410.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information provided for in Rules 17h–1T and 17h–2T (17 CFR 240.17h–1T and 17 CFR 240.17h–2T), under the Securities and Exchange Act of 1934 (17 U.S.C. 78a *et seq.*) (''Exchange Act'').

Rule 17h–1T requires a broker-dealer to maintain and preserve records and other information concerning certain entities that are associated with the broker-dealer. This requirement extends to the financial and securities activities of the holding company, affiliates and subsidiaries of the broker-dealer that are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Rule 17h–2T requires a broker-dealer to file with the Commission quarterly reports and a cumulative year-end report concerning the information required to be maintained and preserved under Rule 17h–1T.

The collection of information required by Rules 17h–1T and 17h–2T, collectively referred to as the ''risk assessment rules,'' is necessary to enable the Commission to monitor the activities of a broker-dealer affiliate whose business activities are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Without this information, the Commission would be unable to assess the potentially damaging impact of the affiliate's activities on the broker-dealer.

There are currently 275 respondents that must comply with Rules 17h–1T and 17h–2T. Each of these 275 respondents requires approximately 10 hours per year, or 2.5 hours per quarter, to maintain the records required under Rule 17h–1T, for an aggregate annual burden of 2,750 hours (275 respondents × 10 hours). In addition, each of these 275 respondents must make five annual responses under Rule 17h–2T. These five responses require approximately 14 hours per respondent per year, or 3.5 hours per quarter, for an aggregate annual burden of 3,850 hours (275 respondents × 14 hours).

In addition, there are approximately twenty-five new respondents per year that must draft an organizational chart required under Rule 17h–1T and establish a system for complying with the risk assessment rules. The staff estimates that drafting the required organizational chart requires one hour and establishing a system for complying with the risk assessment rules requires three hours, thus requiring an aggregate of 100 hours (25 new respondents × 4 hours). Thus, the total compliance burden per year is approximately 6,700 burden hours (2,750 + 3,850 + 100).

Rule 17h–1T specifies that the records required to be maintained under the Rule must be preserved for a period of not less than three years. There is no specific retention period or record keeping requirement for Rule 17h–2T. The collection of information is mandatory and the information required to be provided to the Commission pursuant to the risk assessment rules is deemed confidential, notwithstanding any other provision of law under Section 17(h)(5) of the Exchange Act (15 U.S.C. 78q(h)(5)) and Section 552(b)(3)(B) of the Freedom of Information Act (5 U.S.C. 552(b)(3)(B)).

The Commission 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.

Background documentation for this information collection may be viewed at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: July 24, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–18446 Filed 7–27–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17g–5, SEC File No. 270–581, OMB Control No. 3235–0649.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17g–5 (17 CFR 240.17g–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

The Credit Rating Agency Reform Act of 2006 (Pub. L. 109–291) (''Rating Agency Act''), enacted on September 29, 2006, defines the term ''nationally recognized statistical rating organization,'' or ''NRSRO'' and

provides authority for the Commission to implement registration, recordkeeping, financial reporting, and oversight rules with respect to registered credit rating agencies.

In 2009, the Commission adopted amendments to Rule 17g–5. Rule 17g–5, as amended, imposes additional requirements on NRSROs in order to address concerns about the integrity of their credit rating procedures and methodologies in light of the role they played in determining credit ratings for securities collateralized by or linked to subprime residential mortgages.

Rule 17g–5, as amended, requires NRSROs to disclose and manage certain conflicts of interest. The collection of information obligation imposed by Rule 17g–5 is mandatory for credit rating agencies that are applying to register or are registered with the Commission as NRSROs. Registration with the Commission as an NRSRO is voluntary.

The Rating Agency Act added a new Section 15E, ''Registration of Nationally Recognized Statistical Rating Organizations'' (15 U.S.C. 78o–7) to the Exchange Act. Exchange Act Section 15E(h)(2) provides the Commission with authority to prohibit, or require the management and disclosure of, any potential conflict of interest relating to the issuance of credit ratings by an NRSRO (15 U.S.C. 78o–7(h)(2)).

Rule 17g–5, as amended, requires the disclosure and establishment of procedures to manage an additional conflict of interest and prohibits an NRSRO from issuing a rating for a structured finance product unless information about the transaction and the assets underlying the rated security are disclosed to certain persons. The Commission estimates that it will take 10 NRSROs approximately 300 hours to develop a system, as well as the policies and procedures, for the disclosures required by Rule 17g–5, resulting in a total one-time hour burden of 3,000.

Rule 17g–5, as amended, also requires disclosures on a transaction by transaction basis. The Commission estimates that the total number of structured finance ratings issued by all NRSROs in a given year would be 14,880 and that it would take 1 hour per transaction to make the information publicly available resulting in a total aggregate annual burden to the industry of 14,880 hours.

Rule 17g–5, as amended, also requires arrangers to disclose certain information. The Commission estimates that it would take 200 arrangers subject to the rule approximately 300 hours to develop a system, as well as the policies and procedures, for the disclosures required by Rule 17g–5, resulting in a total one-time hour burden of 60,000.

Rule 17g–5, as amended, also requires disclosures by arrangers on a transaction by transaction basis. The Commission estimates that 200 arrangers would arrange approximately 20 new transactions per year and that it would take 1 hour per transaction to make the information publicly available, resulting in a total aggregate annual burden of 4,000 hours.

Rule 17g–5, as amended, also requires disclosure of information by arrangers on an ongoing basis that is used by an NRSRO to undertake credit rating surveillance on the structured finance product. The Commission estimates this disclosure would be required for approximately 125 transactions a month, and it would take each respondent approximately 0.5 hours per transaction to disclose the information. Therefore, the Commission estimates that it would take each respondent approximately 750 hours on an annual basis to disclose such information, for a total aggregate annual burden of 150,000 hours.

Finally, Rule 17g–5, as amended, requires NRSROs to submit an annual certification to the Commission. The Commission estimates that it would take each NRSRO approximately 2 hours to complete the certification, resulting in a total aggregate annual burden of 20 hours.

Accordingly, the total estimated burden associated with Rule 17g–5 is 63,000 hours on a one-time basis (3,000 + 60,000 = 63,000) and 168,900 on an annual basis (14,880 + 150,000 + 4,000 + 20 = 168,900).

The Commission 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.

The public may view background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

Dated: July 24, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–18447 Filed 7–27–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30145; 812–14022]

Saratoga Investment Corp., et al.; Notice of Application

July 23, 2012.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a) and 61(a) of the Act.

APPLICANTS: Saratoga Investment Corp. (the ''Company''), Saratoga Investment Advisors, LLC (the ''Investment Adviser''), Saratoga Investment Corp. SBIC GP, LLC (the ''General Partner''), and Saratoga Investment Corp. SBIC LP (''Saratoga SBIC'').

SUMMARY OF THE APPLICATION: The Company requests an order to permit it to adhere to a modified asset coverage requirement.

FILING DATES: The application was filed April 2, 2012. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 17, 2012, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: 535 Madison Avenue, NY, NY 10022.

FOR FURTHER INFORMATION CONTACT: Lewis B. Reich, Senior Counsel, at (202) 551–6919, or Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, a Maryland corporation, is an externally managed, non-diversified, closed-end management investment company that has elected to be regulated as a business development company (''BDC'') under the Act.[1] The Company seeks to generate both current income and capital appreciation on its investments primarily through mezzanine debt, leveraged loans and to a lesser extent equity. The Investment Adviser, a Delaware limited liability company, is the investment adviser to the Company. The Investment Adviser is registered under the Investment Advisers Act of 1940.

2. Saratoga SBIC, a Delaware limited partnership, is a small business investment company (''SBIC'') licensed by the Small Business Administration (''SBA'') to operate under the Small Business Investment Act of 1958 (''SBIA''). Saratoga SBIC is excluded from the definition of investment company by section 3(c)(7) of the Act. The Company directly owns 99% of Saratoga SBIC in the form of a limited partnership interest and is the sole member of the General Partner. The General Partner, a Delaware limited liability company that is a wholly-owned subsidiary of the Company, owns 1% of Saratoga SBIC in the form of a general partnership interest. The Company acts as manager of and investment adviser to Saratoga SBIC.

Applicants' Legal Analysis

1. The Company requests an exemption pursuant to section 6(c) of the Act from the provisions of sections 18(a) and 61(a) of the Act to permit it to adhere to a modified asset coverage requirement with respect to any direct or indirect wholly owned subsidiary of the Company that is licensed by the SBA to operate under the SBIA as a SBIC and relies on Section 3(c)(7) for an exception from the definition of ''investment company'' under the 1940 Act (each, a ''SBIC Subsidiary'').[2] Applicants state that companies operating under the SBIA, such as SBIC Subsidiaries, will be subject to the SBA's substantial regulation of permissible leverage in their capital structure.

2. Section 18(a) of the Act prohibits a registered closed-end investment company from issuing any class of senior security or selling any such security of which it is the issuer unless the company complies with the asset coverage requirements set forth in that section. Section 61(a) of the Act makes section 18 applicable to BDCs, with certain modifications. Section 18(k) exempts an investment company operating as an SBIC from the asset coverage requirements for senior securities representing indebtedness that are contained in section 18(a)(1)(A) and (B).

3. Applicants state that the Company may be required to comply with the asset coverage requirements of section 18(a) (as modified by section 61(a)) on a consolidated basis because the Company may be deemed to be an indirect issuer of any class of senior security issued by Saratoga SBIC or another SBIC Subsidiary. Applicants state that applying section 18(a) (as modified by section 61(a)) on a consolidated basis generally would require that the Company treat as its own all assets and any liabilities held directly either by itself, by Saratoga SBIC, or by another SBIC Subsidiary. Accordingly, the Company requests an order under section 6(c) of the Act exempting the Company from the provisions of section 18(a) (as modified by section 61(a)), such that senior securities issued by each SBIC Subsidiary that would be excluded from the SBIC Subsidiary's asset coverage ratio by section 18(k) if it were itself a BDC would also be excluded from the Company's consolidated asset coverage ratio.

4. Section 6(c) of the Act, in relevant part, permits the Commission to exempt any transaction or class of transactions from any provision of the Act if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief satisfies the section 6(c) standard. Applicants contend that, because the SBIC Subsidiary would be entitled to rely on section 18(k) if it were a BDC itself, there is no policy reason to deny the benefit of that exemption to the Company.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

The Company shall not issue or sell any senior security and the Company shall not cause or permit Saratoga SBIC or any other SBIC Subsidiary to issue or sell any senior security of which the Company, Saratoga SBIC or any other SBIC Subsidiary is the issuer except to the extent permitted by section 18 (as modified for BDCs by section 61) of the Act; provided that, immediately after the issuance or sale by any of the Company, Saratoga SBIC or any other SBIC Subsidiary of any such senior security, the Company, individually and on a consolidated basis, shall have the asset coverage required by section 18(a) of the Act (as modified by section 61(a)). In determining whether the Company has the asset coverage on a consolidated basis required by section 18(a) of the Act (as modified by section 61(a)), any senior securities representing indebtedness of Saratoga SBIC or another SBIC Subsidiary shall not be considered senior securities and, for purposes of the definition of ''asset coverage'' in section 18(h), shall be treated as indebtedness not represented by senior securities.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–18449 Filed 7–27–12; 8:45 am]

BILLING CODE 8011–01–P

[1] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[2] All existing entities that currently intend to rely on the order are named as applicants. Any other existing or future entity that may rely on the order in the future will comply with the terms and condition of the order.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–67490; File No. SR–NYSEArca–2012–75]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Amending NYSE Arca Equities Rule 7.37(c) To Provide That the Tracking Order Process Is Available Only for Orders That Are Eligible To Route to an Away Market

July 24, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on July 11, 2012, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Equities Rule 7.37(c) to provide that the Tracking Order Process is available only for orders that are eligible to route to an away market. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rule 7.37(c) to provide that the Tracking Order Process is available only for orders that are eligible to route to an away market.

NYSE Arca Equities Rule 7.37 (''Rule 7.37'') sets forth the Order Execution process at the Exchange. Rule 7.37(c) specifies that during Core Trading Hours only, if an order has not been executed in its entirety pursuant to the Directed Order Process (Rule 7.37(a)), the Display Order Process (Rule 7.37(b)(1)), or the Working Order Process (Rule 7.37(b)(2)), such order may be matched and executed in the Tracking Order Process in price/time priority. The rule specifies that any portion of an order received from another market center or market participant shall be cancelled immediately, and an incoming order that is designated as an ISO will not interact in the tracking order process. Incoming orders that enter the Tracking Order Process execute against Tracking Orders, which are undisplayed, priced round lot orders that are eligible for execution in the Tracking Order Process against orders equal to or less than the aggregate size of the Tracking Order interest at that price.[3]

The Exchange proposes to amend Rule 7.37(c) to specify that only orders that are eligible to route to an away market would participate in the Tracking Order Process. Because the rule would specify that only interest that is eligible to route to an away market would participate, the Exchange proposes to delete the provision that states that incoming orders designated as an ISO will not interact in the Tracking Order Process. In addition, the Exchange proposes to delete the provision concerning the cancellation of any order received from another market center or market participant as moot in today's market structure. The Exchange previously included that rule language to address the operation of the markets under the Intermarket Trading System (''ITS''). ITS was decommissioned in connection with the implementation of Regulation NMS on July 9, 2007. Now that the markets operate pursuant to Regulation NMS, orders received from other market centers are marked as intermarket sweep orders, which by definition, are not routable orders. Accordingly, with the proposed amendment to clarify that the tracking order process is applicable only to routable orders, the existing rule text is now obviated.

The Exchange notes that the proposed rule change is consistent with the manner by which the Exchange operates the Tracking Order Process and would not necessitate any changes to order processing.[4]

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Securities Exchange Act of 1934 (the ''Act''),[5] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market by providing transparency regarding which orders are eligible to interact in the Tracking Order Process. In particular, the proposed rule change eliminates rule text that is obsolete in today's market structure and replaces it with updated rule text.

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.

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 (i)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* NYSE Arca Equities Rule 7.31(f).

[4] The Exchange notes that when it adopted the Tracking Order Process, the Exchange explained in its rule filing that after the Tracking Order Process, an order would be routed to an away market: ''[a]fter the order has been matched against any Tracking Orders, if the order has not been executed in its entirety and the remaining part of the order is an odd lot, the odd lot order would be executed in the Odd Lot Tracking Order Process, as described below. Otherwise *the order would be routed pursuant to the final step of the execution algorithm.*'' *See* Securities Exchange Act Release No. 43608 (Nov. 21, 2000), 65 FR 78822 at 78828 (Dec. 15, 2000) (SR–PCX–00–25) (emphasis added).

[5] 15 U.S.C. 78f(b)(5).

as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove 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–NYSEArca–2012–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2012–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2012–75 and should be submitted on or before August 20, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–18448 Filed 7–27–12; 8:45 am]

BILLING CODE 8011–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Public Hearing

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold a public hearing on August 23, 2012, in Harrisburg, Pennsylvania. At this public hearing, the Commission will hear testimony on the projects listed in the **SUPPLEMENTARY INFORMATION** section of this notice. Such projects are intended to be scheduled for Commission action at its next business meeting, tentatively scheduled for September 20, 2012, which will be noticed separately. The public should take note that this public hearing will be the only opportunity to offer oral comment to the Commission for the listed projects. The deadline for the submission of written comments is September 4, 2012.

DATES: The public hearing will convene on August 23, 2012, at 2:30 p.m. The public hearing will end at 5:00 p.m. or at the conclusion of public testimony, whichever is sooner. The deadline for the submission of written comments is September 4, 2012.

ADDRESSES: The public hearing will be conducted at the North Office Building, Hearing Room 1 (Ground Level), North Street (at Commonwealth Avenue), Harrisburg, PA 17120.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436.

Information concerning the applications for these projects is available at the SRBC Water Resource Portal at *www.srbc.net/wrp.* Materials and supporting documents are available to inspect and copy in accordance with the Commission's Access to Records Policy at *www.srbc.net/pubinfo/docs/2009-02%20Access%20to%20Records%20Policy%209-10-09.PDF.*

Opportunity To Appear and Comment

Interested parties may appear at the hearing to offer comments to the Commission on any project listed below. The presiding officer reserves the right to limit oral statements in the interest of time and to otherwise control the course of the hearing. Ground rules will be posted on the Commission's web site, *www.srbc.net,* prior to the hearing for review. The presiding officer reserves the right to modify or supplement such rules at the hearing. Written comments on any project listed below may also be mailed to Mr. Richard Cairo, General Counsel, Susquehanna River Basin Commission, 1721 North Front Street, Harrisburg, Pa 17102–2391, or submitted electronically through *http://www.srbc.net/pubinfo/publicparticipation.htm.* Comments mailed or electronically submitted must be received by the Commission on or before September 4, 2012, to be considered.

SUPPLEMENTARY INFORMATION: The public hearing will cover the following projects:

Projects for Action

1. Project Sponsor and Facility: Borough of Adamstown, Adamstown Borough, Lancaster County, Pa. Application for renewal of groundwater withdrawal of up to 0.099 mgd (30-day average) from Well 4 (Docket No. 19801104).

2. Project Sponsor and Facility: Anadarko E&P Company LP (Second Fork Larrys Creek), Mifflin Township, Lycoming County, Pa. Application for surface water withdrawal of up to 0.499 mgd (peak day).

3. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Susquehanna River), Susquehanna Depot Borough, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 1.500 mgd (peak day) (Docket No. 20080908).

4. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Susquehanna River), Great Bend Township, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20080905).

5. Project Sponsor and Facility: Caernarvon Township Authority, Caernarvon Township, Berks County, Pa. Application for renewal of groundwater withdrawal of up to 0.035 mgd (30-day average) from Well 6 (Docket No. 19820912).

[6] 17 CFR 200.30–3(a)(12).

6. Project Sponsor and Facility: Carrizo (Marcellus), LLC (Muddy Run), Gulich Township, Clearfield County, Pa. Application for surface water withdrawal of up to 0.720 mgd (peak day).

7. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.070 mgd (30-day average) from S–1 (Baker Spring).

8. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.288 mgd (30-day average) from Well W–1.

9. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.792 mgd (30-day average) from Well W–2.

10. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.288 mgd (30-day average) from Well W–3.

11. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.331 mgd (30-day average) from Well W–4.

12. Project Sponsor and Facility: East Hempfield Township Municipal Authority, East Hempfield Township, Lancaster County, Pa. Application for renewal of groundwater withdrawal of up to 0.792 mgd (30-day average) from Well W–5 (Docket No. 19810203).

13. Project Sponsor and Facility: Enerplus Resources (USA) Corporation (West Branch Susquehanna River), East Keating Township, Clinton County, Pa. Application for surface water withdrawal of up to 2.000 mgd (peak day).

14. Project Sponsor and Facility: EQT Production Company (Pine Creek), Porter Township, Lycoming County, Pa. Application for surface water withdrawal of up to 1.000 mgd (peak day).

15. Project Sponsor and Facility: EXCO Resources (PA), LLC (Larrys Creek), Mifflin Township, Lycoming County, Pa. Application for renewal of surface water withdrawal with modification to increase by an additional 0.413 mgd, for a total of 0.499 mgd (peak day) (Docket No. 20080936).

16. Project Sponsor and Facility: Falling Springs Water Works, Inc. (Falling Springs Reservoir), Ransom Township, Lackawanna County, Pa. Application for surface water withdrawal of up to 0.800 mgd (peak day).

17. Project Sponsor and Facility: Forest Springs Water Company, Wayne Township, Schuylkill County, Pa. Application for groundwater withdrawal of up to 0.075 mgd (30-day average) from Borehole BH–1.

18. Project Sponsor and Facility: Forest Springs Water Company, Wayne Township, Schuylkill County, Pa. Modification to consumptive water use approval removing previous sources Spring 1 and Spring 2 and adding new source Borehole BH–1 (Docket No. 20010206).

19. Project Sponsor and Facility: Gaberseck Brothers (Odin Pond 2), Keating Township, Potter County, Pa. Application for surface water withdrawal of up to 0.249 mgd (peak day).

20. Project Sponsor and Facility: Houtzdale Municipal Authority (Beccaria Springs), Gulich Township, Clearfield County, Pa. Application for surface water withdrawal of up to 10.000 mgd (peak day).

21. Project Sponsor: Hydro Recovery-Antrim LP. Project Facility: Antrim Treatment Plant, Duncan Township, Tioga County, Pa. Modification to project features and to increase surface water withdrawal by an additional 1.152 mgd, for a total of 1.872 mgd (peak day) (Docket No. 20090902).

22. Project Sponsor and Facility: Keystone Clearwater Solutions, LLC (Lycoming Creek), Lewis Township, Lycoming County, Pa. Modification to increase surface water withdrawal by an additional 1.308 mgd, for a total of 2.600 mgd (peak day) (Docket No. 20110616).

23. Project Sponsor and Facility: Keystone Clearwater Solutions, LLC (Moshannon Creek), Snow Shoe Township, Centre County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20080946).

24. Project Sponsor and Facility: Keystone Clearwater Solutions, LLC (West Branch Susquehanna River), Goshen Township, Clearfield County, Pa. Application for renewal of surface water withdrawal of up to 2.160 mgd (peak day) (Docket No. 20080944).

25. Project Sponsor and Facility: Roaring Spring Water—Division of Roaring Spring Blank Book, Roaring Spring Borough, Blair County, Pa. Modification to increase consumptive water use by an additional 0.125 mgd, for a total of 0.255 mgd (peak day) (Docket No. 20120309).

26. Project Sponsor and Facility: Roaring Spring Water—Division of Roaring Spring Blank Book (Roaring Spring), Roaring Spring Borough, Blair County, Pa. Modification to increase surface water withdrawal by an additional 0.131 mgd, for a total of 0.302 mgd (peak day) (Docket No. 20120309).

27. Project Sponsor and Facility: Southwestern Energy Production Company (Middle Lake), New Milford Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.720 mgd (peak day).

28. Project Sponsor and Facility: Talisman Energy USA Inc. (Susquehanna River), Sheshequin Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20080909).

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806–808.

Dated: July 23, 2012.

Thomas W. Beauduy,

Deputy Executive Director.

[FR Doc. 2012–18470 Filed 7–27–12; 8:45 am]

BILLING CODE 7040–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP): Notice of Initiation of the 2012 Annual GSP Product and Country Practices Review; Deadlines for Filing Petitions

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of procedures for submission of petitions from the public.

SUMMARY: This notice announces that the Office of the United States Trade Representative (USTR) is prepared to receive petitions to modify the list of products that are eligible for duty-free treatment under the GSP program and to modify the GSP status of certain GSP beneficiary developing countries because of country practices. USTR is also prepared to receive petitions requesting waivers of competitive need limitations (CNLs).

FOR FURTHER INFORMATION CONTACT: Tameka Cooper, GSP Program, Office of the United States Trade Representative, 600 17th Street NW., Washington, DC 20508. The telephone number is (202) 395–6971; the fax number is (202) 395–9674, and the email address is *Tameka_Cooper@ustr.eop.gov.*

DATES: The GSP regulations (15 CFR part 2007) provide the timetable for conducting an annual review, unless otherwise specified by notice in the **Federal Register**. Notice is hereby given that, in order to be considered in the

2012 Annual GSP Review, all petitions to modify the list of articles eligible for duty-free treatment under GSP or to review the GSP status of any beneficiary developing country must be received by the GSP Subcommittee of the Trade Policy Staff Committee no later than 5:00 p.m. on October 5, 2012. Petitions requesting waivers of CNLs must be received by the GSP Subcommittee of the Trade Policy Staff Committee no later than 5:00 p.m. on November 21, 2012. Petitions submitted after the respective deadlines will not be considered for review. Decisions on which petitions are accepted for review, along with a schedule for any related public hearings and the opportunity for the public to provide comments will be announced at a later date.

SUPPLEMENTARY INFORMATION:

The 2012 Annual GSP Review

GSP Product Review Petitions. Interested parties, including foreign governments, may submit petitions to: (1) Designate additional articles as eligible for GSP benefits, including to designate articles as eligible for GSP benefits only if imported from countries designated as least-developed beneficiary developing countries, or only from countries designated as beneficiary sub-Saharan African countries under the African Growth and Opportunity Act (AGOA); (2) withdraw, suspend or limit the application of duty-free treatment accorded under the GSP with respect to any article; (3) waive the CNL for individual beneficiary developing countries with respect to specific GSP-eligible articles (these limits do not apply to least-developed beneficiary developing countries or AGOA beneficiary sub-Saharan African countries); and (4) otherwise modify GSP coverage.

As specified in 15 CFR 2007.1, all product petitions must include, *inter alia,* a detailed description of the product and the eight-digit subheading of the Harmonized Tariff Schedule of the United States (HTSUS) under which the product is classified.

As noted above, product petitions requesting CNL waivers for GSP-eligible articles imported from beneficiary developing countries that exceed the CNLs in 2012 must be received on or before the November 21, 2012, deadline described above. Before submitting petitions for CNL waivers, prospective petitioners may wish to review the year-to-date import trade data for products of interest. This data is available via the U.S. International Trade Commission's ''Dataweb'' database at *http://dataweb.usitc.gov/.*

Country Practices Review Petitions Any interested party may submit a petition to review the GSP eligibility of any beneficiary developing country with respect to any of the designation criteria listed in sections 502(b) or 502(c) of the Trade Act (19 U.S.C. 2462(b) and (c)). As noted above, such petitions are due no later than 5:00 p.m. on Friday, October 5, 2012.

Requirements for Submissions

All submissions for the GSP Annual Review must conform to the GSP regulations set forth at 15 CFR part 2007, except as modified below. These regulations are available on the USTR Web site at *http://www.ustr.gov/trade-topics/trade-development/preference-programs/generalized-system-preference-gsp/gsp-program-inf.* The GSP Guidebook also contains general instructions on how to submit a GSP petition. Any person or party making a submission is strongly advised to review the GSP regulations and the GSP Guidebook, available at the same link.

All submissions in response to this notice must be submitted electronically via *http://www.regulations.gov*, using docket number USTR–2012–0013. Hand-delivered submissions will not be accepted. Submissions must be submitted in English to the Chairman of the GSP Subcommittee of the Trade Policy Staff Committee by the applicable deadlines set forth in this notice. Submissions that do not provide the information required by sections 2007.0 and 2007.1 of the GSP regulations will not be accepted for review, except upon a detailed showing in the submission that the petitioner made a good faith effort to obtain the information required.

To make a submission using *http://www.regulations.gov*, enter docket number USTR–2012–0013 in the ''Search for'' field on the home page and click ''Search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notice'' under ''Document Type'' in the ''Filter Results by'' section on the left side of the screen and click on the link entitled ''Comment Now.'' The ''*http://www.regulations.gov''* Web site offers the option of providing comments by filling in a ''Type Comment'' field or by attaching a document using the ''Upload file(s)'' field. Given the detailed nature of the information sought by the GSP Subcommittee, the Subcommittee prefers that submissions be provided in an attached document. Submissions must include at the beginning of the submission, or on the first page (if an attachment), the following text (in bold and underlined): (1) ''2012 GSP Annual Review''; and (2) the eight-digit HTSUS subheading number in which the product is classified (for product petitions) or the name of the country (for country practice petitions). Furthermore, interested parties submitting petitions that request action with respect to specific products should also list at the beginning of the submission, or on the first page (if an attachment) the following information: (1) The requested action; and (2) if applicable, the beneficiary developing country. Submissions should not exceed 30 single-spaced, standard letter-size pages in 12-point type, including attachments. Any data attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Each submitter will receive a submission tracking number upon completion of the submissions procedure at *http://www.regulations.gov.* The tracking number will be the submitter's confirmation that the submission was received into *http://www.regulations.gov.* The confirmation should be kept for the submitter's records. USTR is not able to provide technical assistance for the Web site. Documents not submitted in accordance with these instructions may not be considered in this review. If an interested party is unable to provide submissions as requested, please contact the GSP Program at USTR to arrange for an alternative method of transmission.

Business Confidential Petitions

An interested party requesting that information contained in a petition be treated as business confidential information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly designated as such. The submission must be marked ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and each succeeding page, and the submission should indicate, via brackets, the specific information that is confidential. Additionally, ''Business Confidential'' must be included in the ''Type Comment'' field. Any submission containing business confidential information must be accompanied by a *separate,* non-confidential version of the confidential submission, indicating where confidential information has been redacted. The non-confidential version will be placed in the docket and open to public inspection.

Public Viewing of Review Submissions

Submissions in response to this notice, except for information granted ''business confidential'' status under 15 CFR 2003.6, will be available for public viewing pursuant to 15 CFR 2007.6 at *www.regulations.gov* upon completion of processing and no later than approximately two weeks after the relevant due date. Such submissions may be viewed by entering the docket number USTR–2012–0013 in the search field at: *www.regulations.gov*.

James Sanford,

Assistant U.S. Trade Representative for Small Business, Market Access & Industrial Competitiveness,Office of the U.S. Trade Representative.

[FR Doc. 2012–18426 Filed 7–27–12; 8:45 am]

BILLING CODE 3290–F2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Dispute No. WTO/DS431]

WTO Dispute Settlement Proceeding Regarding China—Measures Related to the Exportation of Rare Earths, Tungsten and Molybdenum

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative (''USTR'') is providing notice that the United States has requested the establishment of a dispute settlement panel under the *Marrakesh Agreement Establishing the World Trade Organization* (''WTO Agreement''). That request may be found at *www.wto.org* contained in a document designated as WT/DS431/6. USTR invites written comments from the public concerning the issues raised in this dispute.

DATES: Although USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before August 27, 2012, to be assured of timely consideration by USTR.

ADDRESSES: Public comments should be submitted electronically to *www.regulations.gov,* docket number USTR–2012–0005. If you are unable to provide submissions by *www.regulations.gov,* please contact Sandy McKinzy at (202) 395–9483 to arrange for an alternative method of transmission.

If (as explained below) the comment contains confidential information, then the comment should be submitted by fax only to Sandy McKinzy at (202) 395–3640.

FOR FURTHER INFORMATION CONTACT: Jared Wessel, Assistant General Counsel, or Ben Kostrzewa, Assistant General Counsel, Office of the United States Trade Representative, 600 17th Street NW., Washington, DC 20508, (202) 395–3150.

SUPPLEMENTARY INFORMATION: Section 127(b) of the Uruguay Round Agreements Act (''URAA'') (19 U.S.C. 3537(b)(1)) requires that notice and opportunity for comment be provided after the United States submits or receives a request for the establishment of a WTO dispute settlement panel. Consistent with this obligation, USTR is providing notice that a dispute settlement panel has been requested pursuant to the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* (''DSU''). The panel will hold its meetings in Geneva, Switzerland.

Major Issues Raised by the United States

On June 27, 2012, the United States requested the establishment of a panel regarding China's restraints on the export from China of various forms of rare earths, tungsten and molybdenum (collectively, the ''materials''). These export restraints include export duties on the materials; quantitative restrictions such as quotas on the export of the materials; and additional requirements that impose restrictions on the trading rights of enterprises seeking to export various forms of rare earths and molybdenum, such as prior export performance and minimum registered capital requirements. In addition, China administers these export quotas on the materials in a manner that is not uniform, impartial, or reasonable, such as by the use of criteria in the application and allocation process that lack definition or do not contain sufficient guidelines or standards in how they should be applied.

Forms of rare earths include, but are not limited to, items falling under the following eight-digit HS numbers identified in the *Announcement No. 27 Issuing the 2012 Tariff Implementation Program* (State Council Customs Tariff Commission, shuiweihui, No. 27, issued December 9, 2011, effective January 1, 2012) (hereinafter, the ''*2012 Tariff Implementation Program''*): 25309020, 26122000, 28053011, 28053012, 28053013, 28053014, 28053015, 28053016, 28053017, 28053019, 28053021, 28053029, 28461010, 28461020, 28461030, 28461090, 28469011, 28469012, 28469013, 28469014, 28469015, 28469016, 28469017, 28469019, 28469021, 28469022, 28469023, 28469024, 28469025, 28469026, 28469028, 28469029, 28469031, 28469032, 28469033, 28469034, 28469035, 28469036, 28469039, 28469041, 28469042, 28469043, 28469044, 28469045, 28469046, 28469048, 28469049, 28469091, 28469092, 28469093, 28469094, 28469095, 28469096, 28469099, 72029911, 72029919, 72029991 and 72029999. Forms of rare earths also include, but are not limited to, items falling under the following 10-digit Chinese Customs Commodity Codes (''CCC Codes''), as identified in the *Notice on Issuing the ''2012 Export Licensing Management Commodities List''* (Ministry of Commerce and General Administration of Customs Notice No. 98 (December 30, 2011)), (hereinafter the ''*2012 Export Licensing Management Commodities List''*): 2530902010, 2530902090, 2612200000, 2805301100, 2805301200, 2805301300, 2805301400, 2805301510, 2805301590, 2805301600, 2805301700, 2805301913, 2805301914, 2805301915, 2805301990, 2805302110, 2805302190, 2805302910, 2805302990, 2846101000, 2846102000, 2846103000, 2846109010, 2846109090, 2846901100, 2846901200, 2846901300, 2846901400, 2846901500, 2846901600, 2846901700, 2846901920, 2846901930, 2846901940, 2846901970, 2846901980, 2846901991, 2846901992, 2846901999, 2846902100, 2846902200, 2846902300, 2846902400, 2846902500, 2846902600, 2846902810, 2846902890, 2846902900, 2846903100, 2846903200, 2846903300, 2846903400, 2846903500, 2846903600, 2846903900, 2846904100, 2846904200, 2846904300, 2846904400, 2846904500, 2846904600, 2846904810, 2846904890, 2846904900, 2846909100, 2846909200, 2846909300, 2846909400, 2846909500, 2846909600, 2846909910, 2846909990, 7202991100, 7202991200, 7202999191 and 7202999199.

Forms of tungsten include, but are not limited to, items falling under the following eight-digit HS numbers, as identified in the *2012 Tariff Implementation Program:* 26209910, 28259011, 28259012, 28259019, 28418010, 28418020, 28418030, 28418040, 28418090, 28499020, 72028010, 72028020, 81011000, 81019400 and 81019700. Forms of tungsten also include, but are not limited to, items falling under the following 10-digit CCC Codes, as identified in the *2012 Export Licensing Management Commodities List:* 2611000000, 2620991000, 2825901100, 2825901200, 2825901910, 2841801000, 2841802000, 2841803000, 2841804000, 2849902000, 8101100010, 8101100090, 8101940000 and 8101970000.

Forms of molybdenum include, but are not limited to, items falling under the following eight-digit HS numbers, as identified in the *2012 Tariff Implementation Program:* 26131000, 26139000, 28257000, 28417010, 28417090, 72027000, 81021000, 81029400 and 81029700. Forms of molybdenum also include, but are not limited to, items falling under the following 10-digit CCC Codes, as identified in the *2012 Export Licensing Management Commodities List:* 2613100000, 2613900000, 2825700000, 2841701000, 2841709000, 7202700000, 8102100000, 8102940000 and 8102970000.

USTR believes that these export restraints and China's administration of and manner of imposing these export restraints are inconsistent with China's obligations under Articles X and XI of the *General Agreement on Tariffs and Trade 1994;* paragraphs 2(A)2, 5.1 and 11.3 of Part I of the *Protocol on the Accession of the People's Republic of China* (''Accession Protocol''); and the provisions of paragraph 1.2 of Part I of the Accession Protocol (which incorporates commitments in paragraphs 83, 84, 162 and 165 of the *Report of the Working Party on the Accession of China*).

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in this dispute. Persons may submit public comments electronically to *www.regulations.gov* docket number USTR–2012–0005. If you are unable to provide submissions by *www.regulations.gov,* please contact Sandy McKinzy at (202) 395–9483 to arrange for an alternative method of transmission.

To submit comments via *www.regulations.gov,* enter docket number USTR–2012–0005 on the home page and click ''search''. The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notice'' under ''Document Type'' on the left side of the search-results page, and click on the link entitled ''Submit a Comment.'' (For further information on using the *www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on ''How to Use This Site'' on the left side of the home page.)

The *www.regulations.gov* site provides the option of providing comments by filling in a ''Type Comments'' field, or by attaching a document using an ''upload file'' field. It is expected that most comments will be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type Comments'' field.

A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly designated as such and the submission must be marked ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and each succeeding page. Any comment containing business confidential information must be submitted by fax to Sandy McKinzy at (202) 395–3640. A non-confidential summary of the confidential information must be submitted to *www.regulations.gov.* The non-confidential summary will be placed in the docket and open to public inspection.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter B

(1) Must clearly so designate the information or advice;

(2) Must clearly mark the material as ''SUBMITTED IN CONFIDENCE'' at the top and bottom of the cover page and each succeeding page; and

(3) Must provide a non-confidential summary of the information or advice. Any comment containing confidential information must be submitted by fax. A non-confidential summary of the confidential information must be submitted to *www.regulations.gov.* The non-confidential summary will be placed in the docket and open to public inspection.

Pursuant to section 127(e) of the Uruguay Round Agreements Act (19 U.S.C. 3537(e)), USTR will maintain a docket on this dispute settlement proceeding accessible to the public at *www.regulations.gov,* docket number USTR–2012–0005. The public file will include non-confidential comments received by USTR from the public with respect to the dispute. If a dispute settlement panel is convened or in the event of an appeal from such a panel, the U.S. submissions, any non-confidential submissions, or non-confidential summaries of submissions, received from other participants in the dispute, will be made available to the public on USTR's Web site at *www.ustr.gov,* and the report of the panel, and, if applicable, the report of the Appellate Body, will be available on the Web site of the World Trade Organization, *www.wto.org.* Comments open to public inspection may be viewed on the *www.regulations.gov* Web site.

Bradford L. Ward,

Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. 2012–18429 Filed 7–27–12; 8:45 am]

BILLING CODE 3290–F2–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Public Teleconference

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee Teleconference.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of three teleconferences of the Systems Working Group of the Commercial Space Transportation Advisory Committee (COMSTAC). The teleconferences will take place on: Tuesday August 14, 2012, Tuesday September 18, 2012, and Tuesday October 23, 2012. All teleconferences will begin at 1:00 p.m. Eastern Daylight Time and will last approximately one hour. Individuals who plan to participate should contact Susan Lender, Designated Federal Officer (DFO), (the Contact Person listed below) by phone or email for the teleconference call in number.

The purpose of these three teleconferences is to assist the FAA early in its development of regulations to protect occupants of commercial suborbital and orbital spacecraft. Although the FAA has not yet targeted a date for proposing regulations to protect the health and safety of crew and space flight participants, the FAA believes that the development of sound and appropriate regulations for human space flight can only be achieved with a deliberate, multi-year effort. Moreover, the FAA believes that early industry input into this regulatory effort before any formal proposal by the FAA is critical.

Thus, the FAA would like to engage with COMSTAC on a periodic basis,

approximately once per month, on specific topics. The topics for the first three teleconferences are as follows:

(1) *What Level of Safety Should FAA Target*? We will discuss whether the FAA should regulate to one or multiple levels of space flight safety, what level or levels of safety the FAA should attempt to achieve, and whether the level or levels of safety should be quantified. We will also discuss what level of care, short of a fatality, the FAA should be concerned with.

(2) *What Should FAA Oversight Look Like*? Aircraft-like certification is not feasible at this time, due to current technology and the FAA's statutory mandate only to pursue minimal regulations that take into consideration the evolving standards of safety in the commercial space flight industry. 51 U.S.C. 50905(c)(3). We will discuss what a licensing process should look like in terms of FAA oversight, whether such oversight could or should be called a ''certification,'' and for how long informed consent should remain in effect.

(3) *What Types of Requirements and Associated Guidance Material Should FAA Develop*? In general, the FAA favors space transportation regulations that are performance or process based. We will discuss the level of empirical or analytical data necessary to justify any performance-based human space flight regulation, the possible use of Advisory Circulars to add clarity to regulations, and what place government and industry standards should have in FAA licensing.

Interested members of the public may submit relevant written statements for the COMSTAC working group members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact Susan Lender, DFO, (the Contact Person listed below) in writing (mail or email) by August 7, 2012, for the August 14 teleconference, September 11, 2012, for the September 18 teleconference, and October 16, 2012, for the October 23 teleconference. This way the information can be made available to COMSTAC members for their review and consideration before each teleconference. Written statements should be supplied in the following formats: one hard copy with original signature or one electronic copy via email. The FAA may schedule up to 10 more teleconferences in the coming months to allow the U.S. commercial space transportation industry to share views with the FAA on a number of specific topics related to commercial human space flight safety.

An agenda will be posted on the FAA Web site at *http://www.faa.gov/go/ast.*

Individuals who plan to participate and need special assistance should inform the Contact Person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Susan Lender (AST–5), Office of Commercial Space Transportation (AST), 800 Independence Avenue SW., Room 331, Washington, DC 20591, telephone (202) 267–8029; Email *susan.lender@faa.gov*. Complete information regarding COMSTAC is available on the FAA Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/*.

Issued in Washington, DC, July 23, 2012.

George C. Nield,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2012–18555 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0106]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 12 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective July 30, 2012. The exemptions expire on July 30, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

Background

On June 4, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 33017). That notice listed 12 applicants' case histories. The 12 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 12 applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 12 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including complete loss of vision, corneal scarring, amblyopia, retinal detachment, optic nerve atrophy, presbyopia, enucleation and retinal damage. In most cases, their eye conditions were not recently developed. Nine of the applicants were either born with their vision impairments or have had them since childhood. The individuals that sustained their vision conditions as adults have had it for a period of 25 to 39 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 12 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 5 to 38 years. In the past 3 years, two of the drivers were involved in crashes, and one was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the June 4, 2012 notice (77 FR 33017).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 12 applicants, two of the drivers were involved in crashes, and one was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and

driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 12 applicants listed in the notice of June 4, 2012 (77 FR 33017).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 12 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the 12 exemption applications, FMCSA exempts Robert F. Bennett (NJ), Dale W. Coblentz (MT), Michael L. Dean (MI), Damon G. Gallardo (CA), Marc D. Groszkrueger (IA), Daniel L. Grover (KS), James E. Modaffari (OR), Gerardus C. Molenaar (PA), James J. Narkewich (MA), Philip N. Polcastro (NY), Gregory A. Reinert (MN) and Scott J. Schlenker (WA) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: July 18, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–18567 Filed 7–27–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Information Collection Activities (Depreciation Studies)

ACTION: 60-day notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3519 (PRA), the Surface Transportation Board (Board) gives notice of its intent to request from the Office of Management and Budget (OMB) the information collection—Rail Depreciation Studies—further described below.

Comments are requested concerning (1) whether this collection of information is 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 estimates; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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, when appropriate. Submitted comments will be included and/or summarized in the Board's request for OMB approval.

DATES: Written comments are due on September 28, 2012.

ADDRESSES: Direct all comments to Marilyn Levitt, Surface Transportation Board, Suite 1260, 395 E Street SW., Washington, DC 20423–0001, or to *levittm@stb.dot.gov.* Comments should be identified as ''Paperwork Reduction Act Comments,'' and should refer to the title of the collection commented upon.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s) contact Paul Aguiar at (202) 245–0323 or *aguiarp@stb.dot.gov.* [Federal Information Relay Service (FIRS) for the hearing impaired: (800) 877–8339.]

Subjects: In this notice the Board is requesting comments on the following information collection:

Title: Rail Depreciation Studies.

OMB Control Number: 2140–XXXX.

Form Number: None.

Type of Review: Collection in existence without a Control Number.

Respondents: Class I railroads.

Number of Respondents: 7.

Estimated Time per Response: Between 500 and 540 hours annually, depending on whether the rail-carrier respondent has significant assistance from outside consultants, resulting in an average of 515 hours per response.

Frequency of Response: Every 3 years for equipment; every 6 years for other depreciable property.

Total Annual Hour Burden: 3,605 hours (515 hours × 7 Class I railroads).

Total Annual ''Non-Hour Burden'' Cost: Between $8,340 and $30,000 annually, depending on whether the rail-carrier respondent has significant assistance from outside consultants, resulting in an annual average of $20,500 and a cumulative total for all 7 Class I railroads of $143,500.

Needs and Uses: Under 49 U.S.C. 11145, the Board is required to identify those classes of property for which rail carriers may include depreciation charges under operating expenses and the Board must also prescribe a rate of depreciation that may be charged to those classes of property. Pursuant to the Board's authority under § 11145, Class I (large) rail carriers are required to submit to the Board Depreciation Studies. Information in these studies is not available from any other source. The Board uses the information in these studies to prescribe depreciation rates. These depreciation rate prescriptions state the period for which the depreciation rates therein are applicable. Class I railroads apply the prescribed depreciation rates to their investment base to determine monthly and annual depreciation expense. This expense is included in the railroads' operating expenses, which are reported

in their R–1 reports (OMB Control Number 2140–0009). Operating expenses are used to develop operating costs for application in various proceedings before the Board, such as in rate reasonableness cases and in the determination of railroad revenue adequacy.

SUPPLEMENTARY INFORMATION: Under the PRA, a Federal agency conducting or sponsoring a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Under § 3506(c)(2)(A) of the PRA, Federal agencies are required, prior to submitting a collection to OMB for approval, to provide a 60-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: July 24, 2012.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2012–18428 Filed 7–27–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 25, 2012.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 29, 2012 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Number: 1545–0132.

Type of Review: Extension without change of a currently approved collection.

Title: Amended U.S. Corporation Income Tax Return.

Form: 1120–X.

Abstract: Domestic corporations use Form 1120X to correct a previously filed Form 1120 or 1120A. The data is used to determine if the correct tax liability has been reported.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 300,582.

OMB Number: 1545–0140.

Type of Review: Extension without change of a currently approved collection.

Title: Form 2210, Underpayment of Estimated Tax by Individuals, Estate, and Trusts; Form 2210–F, Underpayment of Estimated Tax by Farmers and Fishermen.

Form: 2210, 2210–F.

Abstract: Internal Revenue Code section 6654 imposes a penalty for failure to pay estimated tax. These forms are used by taxpayers to determine whether they are subject to the penalty and to compute the penalty if it applies. The Service uses this information to determine whether the taxpayer is subject to the penalty, and to verify the penalty amount.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 2,405,663.

OMB Number: 1545–0820.

Type of Review: Extension without change of a currently approved collection.

Title: REG–122917–02 (Final) Statutory Options.

Abstract: The affected public includes corporations that transfer stock to employees after 1979 pursuant to the exercise of a statutory stock option. The corporation must furnish the employee receiving the stock with a written statement describing the transfer. The statement will assist the employee in filing their tax return.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 16,650.

OMB Number: 1545–1086.

Type of Review: Extension without change of a currently approved collection.

Title: Excise Tax on Greenmail.

Form: 8725.

Abstract: Form 8725 is used by persons who receive ''greenmail'' to compute and pay the excise tax on greenmail imposed under section 5881. IRS uses the information to verify that the correct amount of tax has been reported.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 92.

OMB Number: 1545–1225.

Type of Review: Extension without change of a currently approved collection.

Title: Notice of Plan Merger or Consolidation, Spinoff, or Transfer of Plan Assets or Liabilities; Notice of Qualified Separate Lines of Business.

Form: 5310–A.

Abstract: Plan administrators are required to notify IRS of any plan mergers, consolidations, spinoffs, or transfers of plan assets or liabilities to another plan. Employers are required to notify IRS of separate lines of business for their deferred compensation plans. Form 5310–A is used to make these notifications.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 158,800.

OMB Number: 1545–1227.

Type of Review: Extension without change of a currently approved collection.

Title: FI–104–90—Final Tax Treatment of Salvage and Reinsurance (TD 8390).

Abstract: The regulation provides a disclosure requirement for an insurance company that increases losses shown on its annual statement by the amount of estimated salvage recoverable taken into account.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 5,000.

OMB Number: 1545–1241.

Type of Review: Extension without change of a currently approved collection.

Title: PS–92–90 (TD 8395) Special Valuation Rules.

Abstract: Section 2701 of the Internal Revenue Code allows various elections by family members who make gifts of common stock or partnership interests and retain senior interest. The elections affect the value of the gifted interests and the retained interests. This document contains final regulations relating to chapter 14 of the Internal

Revenue Code as enacted in the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, 104 Stat. 1388. These regulations provide special valuation rules for purposes of Federal estate and gift taxes imposed under chapter 1 and 12 of the Code. In addition these regulations provide rules involving lapsing rights and other transactions that are treated as completed transfers under chapter 14.

Affected Public: Individuals or Households.

Estimated Total Burden Hours: 496.

OMB Number: 1545–1380.

Type of Review: Extension without change of a currently approved collection.

Title: IA–17–90 (TD 8571) Reporting Requirements for Recipients of Points Paid on Residential Mortgages.

Abstract: To encourage compliance with the tax laws relating to the mortgage interest deduction, the regulations require the reporting on Form 1098 of points paid on residential mortgage. Only businesses that receive mortgage interest in the course of a trade or business are affected by this reporting requirement.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 283,056.

OMB Number: 1545–1434.

Type of Review: Extension without change of a currently approved collection.

Title: CO–26–96 (TD 8825) Regulations Under Section 382 of the Internal Revenue Code of 1986; Application of Section 382 in Short Taxable Years and With Respect to Controlled Groups.

Abstract: Section 382 limits the amount of income that can be offset by loss carryovers after an ownership change. These regulations provide rules for applying section 382 in the case of short taxable years and with respect to controlled groups.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 875.

OMB Number: 1545–1516.

Type of Review: Revision of a currently approved collection.

Title: Entity Classification Election.

Form: 8832.

Abstract: An eligible entity that chooses not to be classified under the default rules or that wishes to change its current classification must file Form 8832 to elect a classification.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 35,900.

OMB Number: 1545–1536.

Type of Review: Extension without change of a currently approved collection.

Title: REG–209823–96 (TD 8791)—Guidance Regarding Charitable Remainder Trusts and Special Valuation Rules for Transfer of Interests in Trusts.

Abstract: The recordkeeping requirement in the regulation provides taxpayers with an alternative method for complying with Congressional intent regarding charitable remainder trusts. The recordkeeping alternative may be less burdensome for taxpayers.

Affected Public: Private Sector: Business or other for-profits.

Estimated Total Burden Hours: 75.

OMB Number: 1545–1822.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2003–11, Offshore Voluntary Compliance Initiative.

Abstract: Revenue Procedure 2003–11 describes the Offshore Voluntary Compliance Initiative, which is directed at taxpayers that have under-reported their tax liability through financial arrangements outside the United States that rely on the use of credit, debit, or charge cards (offshore credit cards) or foreign banks, financial institutions, corporations, partnership, trusts, or other entities (offshore financial arrangements). Taxpayers that participate in the initiative and provide the information and material that their participation requires can avoid certain penalties.

Affected Public: Individuals or Households.

Estimated Total Burden Hours: 100,000.

OMB Number: 1545–1952.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2005–50—Automatic Consent for Eligible Educational Institution to Change Reporting Methods.

Abstract: This revenue procedure prescribes how an eligible educational institution may obtain automatic consent from the Service to change its method of reporting under section 6050S of the Code and the Income Tax Regulations.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Burden Hours: 300.

OMB Number: 1545–1965.

Type of Review: Extension without change of a currently approved collection.

Title: REG–133446–03 (TD 9360)—Guidance on Passive Foreign Company (PFIC) Purging Elections.

Abstract: The IRS needs the information to substantiate the taxpayer's computation of the taxpayer's share of the PFIC's post-1986 earning and profits.

Affected Public: Individuals and Households.

Estimated Total Burden Hours: 250.

OMB Number: 1545–1979.

Type of Review: Extension without change of a currently approved collection.

Title: Energy Efficient New Home Credit.

Form: 8908.

Abstract: Contractors will use Form 8908 to claim the new energy efficient home credit for homes substantially completed after August 8, 2005, and sold for use as personal residences after January 1, 2006.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 512,820.

OMB Number: 1545–2126.

Type of Review: Extension without change of a currently approved collection.

Title: Credit for Employer Differential Wage Payments.

Form: 8932.

Abstract: Qualified employers will file Form 8932 to claim the credit for qualified differential wage payments paid to qualified employees after June 17, 2008, and before January 1, 2010.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 62,456.

OMB Number: 1545–2127.

Type of Review: Extension without change of a currently approved collection.

Title: Disqualified Corporate Interest Expense Disallowed Under Section 163(j) and Related Information.

Form: 8926.

Abstract: Pursuant to Congressional direction to determine whether the earnings stripping limitation rule of Code Section 163(j) was effective in curbing the erosion of the U.S. tax base, the Treasury created Form 8926, Disqualified Corporate Interest Expense Disallowed Under Section 163(j) and Related Information.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 7,560,000.

OMB Number: 1545–2226.

Type of Review: Extension without change of a currently approved collection.

Title: Work Opportunity Credit for Qualified Tax-Exempt Organizations Hiring Qualified Veterans.

Form: 5884–C.

Abstract: Form 5884–C was developed as a result of VOW to Hire Heroes Act of 2011, Public Law 112–56. Section 261 of Public Law 112–56 expanded the Work Opportunity Credit to tax-exempt organizations that hire unemployed veterans. The tax credit is a reduction in payroll taxes paid by the tax-exempt organization. Form 5884–C allows a tax-exempt organization a way to claim the credit and provides the IRS the information to process the tax credit.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Burden Hours: 397,683.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2012–18444 Filed 7–27–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 25, 2012.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before August 29, 2012 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden to the (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and the (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request may be found at *www.reginfo.gov*.

Financial Management Service (FMS)

OMB Number: 1510–0037.

Type of Review: Extension without change of a currently approved collection.

Title: Voucher for Payment of Awards.

Form: TFS 5135.

Abstract: Awards certified to Treasury are paid annually as funds are received from foreign governments. Vouchers are mailed to award-holders showing payments due. Award-holders sign vouchers certifying that he/she is entitled to payment.

Affected Public: Individuals or Households.

Estimated Total Burden Hours: 700.

OMB Number: 1510–0043.

Type of Review: Revision of a currently approved collection.

Title: Notice of Reclamation and Debit Request for Recurring Benefit Payments.

Form: FMS 133, 135.

Abstract: A program agency authorizes Treasury to recover payments that have been issued after the death of the beneficiary. FMS Form 133 is used to notify the financial institution. If the financial institution does not respond to the 133, a debit request (Form 135) is sent to the Federal Reserve Bank.

Affected Public: Private Sector; Businesses or other for-profits.

Estimated Total Burden Hours: 29,750.

OMB Number: 1510–0045.

Type of Review: Revision of a currently approved collection.

Title: Trace Request for EFT Payments.

Form: FMS 150–1, 150–2.

Abstract: Used to notify the financial institutions that a beneficiary has claimed non-receipt of credit for a payment. The form is designed to help the financial institution locate any problem and to keep the beneficiary informed of any action taken.

Affected Public: Private Sector; Businesses or other for-profits.

Estimated Total Burden Hours: 27,163.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2012–18462 Filed 7–27–12; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Federal Advisory Committee on Insurance

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of Open Meeting.

SUMMARY: The Department of the Treasury's Federal Advisory Committee on Insurance (FACI) will convene an open meeting on Monday, August 6, 2012 at the Department of the Treasury, Cash Room, 1500 Pennsylvania Avenue NW., Washington, DC, beginning at 1:30 p.m. Eastern Time. The meeting is open to the public and the site is accessible to individuals with disabilities.

In this meeting, the FACI members will follow up on the conclusions of the FACI meeting that occurred on March 30, 2012, and will provide direction on the expected work product of the Committee and each subcommittee, if any.

DATES: The meeting will be held on August 6, 2012, commencing at 1:30 p.m. Eastern Time.

Submission of Written Statements: The public is invited to submit written statements to the FACI. Written statements can be submitted by any of the following methods:

Electronic Statements

Email: FACI@treasury.gov, or

Paper Statements

Paper statements should be sent in triplicate to the Federal Advisory Committee on Insurance, Department of the Treasury, Room 2100, 1425 New York Avenue NW., Washington, DC 20220.

The Department of the Treasury will publish all statements in their original form on the Federal Insurance Office Web site, *http://www.treasury.gov/about/organizational-structure/offices/Pages/Federal-Insurance.aspx,* including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department of the Treasury will also make such statements available for public inspection and copying in the Department's Library, Room 1428, 1500 Pennsylvania Avenue NW., Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by calling (202) 622–0990. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: James P. Brown, Designated Federal Officer, Federal Advisory Committee on Insurance, Department of the Treasury, Room 2100, New York Avenue NW., Washington, DC 20220, at (202) 622–6910 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App. II, 10(a)(2), through implementing regulations at 41 CFR 102–3.150, James P. Brown, Designated Federal Officer of FACI, has ordered publication of this notice that the FACI will convene its quarterly meeting on Monday, August 6, 2012. The meeting will be held at the Department of the Treasury, Cash Room, 1500 Pennsylvania Avenue NW., Washington, DC 20220 at 1:30 p.m. Eastern Time.

The meeting will be held in a secured facility and members of the public who plan to attend the meeting must contact James P. Brown, the Designated Federal Officer, at (202) 622–6910 to provide the following information which is required to facilitate entry into the building: full name, organization represented (if any), date of birth, Social Security number, and country of citizenship. This information must be received by 5:00 p.m. Eastern Time on Monday, July 30, 2012. On the date of the meeting, attendees must present a government-issued photo ID, such as a driver's license or passport for entry into the building.

In this meeting, the FACI members will follow up on the conclusions of the FACI meeting that occurred on March 30, 2012, and will provide direction on the expected work product of the Committee and each subcommittee, if any. Due to the logistical difficulties of convening the members of the committee, the meeting is being announced with less than 15 days notice (see 41 CFR 102–3.150(b)).

Michael T. McRaith,

Director, Federal Insurance Office, Department of the Treasury.

[FR Doc. 2012–18460 Filed 7–27–12; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request

AGENCIES: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (collectively, the agencies) 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 Federal Financial Institutions Examination Council (FFIEC), of which the agencies are members, has approved the agencies' publication for public comment of a proposal to extend, with revision, the Foreign Branch Report of Condition (FFIEC 030 and FFIEC 030S), which is a currently approved information collection for each agency. The proposed panel changes would be effective for the FFIEC 030 and FFIEC 030S reports as of the December 31, 2012, report date. At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the FFIEC and the agencies should modify the proposed revisions prior to giving final approval. The agencies will then submit the proposed revisions to OMB for review and approval.

DATES: Comments must be submitted on or before September 28, 2012.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments should refer to the OMB control number and will be shared among the agencies.

OCC: You should direct all written comments to: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mailstop 2–3, Attention: 1557–0099, 250 E Street SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–5274, or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy the comments at the OCC, 250 E 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) 874–4700. 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.

Board: You may submit comments, identified by FFIEC 030 or FFIEC 030S, by any of the following methods:

- *Agency Web Site: www.federalreserve.gov.* Follow the instructions for submitting comments on the *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include the OMB control number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Jennifer J. Johnson, 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 *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* 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 MP–500 of the Board's Martin Building (20th and C Streets NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to ''Foreign Branch Report of Condition, 3064–0011,'' by any of the following methods:

- *Agency Web Site: www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@FDIC.gov.* Include ''Foreign Branch Report of Condition, 3064–0011'' in the subject line of the message.
- *Mail:* Gary A. Kuiper, (202) 898–3877, Counsel, Attn: Comments, Room NYA–5046, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *www.fdic.gov/regulations/laws/federal/notices/html* including any personal information provided. Comments may be inspected at the FDIC Public Information Center, Room E–1002, 3502 North Fairfax Drive, Arlington, VA 22226, between 9:00 a.m. and 5:00 p.m. on business days.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. 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: For further information about the revisions discussed in this notice, please contact any of the agency clearance officers whose names appear below. In addition, copies of the report forms can be obtained at the FFIEC's Web site (*http://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Mary H. Gottlieb, OCC Clearance Officer, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street SW., Washington, DC 20219.

Board: Cynthia Ayouch, Federal Reserve Board Clearance Officer, (202) 452–3829, Division of Research and Statistics, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Gary A. Kuiper, Counsel, (202) 898–3877, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to extend for three years, with revision, the following currently approved collection of information:

Report Title: Foreign Branch Report of Condition.

Form Numbers: FFIEC 030 and FFIEC 030S.

Frequency of Response: Annually, and quarterly for significant branches.

Affected Public: Business or other for profit.

OCC

OMB Number: 1557–0099.

Estimated Number of Respondents: 123 annual branch respondents (FFIEC 030). 310 quarterly branch respondents (FFIEC 030). 34 annual branch respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030). 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 4,651 burden hours.

Board

OMB Number: 7100–0071.

Estimated Number of Respondents: 22 annual branch respondents (FFIEC 030). 24 quarterly branch respondents (FFIEC 030). 14 annual branch respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030). 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 408 burden hours.

FDIC

OMB Number: 3064–0011.

Estimated Number of Respondents: 12 annual respondents (FFIEC 030). 3 quarterly respondents (FFIEC 030). 11 annual respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030). 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 87 burden hours.

General Description of Reports

This information collection is mandatory: 12 U.S.C. 321, 324, and 602 (Board); 12 U.S.C. 602 (OCC); and 12 U.S.C. 1828 (FDIC). This information collection is given confidential treatment pursuant to 5 U.S.C. 552(b)(8).

Abstract

The FFIEC 030 contains asset and liability information for foreign branches of insured U.S. banks and is required for regulatory and supervisory purposes. The information is used to analyze the foreign operations of U.S. banks. All foreign branches of U.S. banks regardless of charter type, file this report with the appropriate Federal Reserve District Bank. The Federal Reserve collects this information on behalf of the U.S. bank's primary federal bank regulatory agency. The FFIEC 030S contains five data items that branches with total assets between $50 million and $250 million file on an annual basis in lieu of the FFIEC 030 reporting form.

On July 21, 2011, supervisory responsibility for federal and state-chartered savings associations was transferred from the former Office of Thrift Supervision to the OCC and the FDIC, respectively, pursuant to Title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203. Accordingly, the Foreign Branch Report of Condition would be applicable to foreign branches, if any, of insured U.S. savings associations beginning as of the December 31, 2012, report date. No other changes are proposed to the FFIEC 030 or FFIEC 030S reporting forms or instructions.

Request for Comment

Public comment is requested on all aspects of this joint notice. Comments are invited on:

a. Whether the information collection is necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

b. The accuracy of the agencies' estimates of the burden of the 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 the 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 the requested information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record.

Subject: FFIEC 030 and FFIEC 030S.

Dated: July 18, 2012.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Subject: FFIEC 030 and FFIEC 030S.

Board of Governors of the Federal Reserve System, July 24, 2012.

Robert deV Frierson,

Deputy Secretary of the Board.

Subject: FFIEC 030 and FFIEC 030S.

Dated at Washington, DC, this 18th day of July 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–18498 Filed 7–27–12; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing the names of 10 individuals and nine entities whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (''Kingpin Act'') (21 U.S.C. §§ 1901–1908, 8 U.S.C. § 1182).

DATES: The designation by the Director of OFAC of the 10 individuals and nine entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on July 24, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department

of the Treasury, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site at *http://www.treasury.gov/ofac* or via facsimile through a 24-hour fax-on-demand service at (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On July 24, 2012, the Director of OFAC designated the following 10 individuals and nine entities whose property and interests in property are blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. ARAUJO MONZON, Elvira, Avenida Ramon Lopez Velarde No. 3240, Colonia Presidentes de Mexico, Culiacan, Sinaloa, Mexico; DOB 25 Jan 1961; POB Bacacoragua, Badiraguato, Sinaloa, Mexico; R.F.C. AAME610125–QP6 (Mexico); C.U.R.P. AAME610125MSLRNL05 (Mexico) (individual) [SDNTK] Linked To: ESTACIONES DE SERVICIOS CANARIAS, S.A. DE C.V.; Linked To: GASOLINERA ALAMOS COUNTRY, S.A. DE C.V.; Linked To: GASOLINERA Y SERVICIOS VILLABONITA, S.A. DE C.V.
2. ESPARRAGOZA GASTELUM, Nadia Patricia, Anillo de Periferico Sur No. 4863 Interior 902, Colonia Tepepan, Delegacion Tlalpan, Mexico City, Distrito Federal C.P. 14610, Mexico; Calle Chichen Itza No. 4644, Colonia Mirador del Sol, Zapopan, Jalisco C.P. 45054, Mexico; Calle Morelos No. 2223, Colonia Arcos Vallarta, Guadalajara, Jalisco C.P. 44130, Mexico; Avenida de la Patria No. 685 Interior 1, Fraccionamiento Jardines Universidad, Zapopan, Jalisco, Mexico; DOB 19 Apr 1976; POB Guadalajara, Jalisco, Mexico; R.F.C. EAGN760419LC8 (Mexico); C.U.R.P. EAGN760419MJCSSD05 (Mexico) (individual) [SDNTK] Linked To: GRUPO CINJAB, S.A. DE C.V.; Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
3. ESPARRAGOZA GASTELUM, Brenda Guadalupe, Calle Calkini Manzana 11 Lote 1, Colonia Residencia Sol del Mayab, Benito Juarez, Quintana Roo C.P. 77533, Mexico; Calle Morelos No. 2223, Colonia Arcos Vallarta, Guadalajara, Jalisco C.P. 44130, Mexico; Circuito Fuentes de Pedregal No. 478 Interior 1103, Colonia Fuentes de Pedregal, Delegacion Tlalpan, Mexico City, Distrito Federal C.P. 14140, Mexico; Avenida de la Patria No. 685 Interior 1, Fraccionamiento Jardines Universidad, Zapopan, Jalisco, Mexico; DOB 27 Mar 1978; POB Guadalajara, Jalisco, Mexico; R.F.C. EAGB780327UB5 (Mexico); C.U.R.P. EAGB780327MJCSSR11 (Mexico) (individual) [SDNTK] Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
4. ESPARRAGOZA GASTELUM, Juan Ignacio, Avenida de la Patria No. 685 Interior 1, Fraccionamiento Jardines Universidad, Zapopan, Jalisco, Mexico; Calle Gutierrez Zamora No. 223, Fraccionamiento Las Aguilas, Delegacion Alvaro Obregon, Mexico City, Distrito Federal C.P. 01020, Mexico; DOB 12 Nov 1972; POB San Luis Rio Colorado, Sinaloa, Mexico; R.F.C. EAGJ721112CI2 (Mexico) (individual) [SDNTK] Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
5. ESPARRAGOZA GASTELUM, Cristian Ivan, Avenida de la Patria No. 685 Interior 1, Fraccionamiento Jardines Universidad, Zapopan, Jalisco, Mexico; Calle Bulgaria No. 139 Interior 4, Colonia Portales, Delegacion Benito Juarez, Mexico City, Distrito Federal C.P. 03300, Mexico; Calle Rumania No. 10, Colonia Portales, Delegacion Benito Juarez, Mexico City, Distrito Federal C.P. 03300, Mexico; Calle Sierra Gorda No. 37 Interior 60, Colonia Lomas de Chapultepec, Delegacion Miguel Hidalgo, Mexico City, Distrito Federal C.P. 11000, Mexico; DOB 17 Jan 1981; POB Guadalajara, Jalisco, Mexico; R.F.C. EAGC810117AY8 (Mexico); C.U.R.P. EAGC810117HJCSSR07 (Mexico) (individual) [SDNTK] Linked To: GRUPO CINJAB, S.A. DE C.V.; Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
6. GASTELUM PAYAN, Maria Guadalupe, Avenida Camino a la Tijera No. 806, Fraccionamiento La Tijera, Tlajomulco de Zuniga, Jalisco, Mexico; Calle Chichen Itza No. 4644, Colonia Mirador del Sol, Zapopan, Jalisco C.P. 45054, Mexico; Calle Morelos No. 2223, Colonia Arcos Vallarta, Guadalajara, Jalisco C.P. 44130, Mexico; DOB 30 Aug 1949; POB Pericos, Sinaloa, Mexico; R.F.C. GAPG4908307H1 (Mexico); C.U.R.P. GAPG490830MSLSYD06 (Mexico) (individual) [SDNTK] Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
7. GONZALEZ PARADA, Juvencio Ignacio; DOB 09 Jan 1947; POB Tepeaca, Puebla, Mexico; C.U.R.P. GOPJ470109HPLNRV00 (Mexico) (individual) [SDNTK] Linked To: GRUPO CINJAB, S.A. DE C.V.; Linked To: GRUPO IMPERGOZA, S.A. DE C.V.
8. GUZMAN OCHOA, Ulises, Calle Golfo de California No. 1585, Colonia Nuevo Culiacan, Culiacan, Sinaloa, Mexico; DOB 03 Jun 1975; POB Culiacan, Sinaloa, Mexico; C.U.R.P. GUOU750603HSLZCL08 (Mexico) (individual) [SDNTK] Linked To: GASODIESEL Y SERVICIOS ANCONA, S.A. DE C.V.; Linked To: GASOLINERA ALAMOS COUNTRY, S.A. DE C.V.; Linked To: GASOLINERA Y SERVICIOS VILLABONITA, S.A. DE C.V.; Linked To: PETROBARRANCOS, S.A. DE C.V.; Linked To: SERVICIOS CHULAVISTA, S.A. DE C.V.
9. MONZON ARAUJO, Ofelia, Calle Bahia de Topolobampo No. 1628, Colonia Nuevo Culiacan, Culiacan, Sinaloa, Mexico; Boulevard Pedro Infante No. 3050, Colonia Recursos Hidraulicos, Culiacan, Sinaloa C.P. 80100, Mexico; DOB 06 Apr 1952; alt. DOB 06 Apr 1953; POB Bacacoragua, Badiraguato, Sinaloa, Mexico; R.F.C.

MOAO520406F27 (Mexico); alt. R.F.C. MOAO–530406 (Mexico); C.U.R.P. MOAO520406MSLNRF03 (Mexico) (individual) [SDNTK] Linked To: ESTACIONES DE SERVICIOS CANARIAS, S.A. DE C.V.; Linked To: GASOLINERA ALAMOS COUNTRY, S.A. DE C.V.; Linked To: GASOLINERA Y SERVICIOS VILLABONITA, S.A. DE C.V.

10. PONCE FELIX, Martin Humberto, Calle Rodolfo G. Robles No. 40, Colonia Centro, Culiacan, Sinaloa, Mexico; Calle Jardines No. 2413 Interior 27, Colonia Los Patios, Culiacan, Sinaloa C.P. 80100, Mexico; DOB 04 Sep 1964; POB Culiacan, Sinaloa, Mexico; R.F.C. POFM640904874 (Mexico); C.U.R.P. POFM640904HSLNLR08 (Mexico) (individual) [SDNTK] Linked To: BUENOS AIRES SERVICIOS, S.A. DE C.V.; Linked To: ESTACIONES DE SERVICIOS CANARIAS, S.A. DE C.V.; Linked To: GASODIESEL Y SERVICIOS ANCONA, S.A. DE C.V.; Linked To: SERVICIOS CHULAVISTA, S.A. DE C.V.

Entities

1. BUENOS AIRES SERVICIOS, S.A. DE C.V., Blvd. Guillermo Batiz Paredes No. 1100, Col. Buenos Aires, Culiacan, Sinaloa C.P. 80199, Mexico; R.F.C. BAS–960417–PY6 (Mexico) [SDNTK].
2. ESTACIONES DE SERVICIOS CANARIAS, S.A. DE C.V., Blvd. Enrique Felix Castro No. 1029, Col. Desarrollo Urbano Tres Rios, Culiacan, Sinaloa C.P. 80020, Mexico; R.F.C. ESC–100224–2J9 (Mexico) [SDNTK].
3. GASODIESEL Y SERVICIOS ANCONA, S.A. DE C.V., Manuel J. Clouthier No. 1800, Col. Libertad, Culiacan, Sinaloa C.P. 80180, Mexico; R.F.C. GSA–100223–M92 (Mexico) [SDNTK].
4. GASOLINERA ALAMOS COUNTRY, S.A. DE C.V., Blvd. Pedro Infante No. 3050, Col. Recursos Hidraulicos, Culiacan, Sinaloa C.P. 80100, Mexico; R.F.C. GAC–100224–GDA (Mexico) [SDNTK].
5. GASOLINERA Y SERVICIOS VILLABONITA, S.A. DE C.V., Av. Alvaro Obregon No. 6040, Col. Villa Bonita, Culiacan, Sinaloa C.P. 80000, Mexico; R.F.C. GSV–100224–773 (Mexico) [SDNTK].
6. GRUPO CINJAB, S.A. DE C.V. (a.k.a. PROVENZA RESIDENCIAL), Av. Adolfo Lopez Mateos No. 5555, Col. Santa Anita, Tlajomulco de Zuniga, Jalisco C.P. 46645, Mexico; R.F.C. GCI–080604–891 (Mexico) [SDNTK].
7. GRUPO IMPERGOZA, S.A. DE C.V. (a.k.a. LA TIJERA PARQUE INDUSTRIAL; a.k.a. PROVENZA CENTER), Av. Adolfo Lopez Mateos No. 5565, Col. Santa Anita, Tlajomulco de Zuniga, Jalisco C.P. 46645, Mexico; Av. Camino A La Tijera No. 806, Col. La Tijera, Tlajomulco de Zuniga, Jalisco C.P. 45645, Mexico; R.F.C. GIM–081015–SIA (Mexico) [SDNTK].
8. PETROBARRANCOS, S.A. DE C.V., Av. Benjamin Hill No. 5602, Col. Industrial el Palmito, Culiacan, Sinaloa C.P. 80160, Mexico; R.F.C. PET–990309–G64 (Mexico) [SDNTK].
9. SERVICIOS CHULAVISTA, S.A. DE C.V., Blvd. Las Torres No. 2622 Pte., Fracc. Prados del Sol, Culiacan, Sinaloa C.P. 80197, Mexico; Calzada Las Torres S/N, Col. Prados del Sol Etapa 1, Culiacan, Sinaloa, Mexico; R.F.C. SCU–070904–T25 (Mexico) [SDNTK].

Dated: July 24, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2012–18485 Filed 7–27–12; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons Pursuant to the Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing the names of ten individuals and nine entities whose property and interests in property have been unblocked pursuant to the Foreign Narcotics Kingpin Designation Act (''Kingpin Act'') (21 U.S.C. Sections 1901–1908, 8 U.S.C. Section 1182).

DATES: The unblocking and removal from the list of Specially Designated Nationals and Blocked Persons (''SDN List'') of the ten individuals and nine entities identified in this notice whose property and interests in property were blocked pursuant to the Kingpin Act, is effective on July 24, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622–2420.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at *www.treasury.gov/ofac* or via facsimile through a 24-hour fax-on demand service at (202) 622–0077.

Background

On December 3, 1999, the Kingpin Act was signed into law by the President of the United States. The Kingpin Act provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and to the benefits of trade and transactions involving U.S. persons and entities.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property or interests in property, subject to U.S. jurisdiction, of persons or entities found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; and/or (3) playing a significant role in international narcotics trafficking.

On July 24, 2012, the Director of OFAC removed from the SDN List the ten individuals and nine entities listed below, whose property and interests in property were blocked pursuant to the Kingpin Act:

Individuals

1. ARANGO MADRIGAL, Hernan Dario, c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o INVARA S.C.S., Bogota, Colombia; c/o PANOS Y SEDAS LTDA., Bogota, Colombia; Carrera 31 No. 74A–16, Bogota, Colombia; DOB 20 Mar 1952; POB Yarumal, Antioquia, Colombia; Cedula No. 19186993 (Colombia) (individual) [SDNTK]

2. BARROSO DEGOLLADO, Javier, c/o ILC EXPORTACIONES, S. DE R.L. DE C.V., Mexico, Distrito Federal, Mexico; DOB 26 Jul 1950; POB Mexico, D.F., Mexico; citizen Mexico; nationality Mexico (individual) [SDNTK]
3. BERNAL BERNAL, Liliana, c/o COLPRETINAS LTDA., Bogota, Colombia; c/o CRIADERO EL TAMBO LTDA., Bogota, Colombia; c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o DISCO S.A., Cota, Cundinamarca, Colombia; c/o JESBEL Y CIA. S. EN C., Cota, Cundinamarca, Colombia; DOB 23 Feb 1973; Cedula No. 52056898 (Colombia) (individual) [SDNTK]
4. BERNAL BERNAL, Lina Maria, c/o T PLUS S.A.S., Cota, Cundinamarca, Colombia; DOB 01 Jul 1984; Cedula No. 52818850 (Colombia) (individual) [SDNTK]
5. BERNAL BERNAL, Luis Fernando, c/o COLPRETINAS LTDA., Bogota, Colombia; c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o DISCO S.A., Cota, Cundinamarca, Colombia; c/o JESBEL Y CIA. S. EN C., Cota, Cundinamarca, Colombia; c/o TEXTILES MODA NOVA LTDA., Bogota, Colombia; DOB 21 Jan 1971; Cedula No. 79187117 (Colombia) (individual) [SDNTK]
6. BERNAL DE BERNAL, Beatriz Eugenia (a.k.a. BERNAL BOTERO, Beatriz Eugenia), c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o DISCO S.A., Cota, Cundinamarca, Colombia; c/o JESBEL Y CIA. S. EN C., Cota, Cundinamarca, Colombia; c/o TEXTILES MODA NOVA LTDA., Bogota, Colombia; DOB 24 Sep 1948; POB La Ceja, Antioquia, Colombia; Cedula No. 41420126 (Colombia) (individual) [SDNTK]
7. BERNAL LONDONO, Jesus Antonio, c/o CRIADERO EL TAMBO LTDA., Bogota, Colombia; c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o DISCO S.A., Cota, Cundinamarca, Colombia; c/o JESBEL Y CIA. S. EN C., Cota, Cundinamarca, Colombia; Calle 56 No. 38–23 Apto. 501, Bogota, Colombia; DOB 10 Apr 1943; POB La Ceja, Antioquia, Colombia; Cedula No. 2911166 (Colombia) (individual) [SDNTK]
8. BOLANOS VITAL, Raul, c/o ILC EXPORTACIONES, S. DE R.L. DE C.V., Mexico, Distrito Federal, Mexico; DOB 26 Dec 1962; POB Mexico, D.F., Mexico; citizen Mexico; nationality Mexico (individual) [SDNTK]
9. LOMELIN MARTINEZ, Arturo, c/o ILC EXPORTACIONES, S. DE R.L. DE C.V., Mexico, Distrito Federal, Mexico; DOB 30 Jun 1947; POB Mexico, Distrito Federal, Mexico; citizen Mexico; nationality Mexico; C.U.R.P. LOMA470630HGTMRR08 (Mexico) (individual) [SDNTK]
10. VELEZ MURILLO, Uberney, c/o CULTIVAR S.A., Fuente de Oro, Meta, Colombia; c/o INVERSIONES AGROINDUSTRIALES DEL ORIENTE LTDA., Granada, Meta, Colombia; Carrera 39B No. 24–21 Casa 9, Villavicencio, Colombia; DOB 05 Sep 1962; POB Fuentedeoro, Meta, Colombia; Cedula No. 86030095 (Colombia) (individual) [SDNTK]

Entities

1. COLPRETINAS LTDA. (a.k.a. CP TEXTILES), Carrera 13 No. 17–55, Bogota, Colombia; NIT # 830034149–6 (Colombia) [SDNTK]
2. CRIADERO EL TAMBO LTDA., Carrera 13 No. 17–55, Bogota,
3. CULTIVAR S.A., Carrera 14 No. 9–04, Fuente de Oro, Meta, Colombia; NIT # 822007334–9 (Colombia) [SDNTK]
4. DISCO S.A., Km. 3.5 Autop. Medellin Via Siberia Costado Sur Terminal Terrestre de Carga Bloque 4 Bod. 32, Cota, Cundinamarca, Colombia; NIT # 860517890–9 (Colombia) [SDNTK]
5. INVARA S.C.S., Carrera 9A No. 12–61 p. 4, Bogota, Colombia; NIT # 800162357–0 (Colombia) [SDNTK]
6. JESBEL Y CIA. S. EN C., Km. 3.5 Autop. Medellin Via Siberia Costado Sur Terminal Terrestre de Carga Bloque 4 Bod. 32, Cota, Cundinamarca, Colombia; NIT # 860522569–9 (Colombia) [SDNTK]
7. PANOS Y SEDAS LTDA. (a.k.a. TELARAMA A Y S), Carrera 9 No. 12–61, Bogota, Colombia; NIT # 830070893–0 (Colombia) [SDNTK]
8. T PLUS S.A.S., Km. 3.5 Autop. Medellin Via Siberia Costado Sur Terminal, Terrestre de Carga Bloque 4 Bod. 32, Cota, Cundinamarca, Colombia; NIT # 900345355–5 (Colombia) [SDNTK]
9. TEXTILES MODA NOVA LTDA., Carrera 13 No. 17–55 piso 2, Bogota, Colombia; NIT # 830072066–5 (Colombia) [SDNTK]

Dated: July 24, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2012–18481 Filed 7–27–12; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons Pursuant to Executive Order 12978

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is publishing the names of nine individuals and four entities whose property and interests in property have been unblocked pursuant to Executive Order 12978 of October 21, 1995, ''Blocking Assets and Prohibiting Transactions With Significant Narcotics Traffickers''.

DATES: The unblocking and removal from the list of Specially Designated Nationals and Blocked Persons (''SDN List'') of the nine individuals and four entities identified in this notice whose property and interests in property were blocked pursuant to Executive Order 12978 of October 21, 1995, is effective on July 24, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*) or via facsimile through a 24-hour fax-on demand service at (202) 622–0077.

Background

On October 21, 1995, the President, invoking the authority, *inter alia,* of the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (''IEEPA''), issued Executive Order 12978 (60 FR 54579, October 24, 1995) (the ''Order''). In the Order, the President declared a national emergency to deal with the threat posed by significant foreign narcotics traffickers centered in Colombia and the harm that they cause in the United States and abroad.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons, of: (1) The foreign persons listed in an Annex

to the Order; (2) any foreign person determined by the Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State: (a) To play a significant role in international narcotics trafficking centered in Colombia; or (b) to materially assist in, or provide financial or technological support for or goods or services in support of, the narcotics trafficking activities of persons designated in or pursuant to the Order; and (3) persons determined by the Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State, to be owned or controlled by, or to act for or on behalf of, persons designated pursuant to the Order.

On July 24, 2012, the Director of OFAC removed from the SDN List the individuals and entities listed below, whose property and interests in property were blocked pursuant to the Order:

Individuals

1. CLAVIJO GARCIA, Hector Augusto, c/o GANADERIAS DEL VALLE S.A., Cali, Colombia; DOB 15 Dec 1958; Cedula No. 16613930 (Colombia) (individual) [SDNT]
2. DOMINGUEZ VELEZ, Jorge Enrique (a.k.a. ''EL ONLI''), c/o ERA DE LUZ LTDA. LIBRERIA CAFE, Cali, Colombia; DOB 09 Aug 1968; Cedula No. 16767305 (Colombia) (individual) [SDNT]
3. GALLEGO RAMOS, Luis Alfredo, Calle 83 No. 14–130, Cali, Colombia; c/o INTERCONTINENTAL DE AVIACION S.A., Bogota, Colombia; c/o AEROVIAS ATLANTICO LTDA., Bogota, Colombia; c/o AEROCOMERCIAL ALAS DE COLOMBIA LTDA., Bogota, Colombia; c/o GREEN ISLAND S.A., Bogota, Colombia; DOB 07 Aug 1954; POB Cali, Colombia; Cedula No. 16585721 (Colombia); Passport AF783512 (Colombia); alt. Passport AE187469 (Colombia); alt. Passport 16585721 (Colombia) (individual) [SDNT]
4. OSPINA PRADA, Maria del Carmen, c/o INVERSIONES INMOBILIARIA QUILICHAO S.A. Y CIA S.C.A., Cali, Colombia; c/o MIRACANA INMOBILIARIA QUILCHAO S.A. & CIA S.C.A., Cali, Colombia; Calle 98 No. 9–41, Apt. 1102, Bogota, Colombia; DOB 04 Jul 1953; POB San Luis, Tolima, Colombia; nationality Colombia; citizen Colombia; Cedula No. 41700627 (Colombia); Passport AH715906 (Colombia); alt. Passport AH456850 (Colombia) (individual) [SDNT]
5. RAMIREZ RIVERA, Sergio Alberto, Cali, Colombia; DOB 14 Jan 1964; POB Cali, Colombia; Cedula No. 16694220 (Colombia); Passport AF771317 (Colombia) (individual) [SDNT]
6. RESTREPO CLAVIJO, Carlos Umberto (a.k.a. RESTREPO CLAVIJO, Carlos Huberto; a.k.a. RESTREPO CLAVIJO, Carlos Humberto), Calle 8 No. 4–47, Cartago, Valle, Colombia; Cedula No. 16205322 (Colombia) (individual) [SDNT]
7. SANDOVAL SALAZAR, Ricardo, c/o AGROPECUARIA LINDARAJA S.A., Cali, Colombia; c/o TARRITOS S.A., Cali, Colombia; Cedula No. 16683550 (Colombia) (individual) [SDNT]
8. TORRES MORENO, Marisol, c/o PROVIDA E.U., Cali, Colombia; DOB 10 May 1969; Cedula No. 31992583 (Colombia); Passport 31992583 (Colombia) (individual) [SDNT]
9. ZAMBRANO MADRONERO, Carmen Alicia, c/o COSMEPOP, Bogota, Colombia; c/o PATENTES MARCAS Y REGISTROS S.A., Bogota, Colombia; c/o COPSERVIR LTDA., Bogota, Colombia; c/o CREDISOL, Bogota, Colombia; c/o DROMARCA Y CIA S.C.S., Bogota, Colombia; c/o FARMACOOP, Bogota, Colombia; c/o GLAJAN S.A., Bogota, Colombia; c/o SHARPER S.A., Bogota, Colombia; DOB 18 Nov 1967; Cedula No. 30738265 (Colombia); Passport 30738265 (individual) [SDNT]

Entities

1. C A V J CORPORATION LTDA., Calle 166 No. 38–50, Bogota, Colombia; NIT #830101426–9 (Colombia) [SDNT]
2. C.A.V.J. CORPORATION, Avenida 20 (detras del Country Club), Edificio Drcenca Barquisimeto, Lara, Venezuela; Calle 18, Zona Industrial 1, Intercomunal de Cabudare Barquisimeto, Lara, Venezuela; Calle 14, Zona Industrial 1, Intercomunal de Cabudare Barquisimeto, Lara, Venezuela; RIF #J–30460672–9 (Venezuela) [SDNT]
3. ERA DE LUZ LTDA. LIBRERIA CAFE, Calle 16 No. 100–98, Cali, Colombia; NIT #805015908–8 (Colombia) [SDNT]
4. VOL PHARMACYA LTDA. (a.k.a. VOL PHARMACIA LTDA.), Calle 12 No. 8–34/36, Cucuta, Colombia; NIT #807005617–4 (Colombia) [SDNT]

Dated: July 24, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2012–18484 Filed 7–27–12; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415 *et al.*

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, 421, 423, 425, 486, and 495

[CMS–1590–P]

RIN 0938–AR11

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule, payments for Part B drugs, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It would also implement provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it would implement statutory changes regarding the termination of non-random prepayment review under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Finally, this proposed rule also includes a discussion regarding the Chiropractic Services Demonstration program.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1590–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''submitting a comment.''

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–1590–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1590–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Corinne Axelrod, (410) 786–5620, for any physician payment issue not identified below.

Ryan Howe, (410) 786–3355, for issues related to practice expense methodology and direct practice expense inputs, telehealth services, and issues related to primary care and care coordination.

Sara Vitolo, (410) 786–5714, for issues related to potentially misvalued services, malpractice RVUs, molecular pathology, and payment for new preventive service HCPCS G-codes.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction and payment for the technical component of pathology services.

Michael Moore, (410) 786–6830, for issues related to geographic practice cost indices and the sustainable growth rate.

Pam West, (410) 786–2302, for issues related to therapy services.

Chava Sheffield, (410) 786–2298, for issues related to certified registered nurse anesthetists.

Roberta Epps, (410) 786–4503, for issues related to portable x-ray.

Anne Tayloe-Hauswald, (410) 786–4546, for issues related to ambulance fee schedule and Part B drug payment.

Amanda Burd, (410) 786–2074, for issues related to the DME provisions.

Debbie Skinner, (410) 786–7480, for issues related to non-random prepayment complex medical review.

Latesha Walker, (410) 786–1101, for issues related to ambulance coverage-physician certification statement.

Alexandra Mugge, (410) 786–4457, for issues related to physician compare.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system, incentives for e-prescribing, and Medicare shared savings program.

Pauline Lapin, (410) 786–6883, for issues related to the chiropractic services demonstration budget neutrality issue.

Gift Tee, (410) 786–9316, for issues related to the Physician Feedback Reporting Program and Value-Based Payment Modifier.

Jamie Hermansen, (410) 786–2064, for issues related to Medicare coverage for hepatitis B vaccine.

Andrew Morgan, (410) 786–2543, for issues related to e-prescribing under Medicare Part D.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

Because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AHRQ [HHS] Agency for Healthcare Research and Quality
AMA American Medical Association
AMA RUC AMA [Specialty Society] Relative [Value] Update Committee
ARRA American Recovery and Reinvestment Act (Pub. L. 111–5)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLS Bureau of Labor Statistics
BN Budget neutrality
CAH Critical access hospital
CBSA Core-Based Statistical Area
CF Conversion factor
CFC Conditions for Coverage
CFR Code of Federal Regulations
CNS Clinical nurse specialist
CoPs Conditions of Participation
CORF Comprehensive Outpatient Rehabilitation Facility
CPI Consumer Price Index
CPT [Physicians] Current Procedural Terminology *(CPT codes, descriptions and other data only are copyright 2011 American Medical Association. All rights reserved.)*
CRNA Certified registered nurse anesthetist
CY Calendar year
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DOTPA Development of Outpatient Therapy Payment Alternatives
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
E/M Evaluation and management
EHR Electronic health record
EMTALA Emergency Medical Treatment and Active Labor Act (part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272)
eRx Electronic prescribing
FFS Fee-for-service
FR **Federal Register**
GAF Geographic adjustment factor
GAO [U.S.] Government Accountability Office
GPRO Group Practice Reporting Option
GPCI Geographic practice cost index
HAC Hospital-acquired conditions
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HIT Health information technology
HITECH Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of Division A of the Recovery Act)
HPSA Health Professional Shortage Area
ICD International Classification of Diseases
IMRT Intensity Modulated Radiation Therapy
IOM Internet-only Manual
IPCI Indirect practice cost index
IPPS Inpatient prospective payment system
IWPUT Intra-service work per unit of time
MAC Medicare Administrative Contractor
MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96)
MedCAC Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC))
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MIEA–TRHCA Medicare Improvements and Extension Act of 2006 (that is, Division B of the Tax Relief and Health Care Act of 2006) (TRHCA) (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MMEA Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173)
MP Malpractice
MPPR Multiple procedure payment reduction
MQSA Mammography Quality Standards Act of 1992 (Pub. L. 102–539)
NP Nurse practitioner
NPP Nonphysician practitioner
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act (Pub. L. 101–239)
OIG [HHS] Office of Inspector General
PA Physician assistant
PC Professional component
PE Practice expense
PE/HR Practice expense per hour
PERC Practice Expense Review Committee
PFS Physician Fee Schedule
PGP [Medicare] Physician Group Practice
PLI Professional liability insurance
PPS Prospective payment system
PQRS Physician Quality Reporting System
PRA Paperwork Reduction Act
PPTRA Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111–286)
PVBP Physician and Other Health Professional Value-Based Purchasing Workgroup
RAC [Medicare] Recovery Audit Contractor
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RVU Relative value unit
SBRT Stereotactic body radiation therapy
SGR Sustainable growth rate
TC Technical component
TIN Tax identification number
TPTCCA Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L.112–78)
TRHCA Tax Relief and Health Care Act of 2006 (Pub. L. 109–432)
VBP Value-based purchasing

Addenda Available Only Through the Internet on the CMS Web site

In the past, the Addenda referred to throughout the preamble of our annual PFS proposed and final rules with comment period were included in the printed **Federal Register**. However, effective with the CY 2012 PFS proposed rule, the PFS Addenda no longer appear in the **Federal Register**. Instead these Addenda to the annual proposed and final rules with comment period will be available only through the Internet. The PFS Addenda along with other supporting documents and tables referenced in this proposed rule with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2013 PFS proposed rule with comment period, refer to item CMS–1590–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule with comment period and posted on the CMS Web site identified above should contact Corinne Axelrod at (410) 786–5620.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2011 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule would revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 2013. It also would implement provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it would implement statutory changes regarding the termination of non-random prepayment review.

2. Summary of the Major Provisions

The Social Security Act (Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) and the relative resources used in furnishing a service. The Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice (MP) expense. In this major proposed rule, we propose payment rates for CY 2013 for the PFS, payments for Part B drugs, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also proposes to implement provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items, and by removing certain regulations regarding the termination of non-random prepayment review. It also proposes new claims-based data reporting requirements for therapy services to implement a provision in the Middle Class Tax Relief and Jobs Creation Act (MCTRCA). In addition, this rule proposes:

- Potentially Misvalued Codes to be Evaluated.
- Additional Multiple Procedure Payment Reductions (MPPR).
- Expanding Medicare Telehealth Services.
- Regulatory Changes regarding Payment for Technical Component of Certain Physician Pathology Services to Conform to Statute.
- Primary Care and Care Coordination Service.
- Payment rates for Newly Covered Preventive Services.
- Definition of Anesthesia and Related Care in the Certified Registered Nurse Anesthetists Benefit.
- Ordering Requirements for Portable X-ray Services.
- Updates to the Ambulance Fee Schedule.
- Part B Drug Payment Rates.
- Ambulance Coverage-Physician Certification Statement.
- Updating the—
  - ++ Physician Compare Web site.
  - ++ Physician Quality Reporting System.
  - ++ Electronic Prescribing (eRx) Incentive Program.
  - ++ Medicare Shared Savings Program.
- Providing Budget Neutrality Discussion on the Chiropractic Demonstration.
- Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program.
- Medicare Coverage of Hepatitis B Vaccine.
- Updating Existing Standards for e-prescribing under Medicare Part D and Lifting the LTC Exemption.

3. Summary of Costs and Benefits

The statute requires that we establish by regulation each year payment amounts for all physicians' service. These payment amounts are required to be adjusted to reflect the variations in the costs of providing services in different geographic areas. The statute also requires that annual adjustments to PFS RVUs not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality.

Several proposed changes would affect the specialty distribution of Medicare expenditures. This proposed rule reflects the Administration's priority on improving payment for primary care services. Overall, payments for primary care specialties would increase and payments to select other specialties would decrease due to several changes in how we propose to calculate payments for CY 2013. Primary care payments would increase because of a proposed payment for managing a beneficiary's care when the beneficiary is discharged from an inpatient hospital, a SNF, an outpatient hospital observation, partial hospitalization services, or a community mental health center. Primary care payments also would increase due to redistributions from proposed reductions in payments for other specialties. Because of the budget-neutral nature of this system, proposed decreases in payments in one service result in proposed increases in payments in others.

Payments to primary care specialties are also impacted by the completion of the 4-year transition to new PE RVUs using the new Physician Practice Information Survey (PPIS) data that was adopted in the CY 2010 PFS final rule with comment period. The projected impacts of using the new PPIS data are generally consistent with the impacts discussed in the CY 2012 final rule with comment period (76 FR 72452).

Proposed changes in how we calculate payment when certain services are furnished together would result in reductions in total payments projected to cardiologists and ophthalmologists. Capital-intensive specialties are projected to decrease due to proposed

changes in how the interest rate used in the PE calculation is estimated. Also, under our potentially misvalued codes initiative, we propose to adjust the payment rates for two common radiation oncology treatment delivery methods, intensity-modulated radiation treatment (IMRT), and stereotactic body radiation therapy (SBRT) to reflect more realistic time projections based upon publicly available data. The combined effect of the PPIS transition and the latter two proposals would be a reduction in payments to radiation therapy centers and radiation oncology.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The Act requires that CMS make payments under the PFS using national uniform relative value units (RVUs) based on the relative resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, PE, and MP expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges. We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, psychologists, or clinical social workers) who are permitted to bill Medicare under the PFS for their services.

1. Development of the Relative Value System

a. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101–239), and OBRA 1990, (Pub. L. 101–508). The final rule published on November 25, 1991 (56 FR 59502) set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges.

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal government, and obtained input from numerous physician specialty groups.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. We established a separate CF for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC).

b. Practice Expense Relative Value Units (PE RVUs)

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), amended section 1848(c)(2)(C)(ii) of the Act to delay implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based PE RVUs to resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians'service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 2002.

This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysician health professionals (for example, registered nurses (RNs)) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians' service. (We have since refined and revised these inputs based on recommendations from the AMA RUC.) The SMS data provided aggregate specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be furnished in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department (HOPD). The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of furnishing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect PEs of furnishing a particular service.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed in CY 2010. Direct PE RVUs were calculated for CY 2013 using this methodology, unless otherwise noted.

In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). For this update, we used the Physician Practice Information Survey

(PPIS) conducted by the AMA. The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) using a survey instrument and methods highly consistent with those of the SMS and the supplemental surveys used prior to CY 2010. We note that in CY 2010, for oncology, clinical laboratories, and independent diagnostic testing facilities (IDTFs), we continued to use the supplemental survey data to determine PE/HR values (74 FR 61752). Beginning in CY 2010, we provided for a 4-year transition for the new PE RVUs using the updated PE/HR data. In CY 2013, the final year of the transition, PE RVUs are calculated based on the new data.

c. Resource-Based Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act requires that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs were based on malpractice insurance premium data collected from commercial and physician-owned insurers from all the States, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently.

The First Five-Year Review of Work RVUs was published on November 22, 1996 (61 FR 59489) and was effective in 1997. The Second Five-Year Review of Work RVUs was published in the CY 2002 PFS final rule with comment period (66 FR 55246) and was effective in 2002. The Third Five-Year Review of Work RVUs was published in the CY 2007 PFS final rule with comment period (71 FR 69624) and was effective on January 1, 2007. The Fourth Five-Year Review of Work RVUs was published in the CY 2012 PFS final rule with comment period (76 FR 73026).

Initially refinements to the direct PE inputs relied on input from the AMA RUC-established the Practice Expense Advisory Committee (PEAC). Through March 2004, the PEAC provided recommendations to CMS for more than 7,600 codes (all but a few hundred of the codes included in the AMAs Current Procedural Terminology (CPT) codes). As part of the CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new bottom-up methodology for determining resource-based PE RVUs and transitioned the new methodology over a 4-year period. A comprehensive review of PE was undertaken prior to the 4-year transition period for the new PE methodology from the top-down to the bottom-up methodology, and this transition was completed in CY 2010. In CY 2010, we also incorporated the new PPIS data to update the specialty-specific PE/HR data used to develop PE RVUs, adopting a 4-year transition to PE RVUs developed using the PPIS data.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the first Five-Year Review of the MP RVUs (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). The second Five-Year Review and update of resource-based malpractice RVUs was published in the CY 2010 PFS final rule with comment period (74 FR 61758) and was effective in CY 2010.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to Section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes with an emphasis on the following categories: (1) Codes and families of codes for which there has been the fastest growth; (2) codes or families of codes that have experienced substantial changes in PEs; (3) codes that are recently established for new technologies or services; (4) multiple codes that are frequently billed in conjunction with furnishing a single service; (5) codes with low relative values, particularly those that are often billed multiple times for a single treatment; (6) codes which have not been subject to review since the implementation of the fee schedule (the so-called ''Harvard valued codes''); and (7) other codes determined to be appropriate by the Secretary.

e. Application of Budget Neutrality to Adjustments of RVUs

Budget neutrality (BN) typically requires that expenditures not increase or decrease as a result of changes or revisions to policy. However, section 1848(c)(2)(B)(ii)(II) of the Act requires adjustment only if the change in expenditures resulting from the annual revisions to the PFS exceeds a threshold amount. Specifically, adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Components of the Fee Schedule Payment Amounts

To calculate the payment for each physicians' service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs). The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated by CMS' Office of the Actuary (OACT).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}.$$

3. Most Recent Changes to the Fee Schedule

The CY 2012 PFS final rule with comment period (76 FR 73026) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2011 interim RVUs and implemented interim RVUs for new and revised codes for CY 2012 to ensure that our payment systems are updated to reflect changes in medical practice and the relative values of services. The CY 2012 PFS final rule with comment period also addressed other policies including certain statutory provisions including provisions of the Affordable Care Act and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

In the CY 2012 PFS final rule with comment period, we announced the

following for CY 2012: the total PFS update of −27.4 percent; the initial estimate for the sustainable growth rate (SGR) of −16.9 percent; and the conversion factor (CF) of $24.6712. These figures were calculated based on the statutory provisions in effect on November 1, 2011, when the CY 2012 PFS final rule with comment period was issued.

A correction notice was issued (77 FR 227) to correct several technical and typographical errors that occurred in the CY 2012 PFS final rule with comment period.

On December 23, 2011, the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112–78) was signed into law. Section 301 of the TPTCCA specified a zero percent update to the PFS claims from January 1, 2012 through February 29, 2012. As a result, the CY 2012 PFS conversion factor was revised to $34.0376 for claims with dates of service on or after January 1, 2012 through February 29, 2012. In addition, TPTCCA extended several provisions affecting Medicare services furnished on or after January 1, 2012 through February 29, 2012, including:

- Section 303—the 1.0 floor on the physician work geographic practice cost index;
- Section 304—the exceptions process for outpatient therapy caps;
- Section 305—the payment to independent laboratories for the TC of physician pathology services furnished to certain hospital patients, and
- Section 307—the five percent increase in payments for mental health services.

On February 22, 2012, the MCTRJCA was signed into law. Section 3003 extended the zero percent PFS update to the remainder of CY 2012. As a result of the MCTRJCA, the CY 2012 PFS CF was maintained as $34.0376 for claims with dates of service on or after March 1, 2012 through December 31, 2012. In addition:

- Section 3004 of MCTRJCA extended the 1.0 floor on the physician work geographic practice cost index through December 31, 2012;
- Section 3006 continued payment to independent laboratories for the TC of physician pathology services furnished to certain hospital patients through June 30, 2012; and
- Section 3005 extended the exceptions process for outpatient therapy caps through CY 2012 and made several other changes related to therapy claims and caps.

On March 1, 2012, as required by Section 1848(d)(1)(E) of the Act, we submitted to the Medicare Payment Advisory Committee (MedPAC) an estimate of the SGR and conversion factor applicable to Medicare payments for physicians' services for CY 2013. The actual values used to compute physician payments for CY 2013 will be based on later data and are scheduled to be published by November 1, 2012 as part of the CY 2013 PFS final rule.

II. Provisions of the Proposed Rule

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have otherwise been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We use a ''bottom-up'' approach to determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing each service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC. For a detailed explanation of the bottom-up direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS), which was expanded (relative to the SMS) to include nonphysician practitioners (NPPs) paid under the PFS.

The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs using a consistent survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and healthcare professional groups. We believe the PPIS is the most comprehensive source of PE survey information available to date. Therefore, we used the PPIS data to update the PE/HR data for almost all of the Medicare-recognized specialties that participated in the survey for the CY 2010 PFS.

When we began using the PPIS data beginning in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we finalized a 4-year transition (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

We do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend these data with Medicare-recognized specialty data. Similarly, we do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty.

Supplemental survey data on independent labs, from the College of American Pathologists, were implemented for payments in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for medical oncology, independent laboratories, and IDTFs were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

Previously, we have established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead use the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for physician time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

There were five specialties whose utilization data were newly incorporated into ratesetting for CY 2012. In accordance with the final policies adopted in the CY 2012 final rule with comment period (76 FR 73036), we use proxy PE/HR values for these specialties by crosswalking values from other, similar specialties as follows: Speech Language Pathology from Physical Therapy; Hospice and Palliative Care from All Physicians; Geriatric Psychiatry from Psychiatry; Intensive Cardiac Rehabilitation from Cardiology, and Certified Nurse Midwife from Obstetrics/gynecology.

For CY 2013, there are two specialties whose utilization data will be newly incorporated into ratesetting. We are proposing to use proxy PE/HR values for these specialties by crosswalking values from other specialties that furnish similar services as follows: Cardiac Electrophysiology from Cardiology; and Sports Medicine from Family Practice. These proposed changes are reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2013 is the final year of the 4-year transition to the PE RVUs calculated using the PPIS data. Therefore, the CY 2013 proposed PE RVUs were developed based entirely on the PPIS data, with the exceptions described in this section.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. For example, if the direct portion of the PE RVUs for a given service was 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be 6.00 since 2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00.
- We then add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 6.00 plus 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- We next incorporate the specialty-specific indirect PE/HR data into the calculation. As a relatively extreme example for the sake of simplicity, assume in our previous example that, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00. In this case, the indirect portion of the PE RVUs of

the first service would be equal to that of the second service.

d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because Medicare makes a separate payment to the facility for its costs of furnishing a service, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

e. Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: a professional component (PC) and a technical component (TC), each of which may be furnished independently or by different providers, or they may be furnished together as a ''global' service. When services have PC and TC components that can be billed separately, the payment for the global component equals the sum of the payment for the TC and PC. This is a result of using a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global components, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global components, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global components.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs, the clinical PE RVUs, and the work RVUs.

For most services the indirect allocator is: Indirect percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

(**Note:** For global services, the indirect allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVUs, clinical PE RVUs, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global components, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global component.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs. This final BN adjustment is required in order to redistribute RVUs from step 18 to all PE RVUs in the PFS and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.)

(5) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Individuals not included in 55, 56, or 57.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
95	Competitive Acquisition Program (CAP) Vendor.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.
3	Medical supply company with pedorthic personnel.

We are proposing to calculate the specialty mix for low volume services (fewer than 100 billed services in the previous year) using the same methodology we use for non-low volume services. We previously have used the survey data from the dominant specialty for these low volume services. However, because these services have such low utilization, the dominant specialty tends to change from year to year. We are proposing to calculate a specialty mix for these services rather than use the dominant specialty in order to smooth year-to-year fluctuations in PE RVUs due to changes in the dominant specialty.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with

current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the physician time file is used; where it is not present, the intraoperative percentage from the payment files used by Medicare contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of physician time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPR) including the proposed ophthalmology and cardiovascular diagnostic services MPPR discussed in section II.B.4. of this proposed rule. We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the budget-neutrality calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These multiple procedure payment reductions are not included in the development of the relative value units.

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs and therefore includes all discounts. A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only occasion where time units are duplicative.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate)∧life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = 0.5 is the standard equipment utilization assumption; 0.75 for certain expensive diagnostic imaging equipment (see 74 FR 61753 through 61755 and section II.A.3. of the CY 2011 PFS final rule with comment period).

price = price of the particular piece of equipment.

interest rate = sliding scale (see proposal below)

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

The interest rate we have previously used was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). In the CY 2012 proposed rule (76 FR 42783), we solicited comment regarding reliable data on current prevailing loan rates for small businesses. In response to that request, the AMA RUC recommended that rather than applying the same interest rate across all equipment, CMS should consider a ''sliding scale'' approach which varies the interest rate based on the equipment cost, useful life, and SBA (Small Business Administration) maximum interest rates for different categories of loan size and maturity. The maximum interest rates for SBA loans are as follows:

- Fixed rate loans of $50,000 or more must not exceed Prime plus 2.25 percent if the maturity is less than 7 years, and Prime plus 2.75 percent if the maturity is 7 years or more.
- For loans between $25,000 and $50,000, maximum rates must not exceed Prime plus 3.25 percent if the maturity is less than 7 years, and Prime plus 3.75 percent if the maturity is 7 years or more.
- For loans of $25,000 or less, the maximum interest rate must not exceed Prime plus 4.25 percent if the maturity is less than 7 years, and Prime plus 4.75 percent, if the maturity is 7 years or more.

The current Prime rate is 3.25 percent.

Based on that recommendation, for CY 2013, we are proposing to use a ''sliding scale'' approach based on the current SBA maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment). Additionally, we are proposing to update this assumption through annual PFS rulemaking to account for fluctuations in the Prime rate and/or changes to the SBA's formula to determine maximum allowed interest rates.

The effects of this proposal on direct equipment inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. Additionally, we note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

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TABLE 3: CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est nonfacility	33533 CABG, arterial, single facility	71020 Chest x-ray nonfacility	71020-TC Chest xray nonfacility	71020-26 Chest xray nonfacility	93000 ECG, complete nonfacility	93005 ECG, tracing nonfacility	93010 ECG, report nonfacility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp.)	Step 1	AMA		0.17	0.58	7.24	7.24	0.00	0.11	0.11	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	85.45	16.38	16.38	0.00	7.42	7.42	0.00
(5) Direct adjustment (Dir. Adj).	Steps 2-4	See footnote*		0.58	0.58	0.58	0.58	0.58	0.58	0.58	0.58
(6) Adjusted Labor	Steps 2-4	=Lab * Dir Adj	=(1)*(5)	7.68	44.68	3.31	3.31	0.00	3.53	3.53	0.00
(7) Adjusted Supplies	Steps 2-4	= Sup * Dir Adj	=(2)*(5)	1.72	4.23	1.95	1.95	0.00	0.69	0.69	0.00
(8) Adjusted Equipment	Steps 2-4	= Eqp * Dir Adj	=(3)*(5)	0.10	0.34	4.17	4.17	0.00	0.06	0.06	0.00
(9) Adjusted direct	Steps 2-4		=(6)+(7)+(8)	9.50	49.25	9.44	9.44	0.00	4.28	4.28	0.00
(10) Conversion Factor (CF)	Step 5	PFS		34.0376	34.0376	34.0376	34.0376	34.0376	34.0376	34.0376	34.0376
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.23	1.31	0.10	0.10	0.00	0.10	0.10	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.06	0.06	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.12	0.12	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.28	1.45	0.28	0.28	0.00	0.13	0.13	0.00

	Step	Source	Formula	99213 Office visit, est nonfacility	33533 CABG, arterial, single facility	71020 Chest x-ray nonfacility	71020-TC Chest xray nonfacility	71020-26 Chest xray nonfacility	93000 ECG, complete nonfacility	93005 ECG, tracing nonfacility	93010 ECG, report nonfacility
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.31	0.18	0.31	0.31	0.31	0.31	0.31	0.31
(17) Ind_pct	Steps 6,7	Surveys		0.69	0.82	0.69	0.69	0.69	0.69	0.69	0.69
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)	((14)/(16)*(17)
(19) Ind. Alloc. (1st part).	Step 8		See (18)	0.82	6.76	0.68	0.68	0.00	0.31	0.31	0.00
(20) Ind. Alloc. Formulas (2nd part).	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc. (2nd part).	Step 8		See (20)	0.97	33.75	0.32	0.10	0.22	0.27	0.10	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.79	40.51	1.00	0.78	0.22	0.59	0.42	0.17
(23) Indirect Adjustment (Ind. Adj.)	Steps 9-11	See footnote**		0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40
(24) Adjusted indirect allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.72	16.25	0.40	0.31	0.09	0.23	0.17	0.07
(25) Ind. Practice Cost Index (IPCI)	Steps 12-16	See Steps 12 - 16		1.12	0.79	0.92	0.92	0.92	0.94	0.94	0.94
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24) * (25)	0.80	12.76	0.37	0.29	0.08	0.22	0.16	0.06
(28) PE RVU	Step 18	=(Adj Dir + Adj Ind) * budn	=((14)+(26)) * budn	1.08	14.19	0.64	0.56	0.08	0.34	0.28	0.06

Note: PE RVUs in table 2, row 28, may not match Addendum B due to rounding. * The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3]** The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10]

Note: The use of any particular conversion factor (CF) in Table 3 to illustrate the PE calculation has no effect on the resulting RVUs.

3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other specific CY 2013 proposals and changes related to direct PE inputs for specific services. We note that we will address comments on the interim direct PE inputs established in the CY 2012 PFS final rule with comment period in the CY 2013 PFS final rule.

a. Equipment Minutes for Interrogation Device Evaluation Services

It has come to our attention that the pacemaker follow-up system (EQ138) associated with two interrogation device management service codes does not have minutes allocated in the direct PE input database. Based on our analysis of these services, we believe that 10 minutes should be allocated to the equipment for each of the following CPT codes: 93294 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim physician analysis, review(s) and report(s)), and 93295 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)). Therefore, we are proposing to modify the direct PE input database to allocate 10 minutes to the pacemaker follow-up system for CPT codes 93294 and 93295.

The proposed CY 2013 direct PE input database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2013 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

b. Clinical Labor for Pulmonary Rehabilitation Services (HCPCS Code G0424)

It has come to our attention that the direct PE input database includes 15 minutes of clinical labor time in the nonfacility setting allocated for a CORF social worker/psychologist (L045C) associated with HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day). Based on our analysis of this service, we believe that these 15 minutes should be added to the 15 minutes currently allocated to the Respiratory Therapist (L042B) associated with this service. Therefore, we are proposing to modify the direct PE input database to allocate 15 additional minutes to the Respiratory Therapist (L042B) (for a total of 30 minutes) and delete the CORF social worker/psychologist (L045C) associated with HCPCS code G0424.

The proposed CY 2013 direct PE input database reflects these changes and is available on the CMS Web site under the supporting data files for the CY 2013 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

c. Transcranial Magnetic Stimulation Services

For CY 2011, the CPT Editorial Panel converted Category III CPT codes 0160T and 0161T to Category I status (CPT codes 90867 (Therapeutic Repetitive Transcranial Magnetic Stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), and 90868 (Therapeutic Repetitive Transcranial Magnetic Stimulation (TMS) treatment; subsequent delivery and management, per session)), which were contractor priced on the PFS. For CY 2012, the CPT Editorial Panel modified CPT codes 90867 and 90868, and created CPT code 90869 ((Therapeutic Repetitive Transcranial Magnetic Stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management.) In the CY 2012 PFS final rule with comment period, we established interim final values based on refinement of RUC recommended work RVUs, direct PE inputs, and malpractice risk factor crosswalks for these services (76 FR 73201).

Subsequent to the development of interim final PE RVUs, it came to our attention that the application of our usual PE methodology resulted in anomalous PE values for these services. As we explain in section II.A.2.c.2 of this proposed rule with comment period, for a given service, we use the direct costs associated with a service (clinical staff, equipment, and supplies) and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator.

For services almost exclusively furnished by one specialty, the average percentage of indirect costs relative to direct costs would ordinarily be used to determine the initial indirect allocator. For specialties that typically incur significant direct costs relative to indirect costs, the initial indirect allocator for their services is generally lower than for the specialties that typically incur lower direct costs relative to indirect costs. Relative to direct costs, the methodology generally allocates a greater proportion of indirect PE to services furnished by psychiatrists, for example, than to services furnished by specialties that typically incur significant direct costs, such as radiation oncologists. In the case of the TMS, however, the direct costs incurred by psychiatrists reporting the codes far exceed the direct costs typical to any other service predominantly furnished by psychiatrists. This drastic difference in the direct costs of TMS relative to most other services furnished by psychiatrists results in anomalous PE values since code-level indirect PE allocation relies on typical resource costs for the specialties that furnish the service. In other words, the amount of indirect PE allocated to TMS services is based on the proportion of indirect expense to direct expense that is typical of other psychiatric services, and is not on par with other services that require similar investments in capital equipment and high-cost, disposable supplies.

Historically, we have contractor-priced services with resource costs that cannot be appropriately valued within the generally applicable PE methodology used to price services across the PFS. Because there is no mechanism to develop appropriate payment rates for these services within our current methodology, we are proposing to contractor price these codes for CY 2013.

d. Spinal Cord Stimulation Trial Procedures in the Nonfacility Setting

Stakeholders have recently brought to our attention that CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) is frequently furnished in the physician office setting but is not priced in that setting. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition. However, because these services are being furnished in the nonfacility setting, we believe that CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. We propose to review CPT code 63650 and request recommendations from the AMA RUC and other public commenters

on the appropriate physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for this service. We understand that disposable leads comprise a significant resource cost for this service and are currently separately reportable to Medicare for payment purposes when the service is furnished in the physician office setting. Disposable medical supplies are not considered prosthetic devices paid under the Durable Medical Equipment, Prosthetic/Orthotic, and Supplies (DMEPOS) fee schedule and generally are incorporated as nonfacility direct PE inputs to PE RVUs. We seek comment on establishing nonfacililty PE RVUs for CPT code 63650.

B. Potentially Misvalued Codes Under the Physician Fee Schedule

1. Valuing Services Under the PFS

To value services under the PFS, section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work; practice expense (PE); and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service.'' In addition, section 1848(c)(2)(C)(i) of the Act specifies that ''the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.''

As discussed in detail in sections I.B.1.b. and I.B.1.c. of this proposed rule, the statute also defines the PE and malpractice components and provides specific guidance in the calculation of the RVUs for each of these components. Section 1848(c)(1)(B) of the Act defines the PE component as ''the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.'' Section 1848(c)(1)(C) of the Act defines the malpractice component as ''the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.'' Sections 1848 (c)(2)(C)(ii) and (iii) of the Act specify that PE and malpractice expense RVUs shall be determined based on the relative PE/malpractice expense resources involved in furnishing the service.

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. On March 23, 2010, the Affordable Care Act was enacted, further requiring the Secretary to periodically identify and review potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. Section 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(K) to the Act, which requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 3134(a) of the Affordable Care Act also added a new section 1848(c)(2)(L) to the Act which requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.B.1.a. of this proposed rule, each year we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the American Medical Association Specialty Society Relative Value Scale Update Committee (AMA RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the AMA RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of data sources, such as claims data, to inform the decision-making process as authorized by the law. We may also consider analyses of physician time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting Initiative (PQRI) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the AMA RUC. We conduct a clinical review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to taking into account the results of consultations with organizations representing physicians. In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services on the PFS

a. Background

In its March 2006 Report to the Congress, MedPAC noted that ''misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services.'' In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time for a number of reasons: For example, MedPAC stated, ''when a new service is added to the PFS, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' That is, the amount of physician work needed to furnish an existing service may decrease as physicians build experience furnishing that service. Services can also become overvalued when PEs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PEs rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years, CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, ''CMS and the AMA RUC have taken several steps to improve the review process.'' Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134(a) of the Affordable Care Act) directed the Secretary to specifically examine, as determined appropriate, potentially

misvalued services in seven categories as follows:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the PFS (the so-called 'Harvard-valued codes'); and
- Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the PFS.

In addition to these requirements, section 3003 (b)(1) of the Middle Class Tax Cut and Job Creation Act of 2012 (Pub. L. 112–96), requires that the Secretary conduct a study that examines options for bundled or episode-based payment to cover physicians' services currently paid under the PFS under section 1848 of the Act for one or more prevalent chronic conditions or episodes of care for one or more major procedures. In conducting the study, the Secretary shall consult with medical professional societies and other relevant stakeholders. Additionally, the study shall include an examination of related private payer payment initiatives. This section also requires that not later than January 1, 2013, the Secretary submit to certain committees of the Congress a report on the study. The report shall include recommendations on suitable alternative payment options for services paid under the PFS and on associated implementation requirements.

Bundling is one method for structuring payment that can improve payment accuracy and efficiency, assuming the bundling proposal has considered the payment system, context, and included services. Current work on bundling to date has targeted specific codes and sets of codes. Specifically, our ongoing work identifying, reviewing, and validating the RVUs of potentially misvalued services on the PFS will support the development of this report. As detailed above, through the potentially misvalued codes initiative we are currently identifying for review codes that are frequently billed together and codes with low relative values billed in multiples. Many of the codes identified through these screens have been referred to the CPT Editorial Panel for the development of a comprehensive or bundled code, and several bundled codes have already been created and valued. Additionally, in section II.B.2.d. of this CY 2013 PFS proposed rule, we discuss improving the value of the global surgical package and request public comment on methods of obtaining accurate and current data on E/M services furnished as part of global surgical procedures. This information on measuring post-operative work in our current payment bundles also will inform our report to the Congress. We will continue to examine options for bundled or episode-based payments and will include our recommendations and implementation options in our report to the Congress submitted no later than January 1, 2013.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

In accordance with our statutory mandate, we have identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. In the current process, we identify potentially misvalued codes for review, and request recommendations from the AMA RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The AMA RUC, through its own processes, identifies potentially misvalued codes for review, and through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,000 potentially misvalued codes to refine work RVUs and direct PE inputs. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews.

Our prior reviews of codes under the potentially misvalued codes initiative have included codes in all seven categories specified in section 1848(c)(2)(K)(ii) of the Act, listed above. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055).

In last year's PFS proposed rule (CY 2012), we identified potentially misvalued codes in the category of ''Other codes determined to be appropriate by the Secretary,'' referring a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through 73068). In the CY 2012 final rule with comment period we finalized policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services to replace the Five-Year review process (76 FR 73058 through 73059). Below we discuss proposals that support our continuing efforts to appropriately identify, review, and adjust values for potentially misvalued codes.

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 3134(a) of the Affordable Care Act added section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through

any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055). In CY 2012 we intend to enter into a contract to assist us in validating RVUs of potentially misvalued codes that will explore a model for the validation of physician work under the PFS, both for new and existing services. We plan to discuss this model further in future rulemaking.

d. Improving the Valuation of the Global Surgical Package

(1) Background

We applied the concept of payment for a global surgical package under the PFS at its inception on January 1, 1992 (56 FR 59502). For each global surgical procedure, we establish a single payment, which includes payment for a package of all related services typically furnished by the surgeon furnishing the procedure during the global period. Each global surgery is paid on the PFS as a single global surgical package. Each global surgical package payment rate is based on the work necessary for the typical surgery and related pre- and post-operative work. The global period may include 0, 10, or 90 days of post-operative care, depending on the procedure. For major procedures, those with a 90-day global period, the global surgical package payment also includes the day prior to the day of surgery.

Some global surgical packages have been valued by adding the RVU of the surgical procedure and all pre- and post-operative evaluation and management (E/M) services included in the global period. Others have been valued using magnitude estimation, in which case, the overall RVU for the surgical package was determined without factoring in the specific RVUs associated with the E/M services in the global period. The number and level of E/M services identified with a global surgery payment are based on the typical case. Even though a surgical package may have been developed with several E/M services included, a physician is not required to furnish each pre- or post-operative visit to bill for the global surgical package.

Similar to other bundled services on the PFS, when a global surgery code is billed, the bundled pre- and post-operative care is not separately payable; surgeons or other physicians billing a surgical procedure, cannot separately bill for the E/M services that are included in the global surgical package.

(2) Measuring Post-Operative Work

The use of different methodologies for valuing global surgical packages since 1992 has created payment rates with a wide range of E/M services included within the post-operative period. This is especially true among those with 90-day global periods. More recently reviewed codes tend to have fewer E/M services in the global period, and the work RVUs of those E/M services are often accounted for in the value for the global surgical package. The value of less recently reviewed global surgeries frequently do not appear to include the full work RVUs of each E/M service in the global surgical package, and the numbers of E/M services included in the post-operative period can be inconsistent within a family of procedures. For example, there is significant variation in the number and level of E/M services included in two transplantation procedures in Table 4. Pre-, intra-, and post-operative times, including the number of post-operative visits, for each global surgical package can be found in the physician time file on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1253669&intNumPerPage=10*.

TABLE 4—TRANSPLANTATION PROCEDURES SHOWING A SIGNIFICANT RANGE IN THE NUMBER OF INCLUDED E/M SERVICES

CPT Code	Short descriptor	Work RVU	E/M services included in global period				Total E/M Work RVU
			99213	99231	99238	99291	
50360	Transplantation of kidney	40.90	9	12	1	10	64.13
47135	Transplantation of liver	83.64	7	0	0	0	6.79

In 2005, the HHS Office of Inspector General (OIG) examined whether global surgical packages are appropriately valued. In its report on eye and ocular surgeries, ''National Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005'' (A–05–07–00077), the OIG reviewed a sample of 300 eye and ocular surgeries, and counted the actual number of face-to-face services in the surgeons' medical records to establish whether the surgeon furnished post-operative E/M services. The OIG findings show that surgeons typically furnished fewer E/M services in the post-operative period than were identified with the global surgical package payment for each procedure. A smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment. The OIG could only review the number of face-to-face services and was not able to review the level of E/M services that the surgeons furnished due to a lack of documentation in surgeons' medical records. The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

Following the 2005 report, the OIG continued to investigate E/M services furnished during the global surgical period. In May 2012, the OIG published a report titled ''Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided'' (A–05–09–00053). For this investigation, the OIG sampled 300 musculoskeletal global surgeries and again found that, for the majority of sampled surgeries, physicians furnished fewer E/M services than were identified as part of the global period for that service. Once again, a smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment.

The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

In both reports, the OIG recommended that we adjust the number of E/M services identified with the global surgical payments to reflect the number of E/M services that are actually being furnished. Under the PFS, we do not ask surgeons to report bundled services on their claim when billing for the global surgical package as we do providers furnishing bundled services under other Medicare payment systems. Since it is not necessary for a surgeon to identify the level and code of the E/M services actually furnished during the global period, there is very limited documentation on the frequency or level of post-operative services. Without sufficient documentation, a review of the medical record cannot accurately determine the number or level of E/M services furnished in the post-operative period.

As noted above, section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), which essentially codified the potentially misvalued codes initiative, requires that the Secretary identify and review potentially misvalued services with an emphasis on several categories, and recognizes the Secretary's discretion to identify additional potentially misvalued codes. Several of the categories of potentially misvalued codes support better valuation of global surgical package codes. We have made efforts to prioritize the review of RVUs for services on the PFS that have not been reviewed recently or for services where there is a potential for misuse. One of the priority categories for review of potentially misvalued codes is services that have not been subject to review since the implementation of the PFS (the so-called ''Harvard-valued codes''). In the CY 2009 PFS proposed rule, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume, low intensity codes (73 FR 38589). For the Fourth Five-Year Review (76 FR 32410), we requested that the AMA RUC review services that have not been reviewed since the original implementation of the PFS with utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In section II.B.3 of this proposed rule, we propose to review Harvard-valued services with annual allowed charges that total at least $10,000,000 (Harvard-valued—Allowed charges ≥ $10,000,000), and request recommendations from the AMA RUC and other public commenters on appropriate values for these services.

Of the more than 1,000 identified potentially misvalued codes, just over 650 are surgical services with a global period of 0, 10, or 90 days. We have completed our review of 450 of these potentially misvalued surgical codes. These efforts are important, but we believe the usual review process does not go far enough to assess whether the valuation of global surgical packages reflects the number and level of post-operative services that are typically furnished. To support our statutory obligation to identify and review potentially misvalued services and to respond to the OIG's concern that global surgical package payments are misvalued, we believe that we should begin gathering more information on the E/M services that are typically furnished with surgical procedures. Information regarding the typical work involved in surgical procedures with a global period is necessary to evaluate whether certain surgical procedures are appropriately valued. While the AMA RUC reviews and recommends RVUs for services on the PFS, we complete our own assessment of those recommendations, and may adopt different RVUs. However, for procedures with a global period, the lack of claims data and documentation restrict our ability to review and assess the appropriateness of their RVUs.

We are seeking comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. We are especially interested in and invite comments on a claims-based data collection approach that would include reporting E/M services furnished as part of a global surgical package, as well as other valid, reliable, generalizable, and robust data to help us identify the number and level of E/M services typically furnished in the global surgical period for specific procedures. We will carefully weigh all comments received as we consider ways to appropriately review values for global surgical packages.

3. CY 2013 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule, we finalized a public nomination process for potentially misvalued codes (76 FR 73058). Under the previous Five-Year Reviews, the public nominated potentially misvalued codes for review. To allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review under our annual potentially misvalued codes initiative, we established a process by which the public can submit codes, along with documentation supporting the need for review, on an annual basis. Stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: Technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and physician time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of physician time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

Under this newly established process, after we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we would evaluate the supporting documentation and assess whether they appear to be potentially misvalued codes appropriate for review under the

annual process. In the following year's PFS proposed rule, we would publish the list of nominated codes, and indicate whether each nominated code will be reviewed as potentially misvalued.

This year is the first year we are considering codes we received through this public nomination process for potentially misvalued codes. In the 60 days following the release of the CY 2012 PFS final rule with comment period, we received nominations and supporting documentation for review of the codes listed in Tables 5 and 6. A total of 36 CPT codes were nominated. The majority of the nominated codes were codes for which we finalized RVUs in the CY 2012 PFS final rule. That is, the RVUs were interim in CY 2011 and finalized for CY 2012, or proposed in either the Fourth Five-Year Review of Work or the CY 2012 PFS proposed rule and finalized for CY 2012. Under this annual public nomination process, we note that it would be highly unlikely that we would determine that a nominated code is appropriate for review under the potentially misvalued codes initiative if it had been reviewed in the years immediately preceding its nomination since we believe that the best information on the level of physician work and PE inputs already would have been available through that recent review. Nonetheless, we evaluated the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code is potentially misvalued.

TABLE 5—CPT CODES NOMINATED AS POTENTIALLY MISVALUED IN CY 2012 FINAL RULE COMMENT PERIOD: PROPOSED ACTION

CPT Code	Short descriptor	Last reviewed For:	CMS proposed action	*Regulations.gov* comment search
33282	Implant pat-active ht record	CY 2000	Review and add nonfacility inputs. Not considered potentially misvalued.	CMS–2011–0131–1422.
33284	Remove pat-active ht record ...	CY 2000	Review and add nonfacility inputs. Not considered potentially misvalued.	CMS–2011–0131–1422.
77336	Radiation physics consult	CY 2003 (PE Only)	Review as a potentially misvalued code	CMS–2011–0131–1617.
94762	Measure blood oxygen level ...	CY 2010 (PE Only)	Propose revisions in the CY 2013 PFS proposed rule.	CMS–2011–0131–1615; CMS–2011–0131–1412; CMS–2011–0131–1632.

CPT codes 33282 (Implantation of patient-activated cardiac event recorder) and 33284 (Removal of an implantable, patient-activated cardiac event recorder) were nominated for review as potentially misvalued codes. The commenter asserted that CPT codes 33282 and 33284 are misvalued in the nonfacility setting because these CPT codes currently are only priced in the facility setting even though physicians perform these services in the office setting. The commenter requested that we establish appropriate payment for the services when furnished in a physician office. Specifically, they requested that CMS establish nonfacility PE RVUs for these services. We do not consider the lack of pricing in a particular setting as an indicator of a potentially misvalued code. However, given that these services are now furnished in the nonfacility setting, we believe that CPT codes 33282 and 33284 should be reviewed to establish appropriate nonfacility inputs. We note, as did the commenter, that the valuation of a service under the PFS in a particular setting does not address whether those services and the setting in which they are furnished are medically reasonable and necessary for a patient's medical needs and condition. We propose to review CPT codes 33282 and 33284 and request recommendations from the AMA RUC and other public commenters on the appropriate physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for these services.

Like CPT codes 33282 and 33284, stakeholders have requested that we establish appropriate payment for CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) when furnished in an office setting. This request was not submitted as a potentially misvalued code nomination. However, given that these services are now furnished in the nonfacility setting, we believe CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. Please see section II.A.3 (Changes to Direct Inputs for Specific Services) for a discussion of spinal code stimulation trial procedures in the nonfacility setting.

CPT code 77336 (Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy) was nominated for review as a potentially misvalued code. The commenter asserted that CPT code 77336 is misvalued because changes in the technique for rendering continuing medical physics consultations have resulted in changes to the knowledge required, time, and effort expended, and complexity of technology associated with the tasks performed by the physicist other staff. Additionally the commenter believes that the direct PE inputs no longer accurately reflect the resources used to deliver this service and may be undervalued. CPT code 77336 was last reviewed for CY 2003. After evaluating the detailed supporting information that the commenter provided, we believe there may have been changes in technology and other PE inputs since we last reviewed the service, and that further review is warranted. As such, we propose to review CPT code 77336 as potentially misvalued and request recommendations from the AMA RUC and other public commenters on the direct PE inputs for this service, and physician work RVUs and direct PE inputs for the other services within this family of CPT codes.

CPT code 94762 (Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)) was nominated for review as a potentially misvalued code. Commenters asserted that CPT code 94762 is misvalued because the time currently allocated to the various direct PE inputs does not accurately reflect current practice. Commenters also asserted that independent diagnostic testing facilities are not appropriately accounted for in the current indirect PE methodology. In response to these

stakeholder concerns, we reviewed the PE inputs for CPT code 94762, which was last reviewed for CY 2010. We believe CPT code 94762 is misvalued, and we are proposing changes to the PE inputs for CY 2013. Following clinical review, we believe that the current time allocated to clinical labor and supplies appropriately reflects current practice. However, we believe that 480 minutes (8 hours) of equipment time for the pulse oximetry recording slot and pulse oximeter with printer are more appropriate for this overnight monitoring procedure code. As such, we are proposing this refinement to the direct PE inputs for CPT code 94762 for CY 2013. These proposed adjustments are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

CPT code 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff) was nominated for review as a potentially misvalued code. CPT code 53445 was identified through the site-of-service anomaly potentially misvalued code screen for CY 2008 and is currently interim for CY 2012 and open to public comment. We will consider the content of the potentially misvalued code nomination and supporting documentation for CPT code 53445 as comments on the interim final value, and will address the comments in the CY 2013 PFS final rule with comment period when we address the final value of the CPT code.

For purposes of CY 2013 rulemaking, we do not consider the other nominated codes, listed in Table 6 to be potentially misvalued because these codes were last reviewed and valued for CY 2012 and the supporting documentation did not provide sufficient evidence to demonstrate that the codes should be reviewed as potentially misvalued for CY 2013 or CY 2014. The supporting documentation for these services generally mirrored the public comments previously submitted, to which CMS has already responded.

TABLE 6—CPT CODES NOMINATED AS POTENTIALLY MISVALUED IN CY 2012 FINAL RULE COMMENT PERIOD: NO FURTHER ACTION PROPOSED

CPT Code	Short descriptor
28820	Amputation of toe.
28825	Partial amputation of toe.
35188	Repair blood vessel lesion.
35612	Artery bypass graft.
35800	Explore neck vessels.
35840	Explore abdominal vessels.
35860	Explore limb vessels.
36819	Av fuse uppr arm basilic.
36825	Artery-vein autograft.
43283	Lap esoph lengthening.
43327	Esoph fundoplasty lap.
43328	Esoph fundoplasty thor.
43332	Transab esoph hiat hern rpr.
43333	Transab esoph hiat hern rpr.
43334	Transthor diaphrag hern rpr.
43335	Transthor diaphrag hern rpr.
43336	Thorabd diaphr hern repair.
43337	Thorabd diaphr hern repair.
43338	Esoph lengthening.
47563	Laparo cholecystectomy/graph.
49507	Prp i/hern init block >5 yr.
49521	Rerepair ing hernia blocked.
49587	Rpr umbil hern block >5 yr.
49652	Lap vent/abd hernia repair.
49653	Lap vent/abd hern proc comp.
49654	Lap inc hernia repair.
49655	Lap inc hern repair comp.
53445* ...	Insert uro/ves nck sphincter.
60220	Partial removal of thyroid.
60240	Removal of thyroid.
60500	Explore parathyroid glands.
95800	Slp stdy unattended.

*CPT code 53445 is currently interim and open for public comment. We are accepting as public comment the nomination information submitted and will address these comments in the CY 2013 PFS final rule with comment period.

b. Potentially Misvalued Code Lists

As mentioned above, in the last several annual PFS proposed rules we have identified lists of potentially misvalued codes for review. We believe it is imperative that we continue to identify new lists of potentially misvalued codes for review to appropriately identify, review, and adjust values for potentially misvalued codes for CY 2013.

(1) Review of Harvard-Valued Services With Medicare Allowed Charges of $10,000,000 or More

For many years, we have been reviewing 'Harvard-valued' CPT codes through the potentially misvalued code initiative. The RVUs for Harvard-valued CPT codes have not been reviewed since they were originally valued in the early 1990s at the beginning of the PFS. While the principles underlying the relative value scale have not changed, over time the methodologies we use for valuing services on the PFS have changed, potentially disrupting the relativity between the remaining Harvard-valued codes and other codes on the PFS. At this time, nearly all CPT codes that were Harvard-valued and had Medicare utilization of over 30,000 allowed services per year have been reviewed. Moving forward, we propose to review Harvard-valued services with Medicare allowed charges of $10 million or greater per year. The CPT codes meeting these criteria have relatively low Medicare utilization (as we have reviewed the services with utilization over 30,000), but account for significant Medicare spending annually and have never been reviewed. We recognize that several of the CPT codes meeting these criteria have already been identified as potentially misvalued through other screens and may currently be scheduled for review for CY 2013. We also recognize that other codes meeting these criteria have been referred by the AMA RUC to the CPT Editorial Panel. In these cases, we are not proposing re-review of these already identified services, but for the sake of completeness, we include them as a part of this category of potentially misvalued services. We recognize that the relatively low Medicare utilization for these services may make gathering information on the appropriate physician work and direct PE inputs difficult. We request recommendations from the AMA RUC and other public commenters, and appreciate efforts expended to provide RVU and input recommendations to CMS for these lower volume services. Because survey sample sizes could be small for these lower volume services, we encourage the use of valid and reliable alternative data sources and methodologies when developing recommended values. In sum, we propose to review Harvard-valued CPT codes with annual allowed charges of $10 million or more as a part of the potentially misvalued codes initiative. Table 7 lists the codes that meet these criteria using CY 2011 Medicare claims data.

TABLE 7—HARVARD-VALUED CPT CODES WITH ANNUAL ALLOWED CHARGES ≥$10,000,000

CPT Code	Short descriptor
13152* ...	Repair of wound or lesion.
27446	Revision of knee joint.
29823	Shoulder arthroscopy/surgery.
36215** ..	Place catheter in artery.
36245** ..	Ins cath abd/l-ext art 1st.
43264** ..	Endo cholangiopancreatograph.
50360	Transplantation of kidney.
52353* ...	Cystouretero w/lithotripsy.
64450* ...	N block other peripheral.

TABLE 7—HARVARD-VALUED CPT CODES WITH ANNUAL ALLOWED CHARGES ≥$10,000,000—Continued

CPT Code	Short descriptor
64590	Insrt/redo pn/gastr stimul.
66180	Implant eye shunt.
67036	Removal of inner eye fluid.
67917	Repair eyelid defect.
92286** ..	Internal eye photography.
92982* ...	Coronary artery dilation.
95860* ...	Muscle test one limb.

*Scheduled for CY 2012 AMA RUC Review.
**Referred by the AMA RUC to the CPT Editorial Panel.

(2) Review of Services With Stand Alone PE Procedure Time

Improving the accuracy of procedure time assumptions used in PFS ratesetting continues to be a high priority of the potentially misvalued codes initiative. Procedure time is a critical measure of the resources typically used in furnishing particular services to Medicare beneficiaries, and procedure time assumptions are an important component in the development of work and PE RVUs. Discussions in the academic community have indicated that procedure times used for PFS ratesetting are overstated (McCall, N., J. Cromwell, *et al.* (2006). ''Validation of physician survey estimates of surgical time using operating room logs.'' *Med Care Res Rev* 63(6): 764–777. Cromwell, J., S. Hoover, *et al.* (2006). ''Validating CPT typical times for Medicare office evaluation and management (E/M) services.'' *Med Care Res Rev* 63(2): 236–255. Cromwell, J., N. McCall, *et al.* (2010). ''Missing productivity gains in the Medicare physician fee schedule: where are they?'' *Med Care Res Rev* 67(6): 236–255.) MedPAC and others have emphasized the importance of using the best available procedure time information in establishing accurate PFS payment rates. (MedPAC, Report to the Congress: Aligning Incentives in Medicare, June 2010, p. 230)

In recent years, CMS and the AMA RUC have taken steps to consider the accuracy of available data regarding procedure times used in the valuation of the physician work component of PFS payment. Generally, the AMA RUC derives estimates of physician work time from survey responses, and the AMA RUC reviews and analyzes those responses as part of its process for developing a recommendation for physician work. These procedure time assumptions are also used in determining the appropriate direct PE input values used in developing nonfacility PE RVUs. Specifically, physician intra-service time serves as the basis for allocating the appropriate number of minutes within the service period to account for the time used in furnishing the service to the patient. The number of intra-service minutes, or occasionally a particular proportion thereof, is allocated to both the clinical staff that assists the physician in furnishing the service and to the equipment used by either the physician or the staff in furnishing the service. This allocation reflects only the time the beneficiary receives treatment and does not include resources used immediately prior to or following the service. Additional minutes are often allocated to both clinical labor and equipment resources in order to account for the time used for necessary preparatory tasks immediately preceding the procedure or tasks typically performed immediately following it. For codes without physician work, the procedure times assigned to the direct PE inputs for such codes assume that the clinical labor performs the procedure. For these codes, the number of intra-service minutes assigned to clinical staff is independent and not based on any physician intra-service time assumptions. Consequently, the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by the AMA RUC and physician community in providing recommendations to CMS, and by CMS in the valuation of the physician work component of PFS payment. These independent clinical labor time assumptions largely determine the RVUs for the procedure. To ensure that procedure time assumptions are as accurate as possible across the Medicare PFS, we believe that codes without physician work should be examined with the same degree of scrutiny as services with physician work.

For CY 2012, a series of radiation treatment services were reviewed as part of the potentially misvalued code initiative. Among these were intensity modulated radiation therapy (IMRT) delivery services and stereotactic body radiation therapy (SBRT) delivery services reported with CPT codes 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) 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), respectively. CPT code 77418 (IMRT treatment delivery) had been identified as potentially misvalued based on Medicare utilization data that indicated both fast growth in utilization and frequent billing with other codes. We identified this code as potentially misvalued in the CY 2009 PFS proposed rule (73 FR 38586). CPT code 77373 (SBRT treatment delivery) had been identified as potentially misvalued by the RUC as a recently established code describing services that use new technologies. There is no physician work associated with either of these codes since other codes are used to bill for planning, dosimetry, and radiation guidance. Both codes are billed per treatment session. Because the physician work associated with these treatments is reported using codes distinct from the treatment delivery, the primary determinant of PE RVUs for these codes is the number of minutes allocated for the procedure time to both the clinical labor (radiation therapist) and the resource-intensive capital equipment included as direct PE inputs.

In the CY 2012 PFS final rule with comment period, we received and accepted without refinement PE recommendations from the AMA RUC for these two codes. (We received the recommendation for CPT code 77418 (IMRT treatment delivery) too late in 2010 to be evaluated for CY 2011 and it was therefore included in the CY 2012 rulemaking cycle.) The AMA RUC recommended minor revisions to the direct PE inputs for the code to eliminate duplicative clinical labor, supplies, and equipment to account for the frequency with which the code was billed with other codes. For CPT code 77373 (SBRT treatment delivery), the RUC recommended no significant changes to the direct PE inputs.

Subsequent to the publication of the final rule, the AMA RUC and other stakeholders informed CMS that the direct PE input recommendation forwarded to CMS for IMRT treatment delivery (CPT code 77418) inadvertently omitted seven equipment items typically used in furnishing the service. These items had been used as direct PE inputs for the code prior to CY 2012. There is broad agreement among stakeholders that these seven equipment items are typically used in furnishing the services described by CPT code 77418. We were unable to reincorporate the items for CY 2012. These omitted items are listed in Table 8. In consideration of the comments from the AMA RUC and other stakeholders, we are proposing to include the seven equipment items omitted from the RUC recommendation for CPT code 77418.

These proposed adjustments are also reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of these proposals.

TABLE 8—EQUIPMENT INPUTS OMITTED FROM RUC RECOMMENDATION FOR CPT CODE 77418

[IMRT Treatment Delivery]

Equipment code	Equipment description
ED011	computer system, record and verify.
ED035	video camera.
ED036	video printer, color (Sony medical grade).
EQ139	intercom (incl. master, pt substation, power, wiring).
ER006	IMRT physics tools.
ER038	isocentric beam alignment device.
ER040	laser, diode, for patient positioning (Probe).

It has come to our attention that there are wide discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries and the general public. Specifically, the direct PE inputs for IMRT treatment delivery (CPT code 77418) reflect a procedure time assumption of 60 minutes. These procedure minutes were first assigned to the code for CY 2002 based on a recommendation from the AMA RUC indicating that the typical treatment time for the IMRT patient was 40 to 70 minutes. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported the procedure time assumption of 60 minutes.

Information publicly available to Medicare beneficiaries and the general public clearly indicates that IMRT sessions typically last between 10 and 30 minutes. For example, the American Society for Radiation Oncology (ASTRO) publishes a patient fact sheet that explains that for all external beam radiation therapy, including IMRT, ''treatment is delivered in a series of daily sessions, each about 15 minutes long.'' [''Radiation Therapy for Prostate Cancer: Facts to Help Patients Make an Informed Decision'' available for purchase at *www.astro.org/MyASTRO/Products/Product.aspx?AstroID=6901*.] This fact sheet is intended for patients with prostate cancer, the typical diagnosis for Medicare beneficiaries receiving IMRT. Similarly, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) co-sponsor a Web site for patients called *http://radiologyinfo.org* that states that IMRT ''treatment sessions usually take between 10 and 30 minutes.''

The direct PE inputs for SBRT treatment delivery (CPT code 77373) reflect a procedure time assumption of 90 minutes. These procedure minutes were first assigned to the code for CY 2007 based on a recommendation from the AMA RUC. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported continuing that procedure time assumption.

In 2012, information publicly available to Medicare beneficiaries and the general public states that SBRT treatment typically lasts no longer than 60 minutes. For example, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) Web site, *http://radiologyinfo.org*, states that SBRT ''treatment can take up to one hour.''

Given the importance of the procedure time assumption in the development of RVUs for these services, using the best available information is critical to ensuring that these services are valued appropriately. We have no reason to believe that information medical societies and practitioners offer to their cancer patients regarding the IMRT or SBRT treatment experience is inaccurate or atypical. Therefore, we believe that the typical procedure time for IMRT delivery is between 10 and 30 minutes and that the typical procedure time for SBRT delivery is under 60 minutes. The services are currently valued using procedure time assumptions of 60 and 90 minutes, respectively. We believe these procedure time assumptions, distinct from necessary preparatory or follow-up tasks by the clinical labor, are clearly outdated and need to be updated using the best information available.

While we generally have not used publicly available resources to establish procedure time assumptions, we believe that the procedure time assumptions used in setting payment rates for the Medicare PFS should be derived from the most accurate information available. In the case of these services, we believe that the need to reconcile the vast discrepancies between our existing assumptions and more accurate information outweighs the potential value in maintaining relativity offered by only considering data from one source. We are proposing to adjust the procedure time assumption for IMRT delivery (CPT code 77418) to 30 minutes. We are proposing to adjust the procedure time assumption for SBRT delivery (CPT code 77373) to 60 minutes. These procedure time assumptions reflect the maximum number of minutes reported as typical in publicly available information. We note that in the case of CPT code 77418, the 'accelerator, 6–18 MV' (ER010) and the 'collimator, multileaf system w-autocrane' (ER017) are used throughout the procedure and currently have no minutes allocated for preparing the equipment, positioning the patient, or cleaning the room. Since these clinical labor tasks are associated with related codes typically reported at the same time, we are also proposing to allocate minutes to these equipment items to account for their use immediately before and following the procedure. All of these proposed adjustments are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from the application of this proposal. We request recommendations from the AMA RUC and other public commenters on the direct PE inputs for these services.

While we recognize that using these procedure time assumptions will result in payment reductions for these particular services, we believe such changes are necessary to appropriately

value these services. Recent attention from popular media sources like the *Wall Street Journal* (*online.wsj.com/article/SB10001424052748703904804575631222900534954.html* December 7, 2010) and the *Washington Post* (*www.washingtonpost.com/wp-dyn/content/article/2011/02/28/AR2011022805378.html*) February 28, 2011 has encouraged us to consider the possibility that potential overuse of IMRT services may be partially attributable to financial incentives resulting from inappropriate payment rates. In its 2010 Report to Congress, MedPAC referenced concerns that financial incentives may influence how cancer patients are treated. In the context of the growth of ancillary services in physicians' offices, MedPAC recommended that improving payment accuracy for discrete services should be a primary tool used by CMS to mitigate incentives to increase volume (Report to Congress: Aligning Incentives in Medicare, June 2010, p. 225). We note that in recent years, PFS nonfacility payment rates for IMRT treatment delivery have exceeded the Medicare payment rate for the same service paid through the hospital Outpatient Prospective Payment System (OPPS). We believe that such high-volume services that are widely furnished in both nonfacility and facility settings are highly unlikely to be more resource-intensive in freestanding radiation therapy centers or physicians' offices than when furnished in facilities like hospitals that generally incur higher overhead costs, maintain a 24 hour, 7 day per week capacity, are generally paid in larger bundles, and generally furnish services to higher acuity patients than the patients who receive services in physician offices or free-standing clinics. Given that the OPPS payment rates are based on auditable data on hospital costs, we believe the seemingly counterintuitive relationship between the OPPS and nonfacility PFS payment rates reflects inappropriate assumptions within the current direct PE inputs for CPT code 77418. The AMA RUC's most recent direct PE input recommendations reflect the same procedure time assumptions used in developing the recommendations for CY 2002. As we explained above, we do not understand how the AMA RUC can recommend these assumptions in the context of the procedure time information available to the general public. We believe that using procedure time assumptions that reflect the maximum times reported as typical to Medicare beneficiaries will improve the accuracy of those inputs and the resulting nonfacility payment rates.

These two treatment delivery codes are PE only codes and are fairly unique in that the resulting RVUs are largely comprised of resources for staff and equipment based on the minutes associated with clinical labor. There are several other codes on the PFS established through the same methodology. As we previously stated, we believe that the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by CMS in the valuation of the physician work component of PFS payment. In light of observations about publicly available procedure times for CPT codes 77418 (IMRT treatment delivery) and 77373 (SBRT treatment delivery) and public awareness of potential adverse financial incentives associated with IMRT treatment delivery in particular, we believe that similar codes are potentially misvalued.

Therefore, consistent with the requirement in section 1848(c)(2)(K)(ii) of the Act to examine other codes determined to be appropriate by the Secretary, we are proposing to review and make adjustments to CPT codes with stand alone procedure time assumptions used in developing nonfacility PE RVUs. These procedure time assumptions are not based on physician time assumptions. We are prioritizing for review CPT codes that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and have PE procedure times of greater than 5 minutes. At this time, we are not including in this category services with payment rates subject to the OPPS cap (as specified in the statute under section 1848(b)(4) of the Act and listed in Addendum G to this proposed rule) or services with PE minutes established through code descriptors. (For example, an overnight monitoring code might contain 480 minutes of monitoring equipment time to account for 8 hours of overnight monitoring.) The CPT codes meeting these criteria appear in Table 9. We recognize that there are other CPT codes that are valued in the same manner. We may consider evaluating those services as potentially misvalued codes in future rulemaking.

For the services in Table 9, we request recommendations from the AMA RUC and other public commenters on the appropriate direct PE inputs for these services. We encourage the use of valid and reliable alternative data sources when developing recommended values, including electronic medical records and other independent data sources. We note that many of the CPT codes in Table 9 have been identified through other potentially misvalued code screens and have been recently reviewed. Given our observed concerns with the inputs for the recently reviewed IMRT and SBRT direct PE inputs discussed above, we believe it is necessary to re-review other recently reviewed services with stand alone PE procedure time.

TABLE 9—SERVICES WITH STAND ALONE PE PROCEDURE TIME

CPT Code	Short descriptor
77280	Set radiation therapy field.
77285	Set radiation therapy field.
77290	Set radiation therapy field.
77301	Radiotherapy dose plan imrt.
77338	Design mlc device for imrt.
77372	Srs linear based.
77373	Sbrt delivery.
77402	Radiation treatment delivery.
77403	Radiation treatment delivery.
77404	Radiation treatment delivery.
77406	Radiation treatment delivery.
77407	Radiation treatment delivery.
77408	Radiation treatment delivery.
77409	Radiation treatment delivery.
77412	Radiation treatment delivery.
77413	Radiation treatment delivery.
77414	Radiation treatment delivery.
77416	Radiation treatment delivery.
77418	Radiation tx delivery imrt.
77600	Hyperthermia treatment.
77785	Hdr brachytx 1 channel.
77786	Hdr brachytx 2–12 channel.
77787	Hdr brachytx over 12 chan.
88348	Electron microscopy.

c. Services With Anomalous Time

Each year when we publish the PFS proposed and final rules, we publish on the CMS Web site several files that support annual PFS rate-setting. One of these supporting files is the physician time file, which lists the physician time associated with the HCPCS codes on the PFS. The physician time file associated with this PFS proposed rule is available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

In our review of potentially misvalued codes and their inputs, we became aware of several HCPCS codes that have anomalous times in our physician time file. Physician work is a measure of physician time and intensity, so there should be no services that have payable physician work RVUs but no physician time in the time file, and there should be no payable services with physician time in the time file and no physician work RVUs. For CY 2013 we are proposing to make the physician time

file changes detailed below to address these anomalous time file entries.

(1) Review of Services With Physician Work and No Listed Physician Time

CPT code 94014 (Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician review and interpretation) has a physician work RVU of 0.52 and is currently listed with 0 physician time. CPT code 94014 is a global service that includes CPT code 94015 (Patient-initiated spirometric recording per 30-day period of time; recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis, and periodic recalibration)) (the technical component), and CPT code 94016 (Patient-initiated spirometric recording per 30-day period of time; physician review and interpretation only) (the professional component). We believe it is appropriate for the physician time of CPT code 94014 to match the physician time of the code's component professional service—CPT code 94016. As such, for CPT code 94014 for CY 2013, we are proposing to assign 2 minutes of pre-service evaluation time, and 20 minutes of intra-service time, which matches the times associated with CPT code 94016. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

HCPCS codes G0117 (Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist) and G0118 (Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist) both have physician work RVUs (0.45, and 0.17, respectively), but neither code is included in the physician time file. HCPCS codes G0117 and G0118 have a PFS procedure status indicator of T indicating that these services are only paid if there are no other services payable under the PFS billed on the same date by the same provider.

In the CY 2002 PFS final rule (66 FR 55274), we crosswalked the physician work of HCPCS code G0117 from CPT code 99212 (Level 2 office or other outpatient visit, established patient), and we crosswalked the physician work of HCPCS code G0118 from CPT code 99211 (Level 1 office or other outpatient visit, established patient). Based on these finalized physician work crosswalks, we propose to assign HCPCS code G0117 physician times matching CPT code 99212, and HCPCS code G0118 physician times matching CPT code 99211. Specifically, we are proposing 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time for HCPCS code G0117, and 5 minutes of intra-service time, and 2 minutes of immediate post-service time for HCPCS code G0118. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

HCPCS code G0128 (Direct (face-to-face with patient) skilled nursing services of a registered nurse provided in a comprehensive outpatient rehabilitation facility, each 10 minutes beyond the first 5 minutes) currently has a physician work RVU (0.08), but is not listed in the physician time file. After review of this HCPCS code, we do not believe that HCPCS code G0128 describes a service that includes physician work. Time for a registered nurse to furnish the service is included in the PE for the code. As such, for CY 2013, we propose to remove the physician work RVU for HCPCS code G0128. HCPCS code G0128 will continue to have PE and malpractice expense RVUs.

HCPCS codes G0245 (Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) The diagnosis of LOPS; (2) a patient history; (3) a physical examination that consists of at least the following elements: (a) Visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of a protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of footwear; and (4) patient education), G0246 (Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) A patient history; (2) a physical examination that includes: (a) Visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of footwear; and (3) patient education), and G0247 (Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include, the local care of superficial wounds (that is, superficial to muscle and fascia) and at least the following if present: (1) Local care of superficial wounds; (2) debridement of corns and calluses; and (3) trimming and debridement of nails) have physician work RVUs of 0.88, 0.45, and 0.50, respectively, but are not listed in the physician time file. HCPCS codes G0245, G0246, and G0247 have a procedure status indicator of R on the PFS indicating that coverage of these services is restricted.

In the CY 2003 PFS final rule (67 FR 79990), we crosswalked the physician work of HCPCS code G0245 from CPT code 99202 (Level 2 office or other outpatient visits, new patient), we crosswalked the physician work of HCPCS code G0246 from CPT code 99212, and we crosswalked the physician work of HCPCS code G0257 from CPT code 11040 (Debridement; skin; partial thickness). Based on these finalized physician work crosswalks, we propose to assign HCPCS code G0245 physician times matching CPT code 99202, HCPCS code G0246 physician times matching CPT code 99212, and HCPCS code G0247 physician times matching CPT code 11040. Specifically, for HCPCS code G0245 we are proposing 2 minutes of pre-service time, 15 minutes of intra-service time, and 5 minutes of immediate post-service time. For HCPCS code G0246 we are proposing 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time. For HCPCS code G0247 we are proposing 7 minutes of pre-service time, 10 minutes of intra-service time, and 7 minutes of immediate post-service time. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

HCPCS code G0250 (Physician review, interpretation, and patient management of home INR (International Normalized Ratio) testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests) has a physician work RVU of 0.18 but is not listed in the physician time file. HCPCS code G0250 has a procedure status indicator of R on the PFS indicating that coverage of this service

is restricted. In the CY 2003 final rule (67 FR 79991), we assigned HCPCS code G0250 a work RVU of 0.18, which corresponds to the work RVU of CPT code 99211. While we did not articulate this as a direct crosswalk in the CY 2003 final rule, after clinical review we believe that HCPCS code G0250 continues to require similar work as CPT code 99211, and should have the same amount of physician time as CPT code 99211. As such, we are proposing to assign HCPCS code G0250 the same physician time as CPT code 99211. Specifically, for HCPCS code G0250 we are proposing 5 minutes of intra-service time and 2 minutes of immediate post-service time. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

During our annual review of new, revised, and potentially misvalued CPT codes, the assessment of physician time used to furnish a service is an important part of the clinical review when determining the appropriate work RVU for a service. However, the time in the physician time file is not used to automatically adjust the physician work RVUs outside of that clinical review process. As such, the proposed addition of physician time to the HCPCS codes discussed above will have no impact on the current physician work RVUs for these services.

The time data in the physician time file is used in the PE methodology described in section II.A.2. In creating the indirect practice cost index (IPCI), we calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty. The proposed addition of physician time to the HCPCS codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and low total time, the impact of the physician time changes on the IPCI is negligible, and likely would have a modest impact if any on the PE RVUs at the individual code level.

(2) Review of Services With Stand Alone PE Procedure Time

There are a number of services that have no physician work RVUs, yet include physician time in the physician time file. Many of these services are not payable under the PFS or are contractor priced services where the physician time is not used to nationally price the services on the PFS. We are not proposing to remove the physician time from the time file for these services as the time has no effect on the calculation of RVUs for the PFS. However, there are several CPT codes, listed in Table 10, that are payable under the PFS and have no physician work RVUs yet include time in the physician time file. We are proposing to remove the physician time from the time file for these seven CPT codes. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

TABLE 10—PAYABLE CPT CODES WITH PHYSICIAN TIME AND NO PHYSICIAN WORK

CPT code	Short descriptor	PFS procedure status	CY 2012 total physician time (minutes)
22841	Insert spine fixation device	B (Bundled, not separately payable)	5
51798	Us urine capacity measure	A (Active, payable)	9
95990	Spin/brain pump refill & main	A (Active, payable)	40
96904	Whole body photography	R (Restricted coverage)	80
96913	Photochemotherapy uv-a or b	A (Active, payable)	90
97545	Work hardening	R (Restricted coverage)	120
97602	Wound(s) care non-selective	B (Bundled, not separately payable)	36

As mentioned above and as discussed in section II.A.2. of this proposed rule, to create the IPCI used in the PE methodology, we calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services performed by the specialty. The proposed removal of physician time from the CPT codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and/or low total time, the impact of the physician time changes on the IPCI is negligible, and likely would have a modest impact if any on the PE RVUs at the individual code level.

4. Expanding the Multiple Procedure Payment Reduction Policy

Medicare has long employed multiple procedure payment reduction (MPPR) policies to adjust payment to more appropriately reflect reduced resources involved with furnishing the service for certain sets of services frequently furnished together. Under these policies, we reduce payment for the second and subsequent services within the same MPPR category furnished in the same session or same day. These payment reductions reflect efficiencies that typically occur in either the practice expense (PE) or professional work or both when services are furnished together. With the exception of a few codes that are always reported along with another code, the Medicare PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. While our general policy for MPPRs precedes the Affordable Care Act, this payment policy approach addresses the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act, as added by section 3134(a) of the Affordable Care Act, which is ''multiple codes that are frequently billed in conjunction with furnishing a single service'' (see 75 FR 73216).

For CY 2013, we are proposing to continue our work to recognize resource efficiencies when certain services are furnished together. We are proposing to apply an MPPR to the technical component (TC) of certain diagnostic tests. As discussed in the CY 2012 final rule with comment period (76 FR 73079), we are also proceeding with

applying the current MPPR policy for imaging services to services furnished in the same session by physicians in the same group practice.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by a single physician or physicians in the same group practice on the same day, largely based on the presence of efficiencies in the PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with this same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, for CY 2006 PFS, we extended the MPPR policy to the TC of certain diagnostic imaging procedures furnished on contiguous areas of the body in a single session (70 FR 70261). This MPPR recognizes that for the second and subsequent imaging procedures furnished in the same session, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent imaging services in the same session and, because equipment time and indirect costs are allocated based on clinical labor time, we also reduced those accordingly.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region and only applied to procedures furnished in a single session involving contiguous body areas within a family of codes, not across families. Additionally, the MPPR policy originally applied to TC-only services and to the TC of global services, and not to professional component (PC) services.

There have been several revisions to this policy since it was originally adopted. Under the current imaging MPPR policy, full payment is made for the TC of the highest paid procedure, and payment for the TC is reduced by 50 percent for each additional procedure subject to this MPPR policy. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of the new OPPS payment cap added by the DRA, we decided in the PFS final rule with comment period for 2006 that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS BN provision. Effective July 1, 2010, section 1848(b)(4)(C) of the Act, as added by section 3135(b)(1) of the Affordable Care Act increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent. Section 1848(c)(2)(B)(v)(IV) of the Act, as added by section 3135(b)(2) of the Affordable Care Act exempted the reduced expenditures attributable to this further change from the PFS BN provision.

In the July 2009 U.S. Government Accountability Office (GAO) report entitled, ''Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together,'' the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO recommended the following: (1) Expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services. In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011, the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedures furnished to the same patient in the same session, regardless of the imaging modality and is not limited to contiguous body areas.

As we noted in the CY 2011 PFS final rule with comment period (75 FR 73228), while section 1848(c)(2)(B)(v)(VI) of the Act specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS BN adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (non-contiguous body areas) that are subject to BN under the PFS. The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 1848(c)(2)(K) of the Act, on January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable ''always therapy'' services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. As we explained in the CY 2011 PFS final rule with comment period (75 FR 73232), the therapy MPPR does not apply to contractor-priced codes, bundled codes,

and add-on codes. The complete list of codes subject to the MPPR policy for therapy services is included in Addendum H.

This MPPR for therapy services was first proposed in the CY 2011 proposed rule (75 FR 44075) as a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single patient in a single day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single patient in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (PPTRA) (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services for which payment is made under a fee schedule under section 1848 (which are services furnished in office settings, or non-institutional services). The payment reduction percentage remains at 25 percent for therapy services furnished in institutional settings. Section 4 of the PPTRA exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS BN provision. Under our current policy as amended by the PPTRA, for institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 25 percent. For non-institutional services, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 20 percent.

This MPPR policy applies to multiple units of the same therapy service, as well as to multiple different ''always therapy'' services, when furnished to the same patient on the same day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. The MPPR applies when multiple therapy services are billed on the same date of service for one patient by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple disciplines, including physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services that are furnished in the office setting and paid under the PFS, as well as institutional services that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid for outpatient therapy services at rates based on the PFS.

In its June 2011 Report to Congress, MedPAC highlighted continued growth in ancillary services subject to the in-office ancillary services exception. The in-office ancillary exception to the general prohibition under section 1877 of the Act as amended by the Ethics in Patient Referrals Act, also known as the Stark law, allows physicians to refer Medicare patients for designated health services, including imaging, radiation therapy, home health care, durable medical equipment, clinical laboratory tests, and physical therapy, to entities with which they have a financial relationship under specific conditions. MedPAC recommended that we apply a MPPR to the PC of diagnostic imaging services furnished by the same practitioner in the same session as one means to curb excess self-referral for these services. The GAO already had made a similar recommendation in its July 2009 report.

In continuing to apply the provisions of section 1848(c)(2)(K) of the Act, in the CY 2012 final rule (76 FR 73071), we expanded the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applied (see Addendum F). Thus, this MPPR policy now applies to the PC and the TC of certain diagnostic imaging codes. Specifically, we expanded the payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished by the same physician (or by two or more physicians in the same group practice) to the same patient in the same session on the same day. However, in response to public comments, in the CY 2012 PFS final rule with comment period, we adopted a 25 percent payment reduction to the PC component of the second and subsequent imaging services.

Under this policy, full payment is made for the PC of the highest paid procedure, and payment is reduced by 25 percent for the PC for each additional procedure furnished to the same patient in the same session. This policy was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work, primarily in the pre- and post-service periods, with smaller efficiencies in the intraservice period.

This policy is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act. This policy is also consistent both with our longstanding policy on surgical and nuclear medicine diagnostic procedures, under which we apply a 50 percent payment reduction to second and subsequent procedures. Furthermore, it was responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010 and June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

In the CY 2012 proposed rule (76 FR 42812), we also invited public comment on the following MPPR policies under consideration. We noted that any proposals would be presented in future rulemaking and subject to further public comment:

- *Apply the MPPR to the TC of All Imaging Services.* This approach would apply a payment reduction to the TC of the second and subsequent imaging services furnished in the same session. Such an approach could define imaging consistent with our existing definition of imaging for purposes of the statutory cap on PFS payment at the OPPS rate (including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography). Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

- *Apply the MPPR to the PC of All Imaging Services.* This approach would apply a payment reduction to the PC of

the second or subsequent imaging services furnished in the same encounter. Such an approach could define imaging consistent with our existing definition of imaging for the cap on payment at the OPPS rate. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on efficiencies due to duplication of physician work primarily in the pre- and post-service periods, with smaller efficiencies in the intraservice period, when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

• *Apply the MPPR to the TC of All Diagnostic Tests.* This approach would apply a payment reduction to the TC of the second and subsequent diagnostic tests (such as radiology, cardiology, audiology, etc.) furnished in the same encounter. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. The approach would apply to approximately 700 HCPCS codes, including the approximately 560 HCPCS codes that are currently subject to the OPPS cap. The savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

b. MPPR Policy Clarifications

(1) Apply the MPPR to Two Nuclear Medicine Procedures

As indicated previously, effective January 1, 1995, we implemented an MPPR for six nuclear medicine codes. Under the current policy, full payment is made for the highest paid procedure, and payment is reduced by 50 percent for the second procedure furnished to the same patient on the same day. Due to a technical error, the MPPR is not being applied to CPT codes 78306 (Bone imaging; whole body when followed by CPT code 78320 (Bone imaging; SPECT). We will apply the MPPR to these procedures effective January 1, 2013.

(2) Apply the MPPR to the PC and TC of Advanced Imaging Procedures to Physicians in the Same Group Practice

As indicated in the CY 2012 final rule (76 FR 73077–73079), we finalized a policy to apply the MPPR to the PC and TC of the second and subsequent advanced imaging procedures furnished to the same patient in the same session by a single physician or by multiple physicians in the same group practice. Due to operational limitations, we were not able to apply this MPPR to multiple physicians in the same group practice during CY 2012. In addition, after we issued the CY 2012 final rule with comment period, some stakeholders asserted that they had not commented on the application of the MPPR to physicians in the same group practice because that policy was not explicit in the CY 2012 proposed rule discussion expanding the MPPR for advanced imaging to the PC. We have resolved the operational problems and, therefore, for services furnished on or after January 1, 2013 we will apply the MPPR to both the PC and the TC of advanced imaging procedures to multiple physicians in the same group practice (same group NPI). Under this policy, the MPPR will apply when one or more physicians in the same group practice furnish services to the same patient, in the same session, on the same day. This policy is consistent with other PFS MPPR policies for surgical and therapy procedures. We continue to believe that the typical efficiencies achieved when the same physician is furnishing multiple procedures also accrue when different physicians in the same group furnish multiple procedures involving the same patient in the same session. It is our general intention to apply this and future MPPRs to services furnished by one or more physicians in the same group unless special circumstances warrant a more limited application. In such circumstances, we will note in our proposal that an MPPR does not apply to one or more physicians in the same group as other MPPR policies do. We continue to welcome public comment on this provision as it applies to advanced diagnostic imaging and to the MPPR policy generally.

c. Proposed MPPR for the TC of Cardiovascular and Ophthalmology Services

As noted above, we continue to examine whether it would be appropriate to apply MPPR policies to other categories of services that are frequently billed together, including the TC for other diagnostic services. For CY 2013, we examined other diagnostic services to determine whether there typically are efficiencies in the technical component when multiple diagnostic services are furnished together on the same day. We have conducted an analysis of the most frequently furnished code combinations for all diagnostic services using CY 2011 claims data. Of the several areas of diagnostic tests that we examined, we found that billing patterns and PE inputs indicated that cardiovascular and ophthalmology diagnostic procedures, respectively, are frequently furnished together and that there is some duplication in PE inputs when this occurs. For cardiovascular diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 75600 through 75893, 78414 through 78496, and 93000 through 93990. For ophthalmology diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 76510 through 76529 and 92002 through 92371. The most frequently billed cardiovascular and ophthalmology diagnostic code combinations are listed in Tables 14 and 15.

Under the resource-based PE methodology, specific PE inputs of clinical labor, supplies, and equipment are used to calculate PE RVUs for each individual service. When multiple diagnostic tests are furnished to the same patient on the same day, most of the clinical labor activities and some supplies are not furnished twice. We have identified the following clinical labor activities that typically would not be duplicated for subsequent procedures:

- Greeting and gowning the patient.
- Preparing the room, equipment and supplies.
- Education and consent.
- Completing diagnostic forms.
- Preparing charts.
- Taking history.
- Taking vitals.
- Preparing and positioning the patient.
- Cleaning the room.
- Monitoring the patient.
- Downloading, filing, identifying and storing photos.
- Developing film.
- Collating data.
- QA documentation.
- Making phone calls.
- Reviewing prior X-rays, lab and echos.

We analyzed the CY 2011 claims data for the most frequently billed cardiovascular and ophthalmology diagnostic code combinations in order to determine the level of duplication present when multiple services are furnished to the same patient on the same day. Our MPPR determination excludes the clinical staff minutes associated with the activities that are not duplicated for subsequent procedures. For purposes of this

analysis, we retained the higher number of minutes for each duplicated clinical activity, regardless of the code in the pair with which those clinical labor minutes were associated. Equipment time and indirect costs are allocated based on clinical labor time; therefore, these inputs were reduced accordingly. While we observed that some supplies are duplicated, we did not factor these into our calculations because they were low cost and had little impact on our estimate of the level of duplication for each code pair.

When we removed the PE inputs for activities that are not duplicated, and adjusted the equipment time and indirect costs, we found support for payment reductions ranging from 8 to 57 percent for second and subsequent cardiovascular procedures (volume-adjusted average reduction across all code pairs of 25 percent); and payment reductions ranging from 9 to 62 percent for second and subsequent ophthalmology procedures (volume-adjusted average reduction across all code pairs of 32 percent). Because we found a relatively wide range of reduction by code pair, we believe that an across-the-board reduction of 25 percent for second and subsequent procedures (which is approximately the average reduction supported by our analysis) would be appropriate. We propose to apply an MPPR to TC-only services and to the TC portion of global services for the procedures listed in Tables 12 and 13. The MPPR would apply independently to second and subsequent cardiovascular services and to second and subsequent ophthalmology services. We propose to make full payment for the TC of the highest priced procedure and to make payment at 75 percent (that is, a 25 percent reduction) of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same patient on the same day. We are not proposing to apply an MPPR to the PC for cardiovascular and ophthalmology services at this time. In Table 11, we provide examples illustrating the current and proposed payment amounts:

TABLE 11—ILLUSTRATION OF CURRENT AND PROPOSED PAYMENTS

Sample Cardiovascular Payment Reduction*

	Code 78452	Code 93306	Total current payment	Total proposed payment	Payment calculation
PC	$77.00	$65.00	$142.00	$142.00	no reduction.
TC	427.00	148.00	575.00	538.00	$427 + (.75 × $148).
Global	504.00	213.00	717.00	680.00	$142 + $427 + (.75 × $148).

Sample Ophthalmology Payment Reduction*

	Code 92235	Code 92250	Total current payment	Total proposed payment	Payment calculation
PC	46.00	23.00	69.00	69.00	no reduction.
TC	92.00	53.00	145.00	131.75	$92 + (.75 × $53).
Global	138.00	76.00	214.00	200.75	$69 + $92 + (.75 × $53).

*Dollar amounts are for illustrative purposes and may not reflect actual payment amounts.

We believe that the proposed MPPR percentage represents an appropriate reduction for the typical delivery of multiple cardiovascular and ophthalmology services on the same day. Because the reduction is based on discounting the specific PE inputs that are not duplicated for second and subsequent services, the proposal is consistent with our longstanding policy on surgical and nuclear medicine diagnostic procedures and advanced imaging procedures which applies a 50 percent reduction to second and subsequent procedures, and our more recent policy on therapy services, which applies a 20 or 25 percent reduction depending on the setting.

Furthermore, it is consistent with section 1848(c)(2)(K) of the Act which specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values.

Finally, it is responsive to continued concerns about significant growth in spending on imaging and other diagnostic services, and to MedPAC (March 2010) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies. Savings resulting from this proposal would be redistributed to other PFS services as required by the general statutory PFS BN provision. In summary, for services furnished on or after January 1, 2013, we plan to apply the MPPR to nuclear medicine procedures to CPT codes 78306 (Bone imaging; whole body when followed by CPT code 78320 (Bone imaging; SPECT). We plan to apply the MPPR to the PC and the TC of advanced imaging procedures to multiple physicians in the same group practice (same group NPI). Therefore, the MPPR will apply when one or more physicians in the same group practice furnish services to the same patient, in the same session, on the same day. Finally, we propose to apply an MPPR to TC-only services and to the TC portion of global services for diagnostic cardiovascular and ophthalmology procedures. The reduction would apply independently to cardiovascular and ophthalmology services. We propose to make full payment for the TC of the highest priced procedure and payment at 75 percent of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same patient on the same day.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION

Code	Descriptor
75600	Contrast x-ray exam of aorta.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Descriptor
75605	Contrast x-ray exam of aorta.
75625	Contrast x-ray exam of aorta.
75630	X-ray aorta leg arteries.
75650	Artery x-rays head & neck.
75658	Artery x-rays arm.
75660	Artery x-rays head & neck.
75662	Artery x-rays head & neck.
75665	Artery x-rays head & neck.
75671	Artery x-rays head & neck.
75676	Artery x-rays neck.
75680	Artery x-rays neck.
75685	Artery x-rays spine.
75705	Artery x-rays spine.
75710	Artery x-rays arm/leg.
75716	Artery x-rays arms/legs.
75726	Artery x-rays abdomen.
75731	Artery x-rays adrenal gland.
75733	Artery x-rays adrenals.
75736	Artery x-rays pelvis.
75741	Artery x-rays lung.
75743	Artery x-rays lungs.
75746	Artery x-rays lung.
75756	Artery x-rays chest.
75774	Artery x-ray each vessel.
75791	Av dialysis shunt imaging.
75809	Nonvascular shunt x-ray.
75820	Vein x-ray arm/leg.
75822	Vein x-ray arms/legs.
75825	Vein x-ray trunk.
75827	Vein x-ray chest.
75831	Vein x-ray kidney.
75833	Vein x-ray kidneys.
75840	Vein x-ray adrenal gland.
75842	Vein x-ray adrenal glands.
75860	Vein x-ray neck.
75870	Vein x-ray skull.
75872	Vein x-ray skull.
75880	Vein x-ray eye socket.
75885	Vein x-ray liver.
75887	Vein x-ray liver.
75889	Vein x-ray liver.
75891	Vein x-ray liver.
75893	Venous sampling by catheter.
78428	Cardiac shunt imaging.
78445	Vascular flow imaging.
78451	Ht muscle image spect sing.
78452	Ht muscle image spect mult.
78453	Ht muscle image planar sing.
78454	Ht musc image planar mult.
78456	Acute venous thrombus image.
78457	Venous thrombosis imaging.
78458	Ven thrombosis images bilat.
78466	Heart infarct image.
78468	Heart infarct image (ef).
78469	Heart infarct image (3D).
78472	Gated heart planar single.
78473	Gated heart multiple.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Descriptor
78481	Heart first pass single.
78483	Heart first pass multiple.
78494	Heart image spect.
78496	Heart first pass add-on.
93005	Electrocardiogram tracing.
93017	Cardiovascular stress test.
93318	Echo transesophageal intraop.
93024	Cardiac drug stress test.
93025	Microvolt t-wave assess.
93041	Rhythm ecg tracing.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93229	Remote 30 day ecg tech supp.
93270	Remote 30 day ecg rev/report.
93271	Ecg/monitoring and analysis.
93278	ECG/signal-averaged.
93279	Pm device progr eval sngl.
93280	Pm device progr eval dual.
93281	Pm device progr eval multi.
93282	Icd device prog eval 1 sngl.
93283	Icd device progr eval dual.
93284	Icd device progr eval mult.
93285	Ilr device eval progr.
93286	Pre-op pm device eval.
93287	Pre-op icd device eval.
93288	Pm device eval in person.
93289	Icd device interrogate.
93290	Icm device eval.
93291	Ilr device interrogate.
93292	Wcd device interrogate.
93293	Pm phone r-strip device eval.
93296	Pm/icd remote tech serv.
93303	Echo transthoracic.
93304	Echo transthoracic.
93306	Tte w/doppler complete.
93307	Tte w/o doppler complete.
93308	Tte f-up or lmtd.
93312	Echo transesophageal.
93314	Echo transesophageal.
93318	Echo transesophageal intraop.
93320	Doppler echo exam heart.
93321	Doppler echo exam heart.
93325	Doppler color flow add-on.
93350	Stress tte only.
93351	Stress tte complete.
93701	Bioimpedance cv analysis.
93724	Analyze pacemaker system.
93786	Ambulatory BP recording.
93788	Ambulatory BP analysis.
93880	Extracranial study.
93882	Extracranial study.
93886	Intracranial study.
93888	Intracranial study.
93890	Tcd vasoreactivity study.
93892	Tcd emboli detect w/o inj.
93893	Tcd emboli detect w/inj.
93922	Upr/l xtremity art 2 levels.

TABLE 12—DIAGNOSTIC CARDIOVASCULAR SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION—Continued

Code	Descriptor
93923	Upr/lxtr art stdy 3+ lvls.
93924	Lwr xtr vasc stdy bilat.
93925	Lower extremity study.
93926	Lower extremity study.
93930	Upper extremity study.
93931	Upper extremity study.
93965	Extremity study.
93970	Extremity study.
93971	Extremity study.
93975	Vascular study.
93976	Vascular study.
93978	Vascular study.
93979	Vascular study.
93980	Penile vascular study.
93981	Penile vascular study.
93990	Doppler flow testing.

TABLE 13—DIAGNOSTIC OPHTHALMOLOGY SERVICES SUBJECT TO THE MULTIPLE PROCEDURE PAYMENT REDUCTION

Code	Descriptor
76510	Ophth us b & quant a.
76511	Ophth us quant a only.
76512	Ophth us b w/non-quant a.
76513	Echo exam of eye water bath.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92132	Cmptr ophth dx img ant segmt.
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92228	Remote retinal imaging mgmt.
92235	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
92265	Eye muscle evaluation.
92270	Electro-oculography.
92275	Electroretinography.
92283	Color vision examination.
92284	Dark adaptation eye exam.
92285	Eye photography.
92286	Internal eye photography.

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TABLE 14: Frequently Billed Diagnostic Cardiovascular Combinations

Code Range 75600-75893							
Code	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**
75710	Artery x-rays arm/leg	75791	Av dialysis shunt imaging				
75625	Contrast x-ray exam of aorta	75716	Artery x-rays arms/legs				
75625	Contrast x-ray exam of aorta	75716	Artery x-rays arms/legs	75774	Artery x-ray each vessel		
75820	Vein x-ray arm/leg	75827	Vein x-ray chest				
75625	Contrast x-ray exam of aorta	75710	Artery x-rays arm/leg				
75791	Av dialysis shunt imaging	75827	Vein x-ray chest				
75658	Artery x-rays arm	75791	Av dialysis shunt imaging	75820	Vein x-ray arm/leg	75827	Vein x-ray chest
75710	Artery x-rays arm/leg	75774	Artery x-ray each vessel				
75820	Vein x-ray arm/leg	93931	Upper extremity study				
75791	Av dialysis shunt imaging	75820	Vein x-ray arm/leg				
Code Range 78414-78496							
Code	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**
78452	Ht muscle image spect mult	93306	Tte w/doppler complete				
78452	Ht muscle image spect mult	93017	Cardiovascular stress test				
78452	Ht muscle image spect mult	93306	Tte w/doppler complete	93880	Extracranial study		
78452TC	Ht muscle image spect mult	93017	Cardiovascular stress test				
78452	Ht muscle image spect mult	93880	Extracranial study				
78452TC	Ht muscle image spect mult	93306	Tte w/doppler complete				
78452	Ht muscle image spect mult	93017	Cardiovascular stress test	93306	Tte w/doppler complete		
78451	Ht muscle image spect sing	93306	Tte w/doppler complete				
78452TC	Ht muscle image spect mult	93306TC	Tte w/doppler complete				
78452	Ht muscle image spect mult	93306	Tte w/doppler complete	93880	Extracranial study	93978	Vascular study
Code Range 93000-93990							
Code	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**		
93306	Tte w/doppler complete	93880	Extracranial study				
93320	Doppler echo exam heart	93325	Lower extremity study	93351	Stress tte complete		
93922	Upr/l xtremity art 2 levels	93925	Lower extremity study				
93923	Upr/lxtr art stdy 3+ lvls	93925	Lower extremity study				
93306TC	Tte w/doppler	93880TC	Extracranial study				

	complete		
93880	Extracranial study	93978	Vascular study
93284	Icd device progr eval mult	93290	Icm device eval
93922	Upr/l xtremity art 2 levels	93926	Lower extremity study
93965	Extremity study	93970	Extremity study
93925	Lower extremity study	93970	Extremity study

TABLE 15: Frequently Billed Diagnostic Ophthalmology Combinations

Code Range 76510-76529					
Code	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**
76514	Echo exam of eye thickness	92133	Cmptr ophth img optic nerve		
76514	Echo exam of eye thickness	92083	Visual field examination(s)	92133	Cmptr ophth img optic nerve
76514	Echo exam of eye thickness	92083	Visual field examination(s)		
76514	Echo exam of eye thickness	92250	Eye exam with photos		
76514	Echo exam of eye thickness	92083	Visual field examination(s)	92250	Eye exam with photos
76512	Ophth us b w/non-quant a	92134	Cptr ophth dx img post segmt		
76512	Ophth us b w/non-quant a	92250	Eye exam with photos		
76514	Echo exam of eye thickness	92286	Internal eye photography		
76514	Echo exam of eye thickness	92134	Cptr ophth dx img post segmt		
76512	Ophth us b w/non-quant a	92235	Eye exam with photos	92250	Eye exam with photos
Code Range 92002-92371					
Code	**Descriptor**	**Code**	**Descriptor**	**Code**	**Descriptor**
92083	Visual field examination(s)	92133	Cmptr ophth img optic nerve		
92235	Eye exam with photos	92250	Eye exam with photos		
92083	Visual field examination(s)	92250	Eye exam with photos		
92083	Visual field examination(s)	92134	Cptr ophth dx img post segmt		
92134	Cptr ophth dx img post segmt	92235	Eye exam with photos		
92134	Cptr ophth dx img post segmt	92250	Eye exam with photos		
92134	Cptr ophth dx img post segmt	92235	Eye exam with photos	92250	Eye exam with photos
92250	Eye exam with photos	92285	Eye photography		
92082	Visual field examination(s)	92250	Eye exam with photos		
92081	Visual field examination(s)	92285	Eye photography		

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C. Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: Work; PE; and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA, which amended section 1848(c) of the Act, required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review and, if necessary, adjust RVUs no less often than every 5 years. The first review and update of resource-

based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), malpractice RVUs for new and revised codes effective before the next Five-Year Review of Malpractice (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk to a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or ''scale'') the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be increased by 10 percent over the source code malpractice RVU. This approach presumes the same risk factor for the new/revised code and source code but uses the work RVU for the new/revised code to adjust for risk-of-service.

For CY 2013, we will continue our current approach for determining malpractice RVUs for new/revised codes. We will publish a list of new/revised codes and the malpractice crosswalk(s) used for determining their malpractice RVUs in the final rule with comment period. The CY 2013 malpractice RVUs for new/revised codes will be implemented as interim final values in the CY 2013 PFS final rule with comment period, where they will be subject to public comment. They will then be finalized in the CY 2014 PFS final rule with comment period.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). While requiring that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier States beginning January 1, 2011.

Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2011. The statute was amended to extend the 1.0 floor for the work GPCIs through February 29, 2012 by section 303 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112–78). The statute was again amended by section 3004 of the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) (Pub. L. 112–399) to extend the 1.0 work floor for GPCIs throughout the remainder of CY 2012 (that is, for services furnished no later than December 31, 2012). During the development of the CY 2012 PFS final rule with comment period, neither TPTCCA nor MCTRJCA had been enacted and, because the work GPCI floor was set to expire at the end of 2011, the GPCIs published in Addendum E of the CY 2012 PFS final rule with comment period did not reflect the 1.0 work floor. Appropriate changes to the CY 2012 GPCIs were made to reflect the 1.0 work floor required by section 303 of the TPTCCA and section 3004 of the MCTRJCA.

Since the 1.0 work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2013 PFS, the proposed CY 2013 work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS proposed rule do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848(e)(1)(G) and section 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier States are applicable in CY 2013.

In the CY 2012 PFS final rule with comment period we made several refinements to the GPCIs (76 FR 73081 through 73092), including revising the sixth GPCI update to reflect the most recent data, with modifications. Specifically, we finalized our proposal to change the GPCI cost share weights for CY 2012 to reflect the most recent rebased and revised Medicare Economic Index (MEI). As a result, the cost share weight for the work GPCI (as a percentage of the total) was updated from 52.466 percent to 48.266 percent, and the cost share weight for the PE GPCI was revised from 43.669 percent to 47.439 percent with a change in the employee compensation component from 18.654 to 19.153 percentage points. The cost share weight for the office rent component of the PE GPCI was changed from 12.209 percent to 10.223 percentage points (fixed capital with utilities), and the medical equipment, supplies, and other miscellaneous expenses component was updated to 9.968 percentage points. In addition, we finalized the weight for purchased services at 8.095 percentage points, of which 5.011 percentage points are adjusted for geographic cost differences. Lastly, the cost share weight for the MP GPCI was revised from 3.865 percent to 4.295 percent. Table 16 displays the cost share weights that were finalized in the CY 2012 final rule with comment period. Note that the employee compensation; office rent; purchased services; and equipment supplies and other cost share weights sum to the total PE GPCI cost share weights of 47.439 percent.

TABLE 16—COST SHARE WEIGHTS FINALIZED IN CY 2012 GPCI UPDATE

Expense category	Cost share weights (%)
Physician Work	48.266
Practice Expense	47.439
Employee Compensation	19.153
Office Rent	10.223
Purchased Services	8.095
Equipment, Supplies, and Other	9.968
Malpractice Insurance	4.295

We also finalized several other policies including the use of 2006 through 2008 American Community Survey (ACS) two-bedroom rental data as a proxy for the relative cost difference in physician office rent. In addition, we created a purchased services index to account for labor-related services within the ''all other services'' and ''other professional expenses'' MEI components. In response to public commenters who recommended that we utilize Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data to capture the ''full range'' of

occupations included in the offices of physician industry to calculate the nonphysician employee wage component (also referred to as the employee wage index) of the PE GPCI, we finalized a policy of using 100 percent of the total wage share of nonphysician occupations in the offices of physicians' industry to calculate the nonphysician employee wage component of the PE GPCI.

2. Recommendations From the Institute of Medicine

Concurrent with our CY 2012 rulemaking cycle, the Institute of Medicine released the final version of its first of two anticipated reports entitled ''Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition'' on September 28, 2011. This report included an evaluation of the accuracy of geographic adjustment factors for the hospital wage index and the GPCIs, as well as the methodology and data used to calculate them. Several of the policies that we finalized in CY 2012 rulemaking addressed several of the recommendations contained in the Institute of Medicine's first report. Because we did not have adequate time to completely address the Institute of Medicine's Phase I report recommendations during CY 2012 rulemaking, we have included a discussion in this proposed rule about the recommendations that were not implemented or discussed in the CY 2012 final rule with comment period. We look forward to receiving comments on these recommendations.

The Institute of Medicine's second report, expected in summer 2012, will evaluate the effects of geographic adjustment factors (hospital wage index and GPCIs) on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. We did not receive the Institute of Medicine's Phase II report in time for consideration for this CY 2013 proposed rule. We intend to address the Institute of Medicine's recommendations in the Phase II report once we have had an opportunity to fully evaluate the report and its recommendations.

3. GPCI Discussion for CY 2013

CY 2013 is the final year of the sixth GPCI update and, because we will propose updates next year, we are not including any proposals related to the GPCIs in this proposed rule. In response to public inquiries about exceptions to the calculated GPCIs, we are providing a brief discussion about the permanent 1.0 PE floor for frontier States, the 1.5 work floor for Alaska, the GPCIs for the Puerto Rico payment locality, and the expiration of the GPCI 1.0 work floor required under section 1848(e)(1)(E) of the Act. We also discuss recommendations from the first Institute of Medicine report that were not addressed during CY 2012 rulemaking in this proposed rule.

a. Alaska Work Floor and PE GPCI Floor for Frontier States

Section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009. Therefore, the 1.5 work floor for Alaska will remain in effect in CY 2013. In addition, section 1848(e)(1)(I) of the Act establishes a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. There are no proposed changes to those States identified as ''Frontier States'' for the CY 2013 proposed rule. The following States are considered to be ''Frontier States'' for CY 2013: Montana, North Dakota, Nevada, South Dakota, and Wyoming.

b. GPCI Assignments for the Puerto Rico Payment Locality

Recently, we have received inquiries from representatives of the Puerto Rico medical community regarding our policies for determining the GPCIs for the Puerto Rico payment locality. While we are not making any proposals related to the GPCIs for Puerto Rico, in response to those inquiries, we are providing the following discussion regarding the GPCIs assigned to the Puerto Rico payment locality. We anticipate recalculating all the GPCI's in the seventh GPCI update currently anticipated in CY 2014.

As noted above, we are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure relative resource cost differences among localities compared to the national average for each of the three fee schedule components: Work, PE and malpractice expense. To calculate these GPCI values, we rely on three primary data sources. We currently use the 2006–2008 BLS OES data to calculate the work GPCI, the nonphysician employee wage component of PE GPCI, and the labor costs associated with the purchased services component of PE GPCI. We use 2006–2008 ACS data to calculate the office rent component of the PE GPCI. Finally, we use 2006–2007 malpractice premium data to calculate the MP GPCI. For all localities, including Puerto Rico, we assume equipment, supplies, and other expenses are purchased in a national market and that the costs do not vary by geographic location. Therefore, we do not use data on the price of equipment, supplies, and expenses across localities in calculating PE GPCIs. With the exception of the MP GPCI, we have current data from the applicable sources allowing us to calculate the work and PE GPCIs for the Puerto Rico payment locality. The 2006–2008 BLS OES data and rental values derived from the 2006–2008 ACS indicate that the costs associated with operating a physician practice in Puerto Rico are the lowest among all payment localities.

In order to calculate the MP GPCI for the various Medicare PFS localities, we collect malpractice insurance market share and premium data from state departments of insurance and from state rate filings. As discussed in our contractor's report (Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule, pg. 41), for the fourth, fifth, and sixth GPCI updates we were not able to collect this data for the Puerto Rico payment locality. Therefore, we carried over the MP GPCI value of 0.249 from previous GPCI updates when malpractice premium data were last available. It is important that we have a source for more current malpractice premium data for Puerto Rico for use in the upcoming seventh GPCI update. We are working with the relevant officials in Puerto Rico to acquire these data for use in future rulemaking. We would encourage comments from stakeholders regarding potential data sources that may be available for calculating the Puerto Rico malpractice GPCI. For a detailed discussion regarding the methodology used to calculate the various components of the Puerto Rico GPCIs, we refer readers to our contractor's report from November of 2010 entitled ''Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule'' available on our Web site at *http://www.cms.gov/PhysicianFeeSched/downloads/GPCI_Report.pdf*.

c. Expiration of GPCI Work Floor

The work GPCIs are designed to capture the relative costs of physician labor by Medicare PFS locality. Previously, the work GPCIs were developed using the median hourly earnings from the 2000 Census of workers in seven professional specialty occupation categories which we used as a proxy for physicians' wages.

Physicians' wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings. That is, including physicians' wages in the work GPCIs would effectively make the indices dependent upon Medicare payments. As required by law, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average. The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. For the sixth GPCI update in CY 2011, we used the 2006 through 2008 BLS OES data as a replacement for the 2000 Census data.

Although we are not proposing any changes to the data or methodology used to calculate the work GPCI for CY 2013, we note that addenda D and E will reflect the expiration of the statutory 1.0 work GPCI floor. As noted above, section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2011 until it was temporarily extended through February 29, 2012 by section 303 of the TPTCCA. The GPCI work floor was extended throughout the remainder of CY 2012 by section 3004 of the MCTRJCA.

4. Institute of Medicine Phase I Report

a. Background

At our request, the Institute of Medicine is conducting a study of the geographic adjustment factors in Medicare payment. It is a comprehensive empirical study of the geographic adjustment factors established under sections 1848(e) (GPCI) and 1886(d)(3)(E) of the Act (hospital wage index). These adjustments are designed to ensure Medicare payment fees and rates reflect differences in input costs across geographic areas. The factors the Institute of Medicine is evaluating include the following:

- Accuracy of the adjustment factors;
- Methodology used to determine the adjustment factors; and
- Sources of data and the degree to which such data are representative.

Within the context of the U.S. healthcare marketplace, the Institute of Medicine is also evaluating and considering the—

- Effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability of hospitals and other facilities to maintain an adequate and skilled workforce; and

++ Patient access to providers and needed medical technologies;

- Effect of adjustment factors on population health and quality of care; and
- Effect of the adjustment factors on the ability of providers to furnish efficient, high value care.

The Institute of Medicine's first report entitled ''Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy'' evaluated the accuracy of geographic adjustment factors and the methodology and data used to calculate them. The recommendations included in the Institute of Medicine's Phase I report that relate to or would have an effect on the methodologies used to calculate the GPCIs and the configuration of Medicare PFS payment locality structure are summarized as follows:

- Recommendation 2–1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.
- Recommendation 2–2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all health care employers.
- Recommendation 5–1: The GPCI cost share weights for adjusting fee-for-service payments to practitioners should continue to be national, including the three GPCIs (work, PE, and liability insurance) and the categories within the PE (office rent and personnel).
- Recommendation 5–2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified.
- Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process.
- Recommendation 5–4: The PE GPCI should be constructed with the full range of occupations employed in physicians' offices, each with a fixed national weight based on the hours of each occupation employed in physicians' offices nationwide.
- Recommendation 5–5 CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare & and Medicaid Services.
- Recommendation 5–6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5–7: Nonclinical labor-related expenses currently included under PE office expenses should be geographically adjusted as part of the wage component of the PE.

This report can be accessed on the Institute of Medicine 's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx*.

As previously noted, the Institute of Medicine will consider the role of Medicare payments on matters such as the distribution of the healthcare workforce, population health, and the ability of providers to produce high-value, high-quality health care in its final report anticipated in summer 2012. We were not able to evaluate the recommendations contained in the Institute of Medicine's Phase II report, in time for discussion in this proposed rule.

b. Institute of Medicine Recommendations Implemented in CY 2012

In the CY 2012 final rule with comment period, we addressed three of the recommendations offered by the Institute of Medicine in their Phase I report. Specifically, the final CY 2012 GPCIs utilized the full range of non-physician occupations in the employee wage calculation consistent with Institute of Medicine recommendation 5–4. Additionally, we created a new purchased service index to account for non-clinical labor related expenses similar to Institute of Medicine recommendation 5–7. Lastly, we have consistently used national cost share weights to determine the appropriate weight attributed to each GPCI component, which is supported by Institute of Medicine recommendation 5–1 (76 FR 73081 through 73092). In order to facilitate a public discussion regarding the Institute of Medicine's remaining recommendations, we are providing a summary analysis of these recommendations in this proposed rule below. We will provide our technical analyses of the remaining Institute of Medicine Phase I recommendations in a report that will be released on the PFS Web site at *http://www.cms.gov/PhysicianFeeSched*. Since we have not yet had an opportunity to review the recommendations in the Institute of Medicine's Phase II report, these analyses focus exclusively on the

recommendations as presented in the Institute of Medicine's Phase I release.

c. Discussion of Remaining Institute of Medicine Recommendations

(1) Institute of Medicine Recommendation Summaries

(A) *Institute of Medicine recommendation 2–1:* The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pages 2–1 thru 2–29)

(i) Locality Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are Statewide areas (that is, only one locality for the entire State). There are 52 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, effective January 1, 1992. Payments under the fee schedule are based on the relative resources required to provide services and vary among areas as resource costs vary geographically as measured by the GPCIs.

Payment localities were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS. As a result, a study was begun in 1994 which resulted in a comprehensive locality revision, which was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89 and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. A full discussion of the methodology can be found in the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As was stated in the CY 2011 final rule with comment period (75 FR 73261), we currently require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, we have sought consensus for any locality changes among the professionals whose payments would be affected. We have also considered more comprehensive changes to locality configurations. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*http://www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf*). The alternative locality configurations in the report are described below.

- *Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration:* CBSAs are a combination of Office of Management and Budget (OMB's) Metropolitan Statistical Areas (MSAs) and their Micropolitan Statistical Areas. Under this option, MSAs would be considered as urban CBSAs. Micropolitan Statistical Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of State) CBSAs. This approach would be consistent with the areas used in the Inpatient Prospective Payment System (IPPS) pre-reclassification wage index, which is the hospital wage index for a geographic area (CBSA or non-CBSA) calculated from submitted hospital cost report data before statutory adjustments reconfigure, or ''reclassify'' a hospital to an area other than its geographic location, to adjust payments for difference in local resource costs in other Medicare payment systems. Based on data used in the 2008 locality report, this option would increase the number of PFS localities from 89 to 439.
- *Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties):* Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.
- *Option 3: Separate MSAs from Statewide Localities (Separate MSAs):* This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.
- *Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers):* This option creates tiers of counties (within each State) that may or may not be contiguous but share similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers.

For a detailed discussion of the public comments on the contractor's 2008 draft report detailing four different locality configurations, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757). There was no public consensus on the options, although a number of commenters expressed support for Option 3 (separate MSAs from Statewide localities) because the commenters believed this alternative would improve payment accuracy and could mitigate potential reductions to rural areas compared to Option 1 (CMS CBSAs).

In response to some public comments regarding the third of the four locality options, we had our contractor conduct an analysis of the impacts that would result from the application of Option 3. Those results were displayed in the final locality report released in 2011. The final report, entitled ''Review of Alternative GPCI Payment Locality Structures—Final Report,'' is accessible from the CMS PFS Web page under the heading ''Review of Alternative GPCI Payment Locality Structures—Final Report.'' The report may also be accessed directly from the following link: *http://www.cms.gov/PhysicianFeeSched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf.*

(ii) Institute of Medicine Recommendation Discussion

The Institute of Medicine recommends altering the current locality structure that was originally based on areas set by local contractors and, in 1996, reduced from 210 to current 89 using a systematic iterative methodology. Rather than using the current uniform fee schedule areas in adjusting for relative cost differences as compared to the national average, the Institute of Medicine recommends a three-tiered system for defining fee schedule areas. In the first tier, the Institute of Medicine proposes applying county-based fee schedule areas to calculate the employee wage component of the PE GPCI. Although the Institute of Medicine's report states that it recommends that ''Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets,'' the Institute of Medicine also recommends applying an out-commuting adjustment, which would permit employee wage index values to vary by county. Since the employee wage index is one component of the PE GPCI, these values also would vary by county under the Institute of Medicine's proposal.

To understand why the employee wage index would vary by county under the Institute of Medicine's recommendation, consider the three steps that would be required to calculate the employee wage index. The first step calculates the average hourly wage (AHW) for workers employed in each MSA or residual (rest of state) area. The wages of workers in each occupation are weighted by the number of workers employed in physicians' offices nationally. The second step applies a commuting-based smoothing adjustment to create area index wages for each county. The commuting-adjusted county index wages are equal to a weighted average of the AHW values calculated in the first step, where the weights are county-to-MSA out-commuting patterns. The Institute of Medicine's out-commuting-based weights equal the share of health care workers that live in a county where a physician's office is located who commute out of the county to work in a physician office in each MSA. The third step sets each physician's employee index wage equal to the estimated area index wage (calculated in Step 2) of the county in which the physician office is located. Because the out-commuting adjustment envisioned by the Institute of Medicine in the second step varies by county, the employee wage index value—and thus the PE GPCI as a whole—would also potentially vary by county depending on the smoothing option chosen. If implemented, the number of employee wage index payment areas could potentially increase from 89 to over 3,000.

The Institute of Medicine's second tier of fee schedule areas would use an MSA-based approach. The Institute of Medicine proposes using the MSA-based system for the work GPCI, the office rent index, the purchased services index, and the MP GPCI. An MSA is made up of one or more counties, including the counties that contain the core urban area with a population of 50,000 or more, as well as surrounding counties that exhibit a high degree of social and economic integration (as measured by commuting patterns) with the urban core. MSAs are designed to be socially and economically integrated units based on the share of workers who commute to work within the urban core of each MSA. Implementing an MSA-based locality structure would expand the number of fee schedule areas from 89 to upwards of 400 plus additional MSAs for U.S. territories (for example, Virgin Islands, American Samoa, Guam, Northern Marianna Islands).

In its third payment area tier, the Institute of Medicine proposes creating a national payment area for the ''equipment, supplies and other'' index. We currently do not adjust PEs associated with supplies and equipment since we believe they are typically purchased in a national market. Thus, this approach is equivalent to using a national fee schedule area to define this index. The Institute of Medicine proposes no change to the fee schedule area used to compute the ''equipment, supplies and other'' index.

Based on our contractor's analysis, there would be significant redistributive impacts if we were to implement a policy that would reconfigure the PFS localities based on the Institute of Medicine's three-tiered recommendation. Many rural areas would see substantial decreases in their corresponding GAF and GPCI values as higher cost counties are removed from current ''Rest of State'' payment areas. Conversely, many urban areas, especially those areas that are currently designated as ''Rest of State'' but reside within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs.

The localities used to calculate the GPCIs have been a subject of substantial discussion and debate since the implementation of the PFS. The intensity of those discussions has increased since the last comprehensive update to the locality structure in 1997. Physicians and other suppliers in areas such as Santa Cruz County, California and Prince William County, Virginia have expressed concern that the current locality structure does not appropriately capture economic and demographic shifts that have taken place since the last PFS locality update. On the other hand, rural practitioners have argued that revisions to the current PFS payment localities will reduce their payments and exacerbate the problems of attracting physicians and other practitioners to rural areas. In the past, we have also heard concerns from representatives of some statewide localities regarding the potential implications of adopting an alternative locality structure that would change their current statewide payment area (74 FR 33536).

The Institute of Medicine stated in its Phase I report regarding its locality recommendation that, ''While the payment areas would stay the same for the HWI (hospital wage index), implementing this recommendation would mean that the GPCI payment areas would expand from 89 to 441 areas, which would be a significant change. The impact of the change in payment areas will be assessed in the Phase II report.'' (''Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition'' on September 28, 2011, pg 5–6.) Moreover, the Institute of Medicine's Phase II report will evaluate the effects of geographic adjustment factors on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Over the years, commenters that have opposed revisions to localities have claimed that changes to the PFS areas could have a significant impact on the ability of rural areas to attract physicians. Certainly, one of our major goals when we last comprehensively revised the Medicare PFS localities in 1996 was to avoid excessively large urban/rural payment differences (61 FR 59494). In 1996, we were hopeful that the revisions would improve access to care for rural areas (61 FR 59494). Some areas may have experienced both economic and demographic shifts since the last comprehensive locality update. Before moving forward with the Institute of Medicine's three tiered locality recommendation, or any other potential locality revision, we need to assess, and prepare to inform the public of, the impact of any change for all Medicare stakeholders. The Institute of Medicine's Phase II report, scheduled for release this summer 2012, should

contain an evaluation of many of these important factors including:

• The effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability for hospitals and other facilities to maintain an adequate and skilled workforce;

++ Patient access to providers and needed medical technologies;

++ Effect of adjustment factors on population health and quality of care; and

++ Effect of adjustment factors on the ability of providers to furnish efficient, high value care.

To fully assess the broader public policy implications associated with the Institute of Medicine's locality recommendation, we must first fully assess and analyze the recommendations contained in the Institute of Medicine's phase II report. Accordingly, we believe that it would be premature to propose any change to the PFS localities at this time.

In conjunction with a specific proposal for changing the locality configuration during future rulemaking, we would provide detailed analysis on the impact of the changes for physicians in each county. We would also provide opportunities for public input (for example, Town Hall meetings or Open Door Forums), as well as opportunities for public comments afforded by the rulemaking process.

While we are making no proposal in this proposed rule to change the current locality configuration, we are seeking public comment regarding Institute of Medicine's recommended three-tiered PFS payment locality definition. In addition, we will make our technical analyses of the Institute of Medicine locality recommendations, specific to the Phase I report, available on the PFS Web site at *http://www.cms.gov/PhysicianFeeSched/*.

(B) *Institute of Medicine Recommendation 2–2:* The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all healthcare employers (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pages 2–1 thru 2–29) and; Recommendation 5–5 CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pg 5–38.)

The Institute of Medicine recommends altering the data used to calculate the employee wage index. Specifically, Institute of Medicine recommends using wage data for workers in the healthcare industry rather than wage data for workers across all-industries. Although all-industry wage data has the largest sample size, the Institute of Medicine ''* * * is concerned that the [all-industry] sample does not represent physician offices.'' BLS OES occupation wage data by MSA, however, are not publicly available for the healthcare industry. Using healthcare-industry wages requires the use of confidential BLS OES data, to which CMS does not have access at this time. Although the Institute of Medicine recommends that CMS secure an agreement with BLS to use the confidential wage data, the current employee wage index relies on publicly-available all-industry wage data. We seek comment on the use of confidential employee wage index data rather than the publicly available all-industry wage data.

Regardless of whether healthcare-industry or all-industry wage data is used, the Institute of Medicine recommends following the current approach adopted by CMS in CY 2012 for calculating the employee wage index. This approach constructs the employee wage index as a weighted average of occupation wages for the full-range of occupations employed in physicians' offices, where the weights are equal to the fixed national weight based on the hours of each occupation employed in physicians' offices nationwide. We adopted this approach for calculating the GPCI employee wage index in the CY 2012 PFS final rule with comment period (76 FR 73088).

(C) *Institute of Medicine recommendation 5–2:* Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pg 5–36) and; Recommendation 5–3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pages 5–36 thru 5–37.)

The Institute of Medicine recommends replacing the current work GPCI methodology with a regression-based approach. We currently use three steps to calculate the work GPCI. These steps include:

(1) Selecting the proxy occupations and calculating an occupation-specific index for each proxy;

(2) Assigning weights to each proxy-occupation index based on the each occupation's share of total national wages to create an aggregate proxy-occupation index; and

(3) Adjusting the aggregate proxy-occupation index by a physician inclusion factor to calculate the final work GPCI.

By using this approach, the current methodology reduces the circularity problem that occurs when work GPCI values are based on direct measurements of physician earnings. Because physician earnings are made up of both wages and a return on investment from ownership of the physician practice, calculating the work GPCI using physician earnings information would assign areas where physician practices are more profitable higher work GPCI values. Although the Institute of Medicine recommends that we continue to use proxy occupations in the work GPCI methodology, its regression-based approach alters each of the three steps described above.

To modify the first step, the Institute of Medicine recommends that we empirically evaluate the validity of seven proxy occupations we currently use. The current proxy occupations in the work GPCI are intended to represent highly educated, professional employee categories. Although the Institute of Medicine recommends re-evaluating the proxy occupations used in the work GPCI, it does not define specific criteria to use for this purpose.

To modify the second step, the Institute of Medicine recommends using a regression-based approach to weight the selected proxy occupation indices based on their correlation with physician earnings. This Institute of Medicine proposal would replace the current approach where occupations are weighted by the size of their share of total national wages. Such an approach presumes that wages for proxy occupations are not related to physician profits.

Finally, the Institute of Medicine proposes an empirically-based approach to determine the inclusion factor for work. The inclusion factor for work refers to section 1848(e)(1)(A)(iii) of the Act requiring that the work GPCI reflect only 25 percent of the difference between the relative value of physicians' work effort in each locality and the national average of such work effort. Therefore, under current law, only one quarter of the measured

regional variation in physician wages is incorporated into the work GPCI. The Institute of Medicine recommends calculating an inclusion factor based on the predicted values of the regression described above. Under the Institute of Medicine's approach, the inclusion factor is larger when the proxy occupations have a higher correlation with physicians' earnings and smaller when the proxy occupations have a lower correlation with physicians' earnings. We note that using such an empirical approach to weight the proxy occupation indices and to estimate the inclusion factor requires the identification of a viable source of physician wage information in addition to the wage information of proxy occupations to accurately measure regional variation in physician wages.

We seek comment on the Institute of Medicine recommendations to revise the work GPCI methodology. In addition, we look forward to the MedPAC study on this issue required under section 3004 of the MCTRJCA. This study will assess whether any geographic adjustment to physician work is appropriate and, if so, what the level should be and where it should be applied.

(D) *Institute of Medicine Recommendation 5–6:* A new source of information should be developed to determine the variation in the price of commercial office rent per square foot. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy, pages 5–38 thru 5–39.)

The Institute of Medicine recommends the development of a new source of data to determine the variation in the price of commercial office rent per square foot. However, the Institute of Medicine does not explicitly recommend where the data should come from or how it should be collected. Before coming to this recommendation, the Institute of Medicine identified and evaluated several public and commercially available sources of data to determine whether an accurate alternative is available to replace the residential rent data currently used as a proxy to measure regional variation in physicians' cost to rent office space in the PE GPCI; these sources include rental data from the U.S. Department of Housing and Urban Development, American Housing Survey, General Services Administration, Basic Allowance for Housing (U.S. Department of Defense), U.S. Postal Service, Medical Group Management Association (MGMA), and REIS, Inc. The Institute of Medicine concluded that these sources had substantial limitations, including lack of representativeness of the market in which physicians rent space, small sample size, low response rates, and sample biases. Although we agree that a suitable source for commercial office rent data would be preferable to the use of residential rent data in our PE office rent methodology, we have still been unable to identify an adequate commercial rent source that sufficiently covers rural and urban areas. We will continue to evaluate possible commercial rent data sources for potential use in the office rent calculation. We also encourage public commenters to notify us of any publicly available commercial rent data sources, with adequate data representation of urban and rural areas that could potentially be used in the calculation of the office rent component of PE.

E. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, or electrocardiogram, or electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment which would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554) (BIPA) added a new section, 1834(m), to the Act which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient and the practitioner at the distant site. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act does allow the use of asynchronous ''store-and-forward'' technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at § 410.78(a)(1), store and forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the individual practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a Federally qualified health center (FQHC) and a hospital (as defined in Section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and

Providers Act of 2008 (Pub. L. 110–275) (MIPPA) expanded the list of telehealth originating sites to include hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural health professional shortage area (HPSA), in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be presented by a practitioner at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;
- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT); and
- Smoking cessation services.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under State law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the –GT (Via interactive audio and video telecommunications system) or –GQ (Via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (Telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the –GT or –GQ modifier appended).

2. Requests for Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of telehealth services to one of two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that

are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.

- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: Individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA in order to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs); subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), and smoking cessation services.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2012 will be considered for the CY 2014 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *www.cms.gov/telehealth/*.

3. Submitted Request and Other Additions to the List of Telehealth Services for CY 2013

We received a request in CY 2011 to add alcohol and/or substance abuse and brief intervention services as Medicare telehealth services effective for CY 2013. The following presents a discussion of this request, and our proposals for additions to the CY 2013 telehealth list.

a. Alcohol and/or Substance Abuse and Brief Intervention Services

The American Telemedicine Association submitted a request to add alcohol and/or substance abuse and brief intervention services, reported by CPT codes 99408 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes) and 99409 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention (SBI) services; greater than 30 minutes) to the list of approved telehealth services for CY 2013 on a category 1 basis.

We note that we assigned a status indicator of ''N'' (Noncovered) to CPT codes 99408 and 99409 as explained in the CY 2008 PFS final rule with comment period (72 FR 66371). At the time, we stated that because Medicare only provides payment for certain screening services with an explicit benefit category, and these CPT codes incorporate screening services along with intervention services, we believed that these codes were ineligible for payment under the PFS. We continue to believe that these codes are ineligible for payment under PFS and, additionally, under the telehealth benefit. We do not believe it would be appropriate to make payment for claims using these CPT codes for the services furnished via telehealth, but not when furnished in person. Because CPT codes 99408 and 99409 are currently assigned a noncovered status indicator, and because we continue to believe this assignment is appropriate, we are not proposing to add these CPT codes to the list of Medicare Telehealth Services for CY 2013.

However, we created two parallel G-codes for 2008 that allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not furnished as screening services, but that are furnished in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397 (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and intervention greater than 30 minutes). Since these codes are used to report comparable alcohol and substance abuse services under certain conditions, we believe that it would be appropriate to consider the ATA's request as it applies to these services when appropriately reported by the G-codes. The ATA asked that CMS consider this request as a category 1 addition based on the similarities between these services and CPT codes 99406 (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and 99407 (Smoking and tobacco use

cessation counseling visit; intensive, greater than 10 minutes). We agree that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to their interaction in smoking cessation services. We also believe that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to the assessment and intervention elements of CPT code 96152 (health and behavior intervention, each 15 minutes, face-to-face; individual), which also is currently on the telehealth list.

Therefore, we are proposing to add HCPCS codes G0396 and G0397 to the list of telehealth services for CY 2013 on a category 1 basis. Consistent with this proposal, we are also proposing to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include alcohol and substance abuse assessment and intervention services as Medicare telehealth services.

b. Preventive Services

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

During CY 2012, CMS added coverage for several preventive services through the national coverage determination (NCD) process as authorized by section 1861(ddd) of the Act. These services add to Medicare's existing portfolio of preventive services that are now available without cost sharing under the Affordable Care Act. We believe that for several of these services, the interactions between the furnishing practitioner and the beneficiary are similar to services currently on the list of Medicare telehealth services. Specifically, we believe that the assessment, education, and counseling elements of the following services are similar to existing telehealth services:

- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse, reported by HCPCS codes G0442 (Annual alcohol misuse screening, 15 minutes) and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes).
- Screening for depression in adults, reported by HCPCS code G0444 (Annual Depression Screening, 15 minutes).
- Screening for sexually transmitted infections (STIs) and high-intensity behavioral counseling (HIBC) to prevent STIs, reported by HCPCS code G0445 (High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: Education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes).
- Intensive behavioral therapy for cardiovascular disease, reported by HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes).
- Intensive behavioral therapy for obesity, reported by HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes). We believe that the interactions between practitioners and beneficiaries receiving these services are similar to individual KDE services reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour), individual MNT reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in the same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes), and HBAI reported by CPT code 96150 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment); CPT code 96151 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient re-assessment); CPT code 96152 (Health and behavior intervention, each 15 minutes, face-to-face; Individual); CPT code 96153 (Health and behavior intervention, each 15 minutes, face-to-face; Group (2 or more patients)); CPT code 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)), all services that are currently on the telehealth list.

Therefore, we are proposing to add HCPCS codes G0442, G0443, G0444, G0445, G0446, and G0447 to the list of telehealth services for CY 2013 on a category 1 basis. We note that all coverage guidelines specific to the services would continue to apply when these services are furnished via telehealth. For example, when the national coverage determination requires that the service be furnished to beneficiaries in a primary care setting, the qualifying originating telehealth site must also qualify as a primary care setting. Similarly, when the national coverage determination requires that the service be furnished by a primary care practitioner, the qualifying primary distant site practitioner must also qualify as primary care practitioner. For more detailed information on coverage requirements for these services, we refer readers to the Medicare National Coverage Determinations Manual, Pub. 100–03, Chapter 1, Section 210, available at *http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf*. Consistent with this proposal, we are also proposing to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include these preventive services as Medicare telehealth services.

4. Technical Correction To Include Emergency Department Telehealth Consultations in Regulation

In the CY 2012 PFS final rule with comment period (76 FR 73103), we finalized our proposal to change the code descriptors for initial inpatient telehealth consultation G-codes to reflect telehealth consultations furnished to emergency department patients in addition to inpatient telehealth consultations effective January 1, 2012. However, we did not amend the description of the services within the regulation at § 414.65(a)(1)(i). Therefore, we are proposing to make a technical revision to our regulation at § 414.65(a)(1)(i) to reflect telehealth consultations furnished to emergency department patients in addition to hospital and SNF inpatients.

F. Extension of Payment for Technical Component of Certain Physician Pathology Services

1. Background and Statutory Authority

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provided payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for a 2-year period beginning on January 1, 2000. This section has been amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), section 3104 of the Affordable Care Act (Pub. L. 111–148), section 105 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309), section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) to continue payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for various time periods. As discussed in detail below, Congress most recently acted to continue this payment through June 30, 2012. The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately billable by the pathologist. When an independent laboratory's pathologist furnishes the PC service, the PC service is usually billed with the TC service as a combined or global service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 and 59409), we stated that this policy has contributed to the Medicare program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) To the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised § 415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC of physician pathology services furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to § 415.130 was delayed 1-year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of § 415.130 was further delayed by section 542 of the BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 PFS final rule with comment period (71 FR 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Section 3104 of the Affordable Care Act amended the prior legislation to extend the payment through CY 2010. Section 105 of the MMEA extended the payment through CY 2011. Subsequent to publication of the CY 2012 PFS final rule with comment period, section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 extended the payment through February 29, 2012 and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 extended the payment through June 30, 2012.

2. Revisions to Payment for TC of Certain Physician Pathology Services

In the CY 2012 PFS final rule with comment period, we finalized our policy that an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished after December 31, 2011, to a hospital inpatient or outpatient (76 FR 73278 through 73279, 73473). As discussed above, subsequent to publication of this final rule with comment period, Congress acted to continue payment to independent laboratories through June 30, 2012. Therefore, the policy that we finalized in the CY 2012 PFS final rule with comment period is superseded by statute for six months. To be consistent with the statutory changes and our current policy, we are proposing conforming changes to § 415.130(d) such that we will continue payment under the PFS to independent laboratories furnishing the TC of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital on or before June 30, 2012. Independent laboratories may not bill the Medicare contractor for the TC of physician pathology services furnished after June 30, 2012, to a hospital inpatient or outpatient.

G. Therapy Services

1. Outpatient Therapy Caps for CY 2013

Section 1833(g) of the Act applies annual, per beneficiary, limitations (therapy caps) on expenses incurred for outpatient therapy services under Medicare Part B. There is one therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined and a second separate therapy cap for outpatient occupational therapy (OT) services. Although therapy services furnished in an outpatient hospital setting have been exempt from the application of the therapy caps, section 3005(b) of the

MCTRJCA amended section 1833(g) of the Act to require therapy services furnished in an outpatient hospital setting during 2012 be subject to the therapy caps beginning not later than October 1, 2012.

The therapy caps amount for CY 2013 will be announced in the CY 2013 PFS final rule with comment period. The annual change in each therapy cap is computed by multiplying the cap amount for CY 2012, which is $1,880, by the MEI for CY 2013, then rounding to the nearest $10. This amount is added to the CY 2012 therapy cap amount to obtain the CY 2013 therapy cap amount.

An exceptions process to the therapy caps has been in effect since January 1, 2006—originally authorized by section 5107 of the DRA, which amended section 1833(g)(5) of the Act. Since that time, the exceptions process for the therapy caps has been extended through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, and TPTCCA). Last amended by section 3005 of the MCTRJCA, the Agency's authority to provide for an exception process to therapy caps expires on December 31, 2012. To request an exception to the therapy caps, therapy suppliers and providers use the KX modifier on claims for services that are over the cap amount. Use of the KX modifier indicates that the services are reasonable and necessary and that there is documentation of medical necessity in the beneficiary's medical record.

Section 3005 of the MCTRJCA also requires two additional changes to Medicare policies for outpatient therapy services. Section 3005(a)(5) adds a new subparagraph (C) to section 1833(g)(5) of the Act, effective October 1 through December 31, 2012, that requires application of a manual medical review process (similar to the process used in 2006 for certain therapy cap exceptions) for exceptions to the therapy caps after expenses incurred for the beneficiary's therapy services (including services furnished in a hospital outpatient department) exceed the threshold of $3,700 for the year. As with the therapy caps, there are two separate thresholds for the manual medical review process—one threshold of $3,700 for PT and SLP services combined and one threshold of $3,700 for OT services. Requests for exceptions to the therapy caps for services above the thresholds are subject to a manual medical review process. The applicable amount of expenses incurred for therapy services counted towards these thresholds for the year begins on January 1, 2012. Since the exceptions process is set to expire on December 31, 2012, the requirement for a manual medical review process will also expire then.

Section 3005(c) adds a new section 1842(t)(2) to the Act, effective beginning on October 1, 2012, that requires the National Provider Identifier (NPI) of the physician (or NPP, where applicable), who periodically reviews the therapy plan of care, to be reported on the claim for therapy services. This reporting requirement applies to all claims for outpatient therapy services.

2. Claims-Based Data Collection Strategy for Therapy Services

a. Introduction

Section 3005(g) of the MCTRJCA requires CMS to implement, beginning on January 1, 2013, ''* * * a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services subject to the limitations of section 1833(g) of the Act. Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes.''

b. History/Background

In 2010, more than 7.6 million Medicare beneficiaries received outpatient therapy services, including physical therapy (PT), occupational therapy (OT), and speech-language-pathology (SLP). Medicare payments for these services exceeded $5.6 billion. Between 1998–2008, Medicare expenditures for outpatient therapy services increased at a rate of 10.1 percent per year while the number of Medicare beneficiaries receiving therapy services only increased by 2.9 percent per year. Although a significant number of Medicare beneficiaries benefit from therapy services, the rapid growth in Medicare expenditures for these services has long been of concern to the Congress and the Agency. To address this concern, efforts have been focused on developing Medicare payment incentives that encourage delivery of reasonable and necessary care while discouraging overutilization of therapy services and the provision of medically unnecessary care. A brief review of these efforts is useful in understanding our proposal for CY 2013.

(1) Therapy Caps

Section 4541 of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) amended section 1833(g) of the Act to impose financial limitations on outpatient therapy services (the ''therapy caps'' discussed above) in an attempt to limit Medicare expenditures for therapy services. Prior to the BBA amendment, these caps had applied to services furnished by therapists in private practice, but the BBA expanded the caps effective January 1, 1999, to include all outpatient therapy services except those furnished in outpatient hospitals. Since that time, the Congress has amended the statute several times to impose a moratorium on the application of the caps or has required us to implement an exceptions process for the caps. The therapy caps have only been in effect without an exceptions process for less than two years. (See the discussion about the therapy cap exceptions process above.) Almost from the inception of the therapy caps, the Congress and the Agency have been exploring potential alternatives to the therapy caps.

(2) Multiple Procedure Payment Reduction (MPPR)

In the CY 2011 PFS final rule with comment period (75 FR 73232–73242), we adopted a MPPR of 25 percent applicable to the practice expense (PE) component of the second and subsequent therapy services when more than one of these services is furnished in a single session. This reduction applies to nearly 40 therapy services. (For a list of therapy services to which this policy applies, see Addenda H.) The Physician Payment and Therapy Relief Act of 2010 (PPTRA) subsequently revised the reduction to 20 percent for services furnished in an office setting, leaving the 25 percent reduction in place for services furnished in institutional settings. We adopted this MPPR as part of our directive under section 1848(c)(2)(k) of the statute (as added by section 3134(a) of the Affordable Care Act) to identify and evaluate potentially misvalued codes. By taking into consideration the expected efficiencies in direct PE resources that occur when services are furnished together, this policy results in more appropriate payment for therapy services. Although we did not adopt this MPPR policy specifically as an alternative to the therapy caps, paying more appropriately for combinations of therapy services that are commonly furnished in a single session reduces the number of beneficiaries impacted by the therapy caps in a given year. For more details on the MPPR policy, see section II.C.4. of this proposed rule.

(3) Studies Performed

A uniform dollar value therapy cap sets a limit on the volume of services furnished unrelated to the specific services furnished or the beneficiary's condition or needs. One uniform cap

does not deter unnecessary care or encourage efficient practice for low complexity beneficiaries. In fact, it may even encourage the provision of services up to the level of the cap. Conversely, a uniform cap without an exceptions process restricts necessary and appropriate care for certain high complexity beneficiaries. Recognizing these limitations in a uniform dollar value cap, we have been studying therapy practice patterns and exploring ways to refine payment for these services as an alternative to therapy caps.

On November 9, 2004, the Secretary delivered the Report to Congress, as required by the BBA as amended by the BBRA, ''Medicare Financial Limitations on Outpatient Therapy Services.'' That report included two utilization analyses. Although these analyses provided details on utilization, neither specifically identified ways to improve therapy payment. In the report, we indicated that further study was underway to assess alternatives to the therapy caps. The report and the analyses are available on the CMS Web site at *http://www.cms.gov/TherapyServices/*.

Since 2004, we have periodically updated the utilization analyses and posted other reports on the CMS Web site to respond to the additional BBRA requirements. Subsequent reports highlighted the expected effects of limiting services in various ways and presented plans to collect data about beneficiary condition, including functional limitations, using available tools. Through these efforts, we have made progress in identifying the outpatient therapy services that are billed to Medicare, the demographics of the beneficiaries who utilize these services, the types of therapy services furnished, the HCPCS codes used to bill the services, the allowed and paid amounts of the services, the providers of these services, the states in which the services are furnished and the type of practitioner furnishing services.

From these and other analyses in our ongoing research effort, we have concluded that without the ability to define the services that are typically needed to address specific clinical cohorts of beneficiaries (those with similar risk-adjusted conditions), it is not possible to develop payment policies that encourage the delivery of reasonable and necessary services while discouraging the provision of services that do not produce a clinical benefit. Although there is widespread agreement that beneficiary condition and functional limitations are critical to developing and evaluating an alternative payment system for therapy services, a system for collecting such data does not exist. Diagnosis information is available from Medicare claims. However, we believe that the primary diagnosis on the claim is a poor predictor for the type and duration of therapy services required. Much additional work is needed to develop an appropriate system for classifying clinical cohorts.

A 5-year CMS project titled ''Development of Outpatient Therapy Payment Alternatives'' (DOTPA) is expected to provide some of this information. The project is now in its final stages of data collection. The purpose of the DOTPA project is to identify a set of measures that we could routinely and reliably collect in support of payment alternatives to the therapy caps. Specifically, the measures being collected are to be assessed in terms of their administrative feasibility and their usefulness in identifying beneficiary need for outpatient therapy services and the outcomes of those services. A final report is expected during the second half of CY 2013. In addition to developing alternatives to the therapy caps, the DOTPA project reflects our interest in value-based purchasing by identifying components of value, namely, beneficiary need and the effectiveness of therapy services. Although we expect DOTPA to provide meaningful data and practical information to assist in developing improved methods of paying for appropriate therapy services, DOTPA will not deliver a standardized measurement instrument for use in outpatient therapy services. Further, it is unlikely that this one project alone will provide adequate information to implement a new payment system for therapy. This study combined with data from a wider group of Medicare beneficiaries would enhance our ability to develop alternative payment policy for outpatient therapy services.

c. Proposal

(1) Overview

As required by section 3005(g) of MCTRJCA, we are proposing to implement a claims-based data collection strategy on January 1, 2013. This claims-based data collection system is designed to gather information on beneficiary function and condition, therapy services furnished, and outcomes achieved. This information will assist in reforming the Medicare payment system for outpatient therapy services. By collecting data on beneficiary function over an episode of therapy services, we hope to better understand the Medicare beneficiary population that uses therapy services, how their functional limitations change as a result of therapy services, and the relationship between beneficiary functional limitations and furnished therapy services over an episode of care. The term ''functional limitation'' generally encompasses both the terms ''activity limitations'' and ''participation restrictions'' as described by the International Classification of Functioning, Disability and Health (ICF). (For information on ICF, see *http://www.who.int/classifications/icf/en/* and for specific ICF nomenclature (including activity limitations and participation restrictions), see *http://apps.who.int/classifications/icfbrowser/*.)

We are proposing to encompass, under this proposal, the Medicare Part B outpatient therapy benefit and PT, OT, and SLP under the Comprehensive Outpatient Rehabilitation Facilities (CORF) benefit. ''Incident to'' therapy services furnished by physicians or nonphysician practitioners (NPPs) would also be included. This broad applicability would include services furnished in hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), CORFs, rehabilitation agencies, and home health agencies (when the beneficiary is not under a home health plan of care) and private offices.

When used in this section ''therapists'' means all practitioners who furnish outpatient therapy services, including physical therapists, occupational therapists, and speech-language pathologists in private practice and those therapists who furnish services in the institutional settings, physicians and NPPs (including, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), as applicable.)

This proposal is based upon an option for claims-based data collection that was discussed during the CY 2011 rulemaking (75 FR 40096 through 40100 and 73284 through 73293). This option was developed under a contract with CMS as part of the Short Term Alternatives for Therapy Services (STATS) project. The STATS project provided three options for alternative payment to the therapy caps that could be considered in the short-term before completion of the DOTPA project. In developing options, the STATS project drew upon the analytical expertise of CMS contractors and the clinical expertise of various outpatient therapy stakeholders to consider policies and available claims data. The options developed were:

• Capturing additional clinical information regarding the severity and complexity of beneficiary functional impairments on therapy claims in order to facilitate medical review and at the same time gather data that would be useful in the long term to develop a better payment mechanism;

• Introducing additional claims edits regarding medical necessity, in order to reduce overutilization; and

• Adopting a per-session bundled payment that would vary based on beneficiary characteristics and the complexity of evaluation and treatment services furnished in a session.

While we did not propose to adopt any of these alternatives at that time, we discussed these three options during the CY 2011 rulemaking and solicited public comments on all aspects of these alternatives, including the potential associated benefits or problems, clinical concerns, practitioner administrative burden, consistency with other Medicare and private payer payment policies, and claims processing considerations. In general, public commenters on the data collection effort questioned the ability to collect the needed information using this type of system. Commenters raised specific concerns about the training and education of therapists that would be needed prior to implementation. Although concerns were expressed about claims-based data reporting, no one questioned the need for data on beneficiary condition and functional limitations. The Congress has now included in section 3005(g) of the MCTRJCA a requirement to implement a claims-based data collection effort. While the proposed system is based upon the data collection alternative discussed in the CY 2011 PFS rulemaking, it has been modified in response to the comments received on the CY 2011 proposed rule.

The long-term goal is to develop an improved payment system for Medicare therapy services. The desired payment system would pay appropriately and similarly for efficient and effective services furnished to beneficiaries with similar conditions and functional limitations who have good potential to benefit from the services furnished. Importantly, such a system would not encourage the furnishing of medically unnecessary or excessive services. At this time, the data on Medicare beneficiaries' use and benefit from therapy services from which to develop an improved system does not exist. This proposed data collection effort would be the first step towards collecting the data needed for this type of payment reform. Once the initial data have been collected and analyzed, we expect to be able to identify gaps in information and determine what additional data are needed to develop a new payment policy. Without a better understanding of the diversity of beneficiaries receiving therapy services and the variations in type and volume of treatments provided, we lack the information to develop a comprehensive strategy to map the way to an improved payment policy. While this claims-based data collection proposal is only the first step in a long-term effort, it is an essential step.

We are proposing to require that claims for therapy services include nonpayable G-codes and modifiers. Through the use of these codes and modifiers, we would capture data on the beneficiary's functional limitations (a) at the outset of the therapy episode, (b) at specified points during treatment and (c) at discharge from the outpatient therapy episode of care. In addition, the therapist's projected goal for functional status at the end of treatment would be reported on the first claim for services and periodically throughout an episode of care.

Specifically, G-codes would be used to identify what is being reported—current status, goal status or discharge status. Modifiers would indicate the extent of the severity/complexity of the functional limitation being tracked. The difference between the reported functional status at the start of therapy and projected functional status at the end of the course of therapy represents the progress the therapist anticipates the beneficiary would make during the course of treatment/episode of care. As the beneficiary progresses through the course of treatment, one would expect progress toward the goal established by the therapist.

By tracking changes in functional limitations throughout the therapy episode and at discharge, we would have information about the furnished therapy services and the outcomes of such services. The ICD–9 diagnosis codes reported on the claim form would provide information on beneficiary condition.

Since 2006, we have paid claims for therapy services that exceed the annual per beneficiary caps when the claims include the KX modifier. The presence of the KX modifier on a therapy claim indicates that the therapist attests that the services on the claim are medically necessary and that the justification for medical necessity is documented in the beneficiary's medical record. We propose to apply the additional G-code and modifier reporting requirements to all claims, including claims with the KX modifier and those subject to any manual medical review process, if such manual medical review or the KX modifier were applicable, after December 31, 2012. (See the discussion about therapy caps above.)

(2) Proposed Nonpayable G-Codes on Beneficiary Functional Status

For the proposed reporting, therapists would report G-codes and modifiers on Medicare claims for outpatient therapy services. Table 17 shows the proposed G-codes and their definitions. (An appropriate status indicator will be assigned to these codes if finalized.)

TABLE 17—PROPOSED NONPAYABLE G-CODES FOR REPORTING FUNCTIONAL LIMITATIONS

Functional limitation for primary functional limitation		
GXXX1	Primary Functional limitation	Current status at initial treatment/episode outset and at reporting intervals.
GXXX2	Primary Functional limitation	Projected goal status.
GXXX3	Primary Functional limitation	Status at therapy discharge or end of reporting.
Functional limitation for a secondary functional limitation if one exists		
GXXX4	Secondary Functional limitation	Current status at initial treatment/outset of therapy and at reporting intervals.
GXXX5	Secondary Functional limitation	Projected goal status.
GXXX6	Secondary Functional limitation	Status at therapy discharge or end of reporting.

TABLE 17—PROPOSED NONPAYABLE G-CODES FOR REPORTING FUNCTIONAL LIMITATIONS—Continued

Provider attestation that functional reporting not required		
GXXX7	.....	Provider confirms functional reporting not required.

The proposed claims-based data collection system using G-codes and severity modifiers builds upon current Medicare requirements for therapy services. Section 410.61 requires that a therapy plan of care (POC) be established before treatment begins. This POC must include: The type, amount, frequency, and duration of the PT, OT, SLP services to be furnished to each beneficiary, the diagnosis and the anticipated goals. Section 410.105(c) contains similar requirements for services furnished in the CORF setting. We have long encouraged therapists, through our manual provisions, to express the POC-required goals for each beneficiary in terms that are measureable and relate to identified functional impairments. See Pub 100–02, Chapter 15, Section 220.1.2. The evaluation and the goals developed as part of the POC would be the foundation for the initial reporting under the proposed system.

Using the first set of G-codes (GXXX1, GXXX2, and GXXX3) with appropriate modifiers, the therapist would report the beneficiary's primary functional limitation or the most clinically relevant functional limitation at the time of the initial therapy evaluation and the establishment of the POC. In combination with appropriate modifiers, these G-codes would describe the current functional limitation (GXXX1) and the projected goal (GXXX2) for the functional limitation and the status at the end of a course of therapy (GXXX3). At specified intervals during treatment, claims would also include GXXX1 to show the status at that time and GXXX2 to show the goal, which would not change during therapy, except as described below. At the time the beneficiary is discharged from therapy, the final claim for this episode of care would use GXXX2 to show the goal and GXXX3 to denote status at the end of reporting for this functional limitation.

Therapists frequently use measurement tools to quantify beneficiary function. The Patient Inquiry by Focus on Therapeutic Outcomes, Inc. (FOTO) and the National Outcomes Measurement System (NOMS) by the American Speech-Language-Hearing Association (ASHA) are two such assessment tools in the public domain that can be used to determine a composite or overall score for an assessment of beneficiary function. Therapists could use the score produced by such measurement tools, provided they are valid and reliable, to select the appropriate modifier for reporting the beneficiary's functional status. While we support the use of consistent, objective tools to determine beneficiary functional limitation, for several reasons, at this time we are not endorsing, nor are we proposing to require, use of a particular tool to determine the severity modifier discussed in the next section. Some tools are proprietary, and others in the public domain cannot be modified to explicitly address this data collection project. Further, this data collection effort spans several therapy disciplines. Requiring a specific instrument could create burdens for therapists that would have to be considered in light of any potential improvement in data accuracy, consistency and appropriateness that such an instrument would generate. We may reconsider this decision once we have more experience with claims-based data collection on beneficiary function associated with furnished therapy services. We are seeking public comment on the use of assessment tools. In particular, we are interested in feedback regarding the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations. We request that those favoring a requirement to use a specific tool provide information on the preferred tool and describe why the tool is preferred.

Early results from the DOTPA project suggest that most beneficiaries have more than one functional limitation at treatment outset. In fact, only 21 percent of the DOTPA assessments reported just one functional limitation. Slightly more than half (54 percent) reported two, three or four functional limitations.

To the extent that the DOTPA experience is typical, the therapist may need to make a determination as to which functional limitation is primary for reporting purposes. In cases where this is unclear, the therapist may choose the functional limitation that is most clinically relevant to a successful outcome for the beneficiary, the one that would yield the quickest and greatest mobility, or the one that is the greatest priority for the beneficiary. In all cases, this primary functional limitation should reflect the predominant limitation that the furnished therapy services are intended to address.

To allow for more complete reporting, the second set of G-codes in Table 17 could be used to describe a secondary functional limitation, when one exists. Two examples demonstrate the applicability of the second set of G-codes.

(1) A beneficiary under a PT plan of care is being treated simultaneously for mobility restriction, for example, ''walking and moving'' (including, for example, climbing stairs) due to complications following a total knee replacement and for a ''self-care'' restriction due to a stabilized and immobilized upper extremity after a shoulder dislocation.

(2) A beneficiary under a SLP plan of care may be treated simultaneously for both a swallowing dysfunction and a communication impairment resulting from a stroke.

This secondary G-code set is used to report the functional limitation that the therapist considers secondary to the primary one at the outset of a course of therapy. For example, in the first scenario above, the therapist determines the ''self-care'' to be secondary to the beneficiary's primary one (''walking and moving''). The therapist would report the secondary functional limitation using a current status (GXXX4) along with the associated goal (GXXX5).

In some cases, a secondary functional limitation may not develop or be identified until after the course of treatment has begun. In such situations, the therapist would begin reporting this secondary set at the time the functional limitation is identified. Just as in the example above, the therapist would report GXXX4 and GXXX5.

For beneficiaries having more than two functional limitations, once the goal for the primary functional limitation has been reached or the beneficiary's potential to reach the goal has been maximized, the reporting on that functional limitation ends and reporting can begin on a new functional limitation. The therapist would use the set of G-codes (and associated modifiers) for the primary functional limitation, that is, GXXX1–GXXX3, to report functional status of the beneficiary's third functional restriction. This process of adding a new functional limitation, for example, for the fourth and the fifth, can continue until therapy

ends. Following this process, the set of G-codes that the therapist uses originally to report each functional limitation does not change throughout the episode of care, even though the originally reported secondary functional limitation (reported with GXXX4 through GXXX6) may have become the primary one, for clinical purposes, once the goal for the originally reported primary functional limitation was reached. The therapist is not expected to change the G-code set used originally to report a particular functional limitation; we believe requiring therapists to do so would be too burdensome and would confuse the data we are collecting for programmatic purposes.

We are seeking comment on specific issues regarding reporting data on a secondary limitation. Specifically, we request comments regarding whether reporting on secondary functional limitations should be required or optional. We would also be interested in information regarding what percentage of Medicare therapy beneficiaries has more than one functional limitation at the outset of therapy, and for those with multiple functional limitations, what is the average number. We would also be interested in information on the percentage of these functional limitations for which therapists go on to measure, document, and develop related therapy goals.

The proposed G-codes differ from the three separate pairs of G-codes discussed in the CY 2011 PFS rulemaking. The CY 2011 discussion included these three pairs of G-codes, all of which reflect specific ICF terminology:

- Impairments of Body Functions and/or Impairments of Body Structures;
- Activity Limitations and Participation Restrictions; and
- Environmental Factors Barriers.

Each pair contained a G-code to represent the beneficiary's current functional status and another G-code to represent the beneficiary's projected goal status. Like the G-codes in this proposal, these G-codes would have been used with modifiers to reflect the severity/complexity of each element.

This set of G-codes appeared to us to be potentially redundant and confusing since we are using the term functional limitations to be synonymous with the ICF terminology ''activity limitations and participation restrictions.'' Requiring separate reporting on three elements would have imposed a burden on therapists without providing a meaningful benefit in the value of the data provided. Further, because environmental barriers as discussed in CY 2011 are contextual, we do not believe collecting information on them would contribute to developing an improved payment system or assist with medical review. Since our goal is to develop a system that imposes the minimal additional burden while providing adequate data to accomplish the statutory directive (to assist in reforming the Medicare payment system for outpatient therapy services), we are proposing to require that just one set of G-codes be used for reporting the primary functional limitation. We added a second set of G-codes for a secondary functional limitation, which are identical to those used for the primary functional limitation. We are interested in public comment on whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations. We would particularly appreciate receiving specific suggestions for any missing elements.

(3) Severity/Complexity Modifiers

For each functional G-code used on a claim, a modifier would be required to report the severity/complexity for that functional limitation. We propose to adopt a 12-point scale to report the severity or complexity of the functional limitation involved. The proposed modifiers are listed in Table 18.

TABLE 18—PROPOSED MODIFIERS

Modifier	Impairment limitation restriction difficulty
XA	0%.
XB	Between 1–9%.
XC	Between 10–19%.
XD	Between 20–29%.
XE	Between 30–39%.
XF	Between 40–49%.
XG	Between 50–59%.
XH	Between 60–69%.
XI	Between 70–79%.
XJ	Between 80–89%.
XK	Between 90–99%.
XL	100%.

An example of how a therapist would translate data from another assessment tool to this scale may be helpful. In our example, the physical therapist used the Berg Balance Scale (the long original version) to document the beneficiary's functional balance restriction and the beneficiary's test score is 33. (The scores on this test range from 0–56. A score below 41 is considered to be at moderate risk of falling.) Once the test is completed, the therapist maps the beneficiary's score to our severity modifier scale. To do so, the beneficiary's score must first be converted to a percentage. A score of 33 on a scale of 56 would equal 59 percent. To map the percentage from the Berg Balance Scale to the modifier scale, it must be subtracted from 100, since zero on the Berg Balance Scale reflects 100 percent limitation/disability. When 59 percent is subtracted from 100 percent, the result is 41 percent. This number falling between 40 percent and 49 percent is mapped to the severity modifier of ''XF.''

As already noted, there are many other valid and reliable measurement tools that therapists use to quantify functional limitations. Among these are four assessment tools we discussed in CY 2011 PFS rulemaking—namely, the Activity Measure—Post Acute Care (AM–PAC) tool, the FOTO Patient Inquiry, OPTIMAL, and NOMS. We list these tools as recommended for use by therapists, though not required, in the outpatient therapy IOM provision of the Benefits Policy Manual, Chapter 15, Section 220.3C ''Documentation Requirements for Therapy Services.'' The scores from these and other measurement tools already in use by therapy disciplines produce numerical or percentage scores that can be mapped or crosswalked to the proposed severity modifier scale. The advantage of using an assessment tool that yields a composite score, such as NOMS, would be that only the G-codes for the primary functional limitation would need to be reported even if we required reporting of secondary limitations.

In assessing the ability of therapists to provide the required severity information regardless of what assessment tool they use, if any, we considered the comments received on the CY 2011 PFS proposed rule discussion and our preliminary experience from the DOTPA project. Both indicated that we needed greater granularity in our severity scale to more accurately assess changes in functional limitation over the course of therapy. Specifically, most commenters favored the 7-point scale over the 5-point ICF-based scale. They preferred a scale with more severity levels since it would allow the therapist to document smaller changes that many therapy beneficiaries make towards their goals. For example, the ''severe'' level of the 5-point scale includes a 45-point spread (from 50–95 percent) making it difficult to document a change or improvement in a beneficiary's condition whose limitation being rated falls into this category. Commenters also liked the equal increments of the 7-point scale.

We believe that neither the five- or seven-point scales are adequate for this reporting system, and developed a new scale. The 12-point scale we are proposing is an enhancement of the 7-

point scale. It achieves the ability to more accurately capture changes in functional limitations over the course of treatment and is easier to use and understand. It addresses the concern of a major association, which supported the 7-point scale, but suggested that an even more sensitive rating scale (one with more increments) might be necessary to show progress of certain beneficiaries toward their projected goals, particularly those beneficiaries with neurological conditions, such as strokes. In addition, the proposed scale's 10-percentage point increments make it easier for therapists to convert composite and overall scores from assessment instruments or other measurement tools to this scale.

(4) Adaptation for G-Codes by Select Categories of Functional Limitations

The ultimate goal of gathering information on beneficiary function is to have adequate information to develop an alternative payment system for therapy services. Although the information that would be collected pursuant to the proposal discussed above would greatly increase our understanding of the therapy services furnished and any progress made as a result of these services, it would leave us far short of the data needed for developing a new payment system. A significant limitation of this proposal is that it would not provide data by type of functional limitation involved. We have been unable to identify an existing system that categorizes the variety of functional limitations addressed by therapists. Without an existing system that could be used to collect data on specific functional limitations, we could not develop and implement a complete system categorizing all functional limitations within the time period allowed by the statute.

However, we could begin to collect data on select categories of functional limitations by adapting the reporting system described above to include some category specific-reporting in addition to the generic reporting. Should we decide to use a system with category-specific reporting, we would expect to develop specific nonpayable G-codes for select categories of functional limitations in the final rule. Under this adaptation, if one of the select categories of functional limitations created describes the functional limitation being reported, that G-code set would be used to report the current, projected goal, and discharge status of the beneficiary.

Any functional limitation not identified in this limited G-code set would be reported using the generic G-codes previously described.

To demonstrate this approach, we have created G-codes that describe the two most frequently reported functional limitations by each of the three therapy disciplines in the DOTPA project. (See Table 19.) When appropriate, these G-codes would be used exactly as the generic ones.

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TABLE 19: Select Categories of G-Codes

Walking & Moving Around	
Walking & moving around functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXXX8
Walking & moving around functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy	GXXX9
Walking & moving around functional limitation, discharge status, at discharge from therapy/end of reporting on limitation	GXX10
Changing & Maintaining Body Position	
Changing & maintaining body position functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX11
Changing & maintaining body position functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX12
Changing & maintaining body position functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX13
Carrying, Moving & Handling Objects	
Carrying, moving & handling objects functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX14
Carrying, moving & handling objects functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX15
Carrying, moving & handling objects functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX16
Self Care (washing oneself, toileting, dressing, eating, drinking)	
Self care functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX17
Self care functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX18
Self care functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX19
Communication: Reception (spoken, nonverbal, sign language, written)	
Communication: Reception functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX20
Communication: Reception functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX21
Communication: Reception functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX22
Communication: Expression (speaking, nonverbal, sign language, writing)	
Communication: Expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals	GXX23
Communication: Expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy	GXX24
Communication: Expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation	GXX25

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The benefit of having these select G-code sets in addition to the general G-codes is that the data collected could be analyzed by specific diagnoses/conditions and categories of functional limitations. We believe that in order to develop an improved payment system for therapy services this type of information is needed. Moreover, expansion of these categorical G-codes to encompass many more categories of functional limitations is essential. However, implementing specific G-codes for a select set of functional limitations could be a starting point. An

initial data set could allow us to begin collecting the necessary data. It would also help us to evaluate how such a system works and make improvements before imposing requirements across the board.

We seek input from therapists on categories of functional limitations, such as those described in this section. We specifically request comments regarding the following questions. Would data collected on categories of functional limitations provide more meaningful data on therapy services than that collected through use of the generic G-codes in our proposal? Should we choose to implement a system that is based on at least some select categories of functional limitation, which functional limitations should we collect data on in 2013? Is it more, less or the same burden to report on categories of functional limitations or generic ones? The categories of functional limitations described above are based on the ICF categories, but these ICF categories also have subcategories. Should we use subcategories for reporting? Are there specific conditions not covered by these ICF categories? Would we need to have G-codes for the same categories of secondary limitations?

(5) Reporting Frequency

We propose to require this claims-based reporting in conjunction with the initial service at the outset of a therapy episode, at established intervals during treatment and at discharge. The number of G-codes required on a particular claim would vary from one to four, depending on the circumstances. Table 20 shows a graphic example of which codes are used for specified reporting. We would note that the example represents a therapy episode of care occurring over an extended time period. This example might be typical for a beneficiary receiving therapy for the late effects of a stroke. We chose to use an example with a much higher than average number of treatment days in order to show a greater variety of reporting scenarios.

TABLE 20: Example

	Evaluation/Treatment Day 1 Begin Reporting Period #1	End Reporting Period #1	Begin Reporting Period #2	Claim for treatment days 5 and 6 in Period #2	End Reporting Period #2	Begin Reporting Period #3	Discharge /End of reporting on Primary Functional Limitation	End Reporting Period #3
Primary Function Status								
GXXX1 – Current	X	X	X		X	X		
GXXX2 – Goal	X		X			X	X	
GXXX3 – Discharge							X	
Secondary Function								
GXXX4 – Current			X		X	X		X
GXXX5 – Goal			X			X		
GXXX6 – Discharge								
No Functional Reporting Required								
GXXXX7				X				

• *Outset.* Under this proposal, the first reporting of G-codes and modifiers would occur when the outpatient therapy episode of care begins. This would typically be the date of service when the therapist furnishes the evaluation and develops the required plan of care for the beneficiary. At the outset, the therapist would use the G-codes and modifiers to report a current status and a projected goal for the primary functional limitation. If a secondary functional limitation needs to be reported at this time, the same information would be reported using G-codes and associated modifiers for the secondary functional limitation.

• *Every 10 Treatment Days or 30 Calendar Days, Whichever Is Less.* We propose to require that the reporting frequency for G-codes and associated modifiers be once every 10 treatment days or at least once during each 30 calendar days, whichever time period is shorter. The first treatment day for purposes of reporting would be the day that the initial visit takes place. The date the episode of care begins, typically at the evaluation, even when the therapist does not furnish a separately billable procedure in addition to the evaluation for this day, would be considered treatment day one, effectively beginning the count of treatment days or calendar days for the first reporting period.

In calculating the 10 treatment days, a treatment day is defined as a calendar day in which treatment occurs resulting in a billable service. Often a treatment day and a therapy ''session'' or ''visit'' may be the same, but the two terms are not interchangeable. Infrequently, for example, a beneficiary might receive certain services twice a day—these two different sessions (or visits) in the same day are counted as one treatment day).

On the claim for service on the 10th treatment day or the 30th calendar day after treatment day one, the therapist would only report GXXX1 and the appropriate modifier to show the beneficiary's functional status at the end of this reporting period. If also reporting on a secondary functional limitation, GXXX4 and the appropriate modifier would be included as well.

The next reporting period begins on the next treatment day, that is, the time period between the end of one reporting period and the next treatment day does not count towards the 30 calendar day period. On the claim for services furnished on this date, the therapist would report both the G-code and modifier showing the current functional status at this time along with the G-code and modifier reflecting the projected goal that was identified at the outset of the therapy episode. This process would continue until the beneficiary concludes the course of therapy treatment.

On a claim for a service that does not require specific reporting of a G-code with modifier (that is, a claim for services between the first and the tenth day of service and that is less than 30 days from the initial assessment), GXXX7 would be used. By using this code, the therapist would be confirming that the claim does not require specific functional limitation reporting. This is the only G-code that is reported without a severity modifier.

The count of days, both treatment and calendar, for the second reporting period and any others thereafter, would begin on the first treatment day after the end of the previous reporting period.

We selected the 10/30 frequency of reporting to be consistent with our timing requirements for progress reports. These timing requirements are included in the *Documentation Requirements for Therapy Services* (see Pub. 100–02, Chapter 15, Section 220.3, Subsection D). By making these reporting timeframes consistent with Medicare's other requirements, therapists, who are already furnishing therapy services to Medicare outpatients, would have a familiar framework for successfully adopting our new reporting requirement. This should minimize the additional burden. In addition to reflecting the Medicare required documentation for progress reports, we believe that this simplifies the process and minimizes the new burden on practitioners since many therapy episodes would be completed by the 10th treatment day. In 2008, the average number of days in a therapy episode was nine treatment days for SLP, 11 treatment days for PT, and 12 treatment days for OT. When reporting on two functional limitations, the therapist would report the G-codes and modifiers for the second condition in the manner described above. In other words, at the end of the reporting period, two G-codes would be reported to show current functional status—one for the primary (GXXX1) and one for the secondary (GXXX4) limitation. Similarly, at the beginning of the reporting period four G-codes would be reported. GXXX1 and GXXX4 would be used to report current status for the primary and secondary functional limitations, respectively; and, GXXX2 and GXXX5 would be used to report the goal status for the primary and secondary functional limitations, respectively.

The reporting periods must be the same for both the primary and secondary functional limitation. The therapist can accomplish this by starting them at the same time or if the secondary functional limitation is added at some point in treatment, the primary functional limitation's reporting period must be re-started by reporting GXXX1 and GXXX2 at the same time the new secondary functional limitation is added using GXXX4 and GXXX5.

Further, for those therapy treatment episodes lasting longer periods of time, the periodic reporting of the G-codes and associated modifiers would reflect any progress that the beneficiary made toward the identified goal. In summary, we propose to require the reporting of G-codes and modifiers at episode outset (evaluation or initial visit), and once every 10th treatment day or at least every 30 calendar days, whichever time period is less.

We believe it is important that the requirements for this reporting system be consistent with the requirements for documenting any progress in the medical record as specified in our manual. Given the current proposal for claims-based data collection, we believe it is an appropriate time to reassess the manual requirements. Toward this vein, we are seeking comment on whether it would be appropriate to modify the progress note requirement in the IOM to one based solely on the number of treatment days, such as six or ten. Should this modification be made, a corresponding change would be made in the reporting periods. We seek comments regarding clinical impact of such a change.

- *Discharge.* In addition, we are proposing to require reporting of the G-code/modifier functional data at the conclusion of treatment so that we have a complete set of data for the therapy episode of care. Requiring the reporting at discharge mirrors the IOM requirement of a discharge note or summary. This set of data would reveal any functional progress or improvement the beneficiary made toward the projected therapy goal during the entire therapy episode. Specifically, having information on the beneficiary's functional status at the time of discharge shows whether or to what degree the projected therapy goal was met.

To report the current status of the functional limitation at the time of discharge, the therapist would use GXXX3 and the appropriate modifier. Where there is a secondary functional limitation, GXXX6, along with its appropriate modifier, would also be reported. In addition, GXXX2, along with the modifier established at the outset of therapy, is used to report the projected goal status of the primary functional limitation. And, GXXX4 and its corresponding modifier is reported to show the projected goal status for the secondary functional limitation that was established at the outset of therapy. The imposition of this reporting requirement does not justify scheduling an additional, and perhaps medically unnecessary, final session in order to measure the beneficiary's function for the sole purpose of reporting.

Although collection of discharge data is important in achieving our goals, we recognize that data on functional status at the time therapy concludes is likely to be incomplete for some beneficiaries receiving outpatient therapy services. The DOTPA project has found this to be true. There are various reasons as to why the therapist would not be able to report functional status using G-codes and modifiers at the time therapy ends. Sometimes, beneficiaries may discontinue therapy without alerting their therapist of their intention to do so, simply because they feel better, they can no longer fit therapy into their work schedules, or their transportation is unavailable. Whatever the reason, there would be situations where the therapy ends without a discharge visit. In these situations, we would not require the reporting at discharge. However, we encourage therapists to include discharge reporting whenever possible on the final claims.

For example, since the therapist is typically reassessing the beneficiary during the therapy sessions, the data critical to the severity/complexity of the functional measure may be available even when the final therapy session does not occur. In these instances, the G-codes and modifiers appropriate to discharge should be reported.

We are particularly interested in how often the therapy community finds that beneficiaries discontinue therapy

without the therapist knowing in advance that it is the last treatment session and other situations in which the discharge data would not be available for reporting.

• *Significant Change in Beneficiary Condition.* We are proposing that, in addition to reporting at the intervals discussed above, the G-code/modifier measures would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC. This could result from new clinical findings, an added comorbidity, or a failure to respond to treatment described in the POC. This reporting affords the therapist the opportunity to explain a beneficiary's failure to progress toward the initially established goal(s) and permits either the revision of the severity status of the existing goal or the establishment of a new goal or goals. The therapist would be required to begin a new reporting period when submitting a claim containing a CPT code for an evaluation or a re-evaluation. These G-codes, along with the associated modifiers, could be used to show an increase in the severity of one or two functional limitations; or, they could be used to reflect the severity of newly identified functional limitations as delineated in the revised plan of care.

(6) Documentation

We propose to require that documentation of the information used for reporting under this system must be included in the beneficiary's medical record. The therapist would need to track in the medical record the G-codes and the corresponding severity modifiers that were used to report the status of the functional limitations at the outset of the therapy episode, at the beginning and end of each reporting period, and at the time of discharge (or to report that the projected goal has been achieved and reporting on the particular functional limitation has ended). It is important to include this information in the record in order to create an auditable record and so that this record would also serve to improve the quality of data CMS collects as it will help the therapist keep track of assessment and treatment information for particular beneficiaries.

For example, the therapist selects the functional limitation of ''walking and moving'' as the primary limitation and determines that at therapy outset the beneficiary has a 60 percent limitation and sets the goal to reduce the limitation to 5 percent. The therapist uses GXXX1–XH to report the current status of the functional impairment; and GXXX2–XB to report the goal. The therapist should note in the beneficiary's medical record that the functional limitation is ''walking and moving'' and document the G-codes and severity modifiers used to report this functional limitation on the claim for therapy services.

(7) Claims Requirements

Except for the addition of the proposed G-codes and modifiers, nothing in this proposal would modify other existing requirements for submission of therapy claims. For example, the therapy modifiers—GO, GP, and GN—are still required to indicate that the therapy services, for which the G-codes and modifiers are used to report function on, are furnished under a OT, PT, or SLP plan of care, respectively.

Claims from institutional providers, which are submitted to the fiscal intermediaries (FIs) and A/B MACs, would require that a charge be included on the service line for each one of these G-codes in the series, GXXX1–GXXX7. This charge would not be used for payment purposes and would not affect processing. Claims for professional services submitted to carriers and A/B MACs do not require that a charge be included for these nonpayable G-codes but reporting a charge for the nonpayable G-codes would not affect claims processing.

Medicare does not process claims that do not include a billable service. As a result, reporting under this system would need to be included on the same claim as a furnished service that Medicare covers.

(8) Implementation Date

In accordance with section 3005(g) of the MCTRJCA, we propose to implement these data reporting requirements on January 1, 2013. We recognize that with electronic health records and electronic claims submission, therapists may encounter difficulty in including this new data on claims. To accommodate those that may experience operational or other difficulties with moving to this new reporting system and to assure smooth transition, we are proposing a testing period from January 1, 2013 until July 1, 2013. We would expect that all those billing for outpatient therapy services would take advantage of this testing period and begin attempting to report the new G-codes and modifiers as quickly as possible on or after January 1, 2013, in preparation for required reporting beginning on July 1, 2013. Taking advantage of this testing period would help to minimize potential problems after July 1, 2013, when claims without the appropriate G-codes and modifiers would be returned unpaid.

(9) Compliance Required as a Condition for Payment and Regulatory Changes

To implement the reporting system required by MCTRJCA and described above we are proposing to amend the regulations establishing the conditions for payment governing PT, OT, SLP, and CORFs to add a requirement that the claims include information on beneficiary functional limitations. In addition, we propose to amend the plan of care requirements set forth in the regulations for outpatient therapy services and CORFs to require that the therapy goals, which must be included in the POC, are consistent with the beneficiary function reporting on claims for services.

Specifically, we propose to amend the regulations for outpatient OT, PT, and SLP (§ 410.59, § 410.60, and § 410.62, respectively) by adding a new paragraph (a)(4) to require that claims submitted for furnished services contain the information on beneficiary functional limitations as described in this rule.

We also propose to amend the plan of care requirements set forth at § 410.61(c) to require that the therapy goals, which must be included in the treatment plan, must be consistent with those reported on claims for services. This requirement is in addition to those already existing conditions for the POC

To achieve consistency in the provision of PT, OT, and SLP services across settings, we propose to amend § 410.105 to include the same requirements for these services furnished in CORFs. These proposed revisions would require that the goals in the treatment plan be consistent with the beneficiary function reported on claims for services and that claims submitted for furnished services contain specified information on beneficiary functional limitations, respectively. Respiratory therapy services furnished in CORFs are not subject to the reporting requirements, and therefore, these requirements would not apply to them.

(10) Consulting With Relevant Stakeholders

Section 3005(g) of the MCTRJCA requires us to consult with relevant stakeholders as we propose and implement this reporting system. We are meeting this requirement through the publication of this proposal, and specifically solicit public comment on the various aspects of our proposals. In

addition, we plan to meet with key stakeholders and will discuss this issue in Open Door Forums over the course of the summer.

H. Primary Care and Care Coordination

In recent years, we have recognized primary care and care coordination as critical components in achieving better care for individuals, better health for individuals, and reduced expenditure growth. Accordingly, we have prioritized the development and implementation of a series of initiatives designed to ensure accurate payment for, and encourage long-term investment in, primary care and care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule'' which appeared in the **Federal Register** on November 2, 2011 (76 FR 67802)).

++ The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *http://innovations.cms.gov/initiatives/ACO/Pioneer/index.html*).

++ The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on Innovation Center's Web site at *http://innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html*).

- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf*).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available. (described on the CMS Web site at *http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf*). The goal of the MAPCP demonstration is to take a multi-payer approach to creating more advanced primary care services or ''medical homes'' that utilize a team approach to care, while emphasizing prevention, health information technology, care coordination, and shared decision making. CMS will pay a monthly care management fee for Medicare fee-for-service beneficiaries receiving primary care from advanced primary care practices participating in the demonstration. The following states are participating in the MAPCP demonstration: Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota.[1]
- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Web site at *http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf* and Innovation Center's Web site at *http://innovations.cms.gov/initiatives/FQHCs/index.html*). Participating FQHCs in the demonstration are expected to achieve National Committee for Quality Assurance (NCQA) Level 3 Patient-Centered Medical Home recognition by the end of the demonstration as well as help patients manage chronic conditions and actively coordinate care for patients. To help participating FQHCs make the needed investments in patient care and infrastructure, CMS is paying a monthly care management fee for each eligible Medicare fee-for-service beneficiary receiving primary care services. In addition, both CMS and the Health Resources Services Administration (HRSA) are providing technical assistance to FQHCs participating in the demonstration.
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site at *http://innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in the following markets: Arkansas, Colorado, New Jersey, New York in the Capital-District-Hudson Valley Region, Ohio and Kentucky in the Cincinnati-Dayton Region, Oklahoma in the Greater Tulsa Region, and Oregon. CMS pays a monthly care management fee to selected primary care practices on behalf of their fee-for-service Medicare beneficiaries and in years 2–4 of the initiative, each practice has the potential to share in savings to the Medicare program.

In coordination with these initiatives, we also continue to explore other potential refinements to the PFS that would appropriately value primary care and care coordination within Medicare's statutory structure for fee-for-service physician payment and quality reporting. We believe that improvements in payment for primary care and recognizing care coordination initiatives are particularly important as EHR technology diffuses and improves the ability of physicians and other providers of health care to work together to improve patient care. We view these potential refinements to the PFS as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

The annual PFS notice and comment rulemaking process provides an important avenue for interested parties to provide input on discrete proposals intended to achieve these goals. Should any of these discrete proposals become final policy, we would expect many of them to be short-term payment strategies that would be modified and/or revised to be consistent with broader primary care and care management and coordination services if the agency decides to pursue payment for a broader set of management and coordination services in future rulemaking.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794), we initiated a discussion to gather information about how primary care services have evolved to focus on preventing and managing chronic disease. We also proposed to review evaluation and management (E/M) services as potentially misvalued and suggested that the American Medical Association Relative (Value) Update Committee (AMA RUC) might consider changes in the practice of chronic disease management and care coordination as key reason for undertaking this review. In the CY 2012 PFS final rule with comment period, we did not finalize our proposal to review E/M codes due to consensus from an overwhelming majority of commenters that a review of E/M services using our current processes could not appropriately value the evolving practice of chronic care coordination, and therefore, would not accomplish the agency's goal of paying appropriately for primary care services. We stated that we would continue to consider ongoing research projects, demonstrations, and the numerous policy alternatives suggested by commenters. In addition, in the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public discussion regarding payments for post-discharge care management services. We sought broad public

[1] More information about the MAPCP demonstration is available at *http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1230016.html.*

comment on how to further improve care management for a beneficiary's transition from the hospital to the community setting within the existing statutory structure for physician payment and quality reporting. We specifically discussed how post discharge care management services are coded and valued under the current E/M coding structure, and we requested public comment.

The physician community responded that comprehensive care coordination services are not adequately represented in the descriptions of, or payments for, office/outpatient E/M services. The American Medical Association (AMA) and the American Academy of Family Physicians (AAFP) created workgroups to consider new options for coding and payment for primary care services. The AAFP Task Force recommended that CMS create new primary care E/M codes and pay separately for non-face-to-face E/M Current Procedural Terminology (CPT) codes. (A summary of these recommendations is available at *http://www.aafp.org/online/en/home/publications/news/news-now/inside-aafp/20120314cmsrecommendations.html*.) The AMA workgroup, Chronic Care Coordination Workgroup (C3W), is developing codes to describe care transition and care coordination activities. (Several workgroup meeting minutes and other related items are available at *http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/care-coordination.page*.) We are continuing to monitor the progress of this workgroup and look forward to receiving its final recommendations. For this CY 2013 PFS proposed rule, we have decided to proceed with a proposal to refine PFS payment for post discharge care management services. We also include a discussion of how we could incorporate the idea of advanced primary care through practices certified as medical homes in the FFS setting. In developing the proposal and discussion described below, we have thoroughly considered documented concerns regarding Medicare payment for non-face-to-face elements of E/M services that are crucial to care coordination. We will continue to consider other enhancements to payment for primary care services and complex chronic care coordination services, and we may make further proposals to improve payment mechanisms and foster quality care for these and similar services in future rulemaking.

Under current PFS policy, care coordination is a component of E/M services which are generally reported using E/M CPT codes. The pre- and post-encounter non face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care coordination work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include providing care coordination, communication, and other necessary care management related to the office visit in the post-service work. We also highlighted vignettes that describe a typical service for hospital discharge day management (CPT codes 99238 and 99239), which include providing care coordination, communication, and other necessary management related to the hospitalization in the post-service work.

As we have indicated many times in prior rulemaking, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits. Moreover, Medicare does not pay for services that are furnished to parties other than the beneficiary and which Medicare does not cover, for example, communication with caregivers. Accordingly, we do not pay separately for CPT codes for telephone calls, medical team conferences, prolonged services without patient contact, or anticoagulation management services.

However, we continue to hear concerns from the physician community that the care coordination included in many of the E/M services, such as office visits, does not adequately describe the non-face-to-face care management work involved in primary care. Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries such as those who are returning to a community setting following discharge from a hospital or SNF stay. We are therefore considering new options to recognize the additional resources typically involved in furnishing coordinated care to particular types of beneficiaries.

As described below, we are proposing to address the significant non-face-to-face work involved in coordinating services for a beneficiary after discharge from a hospital or skilled nursing facility (SNF). Specifically, we propose to create a HCPCS G-code to describe care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial hospitalization), SNF stay, or community mental health center (CMHC) partial hospitalization program to care furnished by the beneficiary's primary physician in the community. We consider this proposal to be part of a multiple year strategy exploring the best means to encourage care coordination services. Furthermore, in the interest of encouraging comprehensive primary care services furnished in advanced primary care practices, we have included a discussion regarding how care furnished in these settings might be incorporated into the current fee-for-service structure of the PFS. We look forward to continued development of these ideas through current research and demonstration projects, experience with ACOs and other programs, and further discourse on these issues with stakeholders.

1. Hospital, SNF, or CMHC Post-Discharge Care Management

a. Background

Care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital, SNF, or CMHC stay to the beneficiary's primary physician in the community can avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care management and care transitions could improve the quality of care while simultaneously decreasing costs.

Currently, there are several agency initiatives aimed at hospital and community-based organizations. In April 2011, HHS launched the Partnership for Patients, a national public-private patient safety initiative for which more than 6,000 organizations—including physician and nurses' organizations, consumer groups, employers and over 3,000 hospitals—have pledged to help achieve the Partnership's goals of reducing hospital complications and improving care transitions. (More information on this initiative is available at *http://innovations.cms.gov/initiatives/partnership-for-patients/index.html*.) The Partnership for Patients includes the Community-based Care Transitions

Program, created by section 3026 of the Affordable Care Act, which provides funding to community-based organizations partnering with eligible hospitals to coordinate a continuum of post-acute care to test models for improving care transitions for high risk Medicare beneficiaries.

Section 1886(q) of the Act (as added by section 3025 of the Affordable Care Act) directs the Secretary to establish a Hospital Readmissions Reduction Program, beginning in FY 2013, for certain potentially preventable Medicare inpatient hospital readmissions covering three conditions: heart attack; pneumonia; and congestive heart failure. Beginning in FY 2015, the number of applicable conditions can be expanded beyond the initial three conditions. Under this program, a portion of Medicare's payment amounts for inpatient services to certain hospitals will be reduced by an adjustment factor based the hospital's excess Medicare readmissions. In the FY 2012 IPPS final rule (76 FR 51662–51676), we provided an overview of the Hospital Readmission Reduction program and finalized policies regarding selection of applicable conditions, definition of ''readmissions,'' measures of the applicable conditions chosen for readmissions, methodology for calculating the excess readmissions ratio, public reporting of readmission data, and definition of applicable period. In the FY2013 IPPS proposed rule (77 FR 27955–27968), we made proposals regarding the base operating DRG payment amount, the adjustment factor, aggregate payments for excess readmissions, and the hospitals that would be included in the program.

In its 2007 Report to Congress: Promoting Greater Efficiency in Medicare, MedPAC found that, in 2005, 17.6 percent of admissions resulted in readmissions within 30 days of discharge, accounting for $15 billion in spending. MedPAC estimated that 76 percent of the 30 day readmissions were potentially preventable, resulting in $12 billion in spending. In the same report, MedPAC also found that the rate of potentially avoidable rehospitalizations after discharges from skilled nursing facilities was 17.5 percent in 2004 (an increase of 2.8 percentage points from 2000.) MedPAC noted: ''We focus on the hospital's role but recognize that other types of providers, including physicians and various post-acute care providers, can be instrumental in avoiding readmissions * * * [C]ommunity physicians and post-acute care providers receiving the patient may not be sufficiently informed about the patient's care needs and history to enable effective care.'' We agree with MedPAC that primary care physicians and practitioners play a key role in post-acute care and reducing hospital readmissions.

In the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public discussion regarding payments for post-discharge care coordination services. We sought broad public comment on how to further improve physician care coordination within the statutory structure for physician payment and quality reporting, particularly for a beneficiary's transition from the hospital to the community. As noted above, we also proposed to review E/M services as potentially misvalued and suggested that the AMA RUC might consider chronic disease management and care coordination in its review (76 FR 42793). While the commenters agreed that care coordination would lead to better care for beneficiaries, they believed this care would be better described by new codes, and not the current E/M codes.

b. Hospital and SNF Discharge Services

We believe that the successful transition of a beneficiary from care furnished by a hospitalist physician to care furnished by the beneficiary's primary physician or qualified nonphysician practitioner could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system.

We also believe that the current hospital discharge management codes (CPT codes 99238 and 99239) and nursing facility discharge services (CPT codes 99315 and 99316) adequately capture the care coordination services required to discharge a beneficiary from hospital or skilled nursing facility care. The work relative values for those discharge management services include a number of pre-, post-, and intra-care coordination activities. For example, the hospital discharge management codes include the following pre-, intra-, and post-service activities relating to care coordination:

Pre-service care coordination activities include:

- Communicate with other professionals and with patient or patient's family. Intra-service care coordination activities include:
- Discuss aftercare treatment with the patient, family and other healthcare professionals;
- Provide care coordination for the transition including instructions for aftercare to caregivers;
- Order/arrange for post discharge follow-up professional services and testing; and
- Inform the primary care or referring physician or qualified nonphysician practitioner of discharge plans.

Post-service care coordination activities include:

- Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization; and
- Revise treatment plan(s) and communicate with patient and/or caregiver, as necessary.

The hospital and nursing facility discharge management codes also include a number of other pre-, intra- and post-service activities.

Because these activities are critical to successfully avoiding readmissions, we seek comment about the best ways to ensure that all the activities of the discharge day management codes for hospital and nursing facility discharge, including the care coordination activities, are understood and furnished by the physicians or qualified nonphysician practitioners who bill for these services. Potential ways could include physician education or MEDLEARN articles.

c. Defining Post-Discharge Transitional Care Management Services

While we believe that current hospital and nursing facility discharge management service codes adequately capture the care management activities involved with discharging a beneficiary from a hospital or skilled nursing facility, we do not believe that current E/M office or other outpatient visit CPT codes appropriately describe comparable care management work of the community physician or qualified nonphysician practitioner coordinating care for the beneficiary post-discharge. This is because the E/M codes represent the typical outpatient office visit and do not capture or reflect the significant care coordination activities that need to occur when a patient transitions from institutional to community-based care. We believe that the work of the discharging physician or qualified nonphysician practitioner should be complemented by corresponding work of a receiving physician or qualified nonphysician practitioner in the community in order to ensure better continuity of care through establishing or revising a plan of care for the beneficiary after discharge. We acknowledge that many, if not most, physicians or qualified nonphysician practitioners caring for beneficiaries following a hospital or nursing facility

discharge have been furnishing coordinated care and reporting office or other outpatient CPT codes. However, we agree with commenters to the CY 2012 proposed and final rules that the services described by current E/M office or other outpatient CPT codes 99201 through 99215 may not appropriately capture the significant coordination services involved in post-discharge care.

We are proposing to create a HCPCS G-code that specifically describes post-discharge transitional care management services. The code would describe all non-face-to-face services related to the transitional care management furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services; and a partial hospitalization program at a CMHC to community-based care. The post-discharge transitional care management service includes non-face-to-face care management services furnished by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner. We use the term community physician and practitioner in this discussion to refer to the community-based physician managing and coordinating a beneficiary's care in the post-discharge period. We anticipate that most community physicians will be primary care physicians and practitioners. We have based the concept of this proposal, in part, on our policy for care plan oversight services. We currently pay physicians for the non face-to-face care plan oversight services furnished for patients under care of home health agencies or hospices. These patients require complex and multidisciplinary care modalities that involve: regular physician development and/or revision of care plans, subsequent reports of patient status, review of laboratory and other studies, communication with other health professionals not employed in the same practice who are involved in the patient's care, integration of new information into the care plan, and/or adjustment of medical therapy. Physicians providing these services bill HCPCS codes G0181 (Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more), or G0182 (Physician supervision of a patient under a Medicare-approved hospice (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more). (See the Medicare benefit manual, 100–02, Chapter 15, Section 30 for detailed description of these services.)

For CY 2013, we are proposing to create a new code to describe post-discharge transitional care management. This service would include:

• Assuming responsibility for the beneficiary's care without a gap.

++ Obtaining and reviewing the discharge summary.

++ Reviewing diagnostic tests and treatments.

++ Updating of the patient's medical record based on a discharge summary to incorporate changes in health conditions and on-going treatments related to the hospital or nursing home stay within 14 business days of the discharge.

• Establishing or adjusting a plan of care to reflect required and indicated elements, particularly in light of the services furnished during the stay at the specified facility and to reflect result of communication with beneficiary.

++ An assessment of the patient's health status, medical needs, functional status, pain control, and psychosocial needs following the discharge.

• Communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including education of patient and/or caregiver within 2 business days of discharge based on a review of the discharge summary and other available information such as diagnostic test results, including each of the following tasks:

++ An assessment of the patient's or caregiver's understanding of the medication regimen as well as education to reconcile the medication regimen differences between the pre- and post-hospital, CMHC, or SNF stay.

++ Education of the patient or caregiver regarding the on-going care plan and the potential complications that should be anticipated and how they should be addressed if they arise.

++ Assessment of the need for and assistance in establishing or re-establishing necessary home and community based resources.

++ Addressing the patient's medical and psychosocial issues, and medication reconciliation and management.

When indicated for a specific patient, the post-discharge transitional care service would also include:

• Communication with other health care professionals who will (re)assume care of the beneficiary, education of patient, family, guardian, and/or caregiver.

• Assessment of the need for and assistance in coordinating follow up visits with health care providers and other necessary services in the community.

• Establishment or reestablishment of needed community resources.

• Assistance in scheduling any required follow-up with community providers and services.

The post-discharge transitional care services HCPCS G-code we are proposing would be used by the community physician or qualified nonphysician practitioner to report the services furnished in the community to ensure the coordination and continuity of care for patients discharged from a hospital (inpatient stay, outpatient observation, or outpatient partial hospitalization), SNF stay, or CMHC. The post-discharge transitional care service would parallel the discharge day management service for the community physician or qualified nonphysician practitioner and complement the E/M office/outpatient visit CPT codes.

The post-discharge transitional care service would support the patient's physical and psychosocial health. In our recent Decision Memorandum for Screening for Depression in Adults, CAG–00425N, we noted that depression in older adults occurs in a complex psychosocial and medical context and that, currently, we believe opportunities are missed to improve mental health and general medical outcomes when mental illness is under-recognized and undertreated in primary care settings. We wish to emphasize the equal importance of the patient's mental

health to the patient's physical condition to successful re-entry into the community.

We propose that the post-discharge transitional care service HCPCS G-code would be used to report physician or qualifying nonphysician practitioner services for a patient whose medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from hospital (inpatient stay, outpatient observation, and partial hospitalization), SNF stay, or CMHC settings to community-based care. Moderate and high complexity medical decision making are defined in the Evaluation and Management Guidelines. In general, moderate complexity medical decision-making includes multiple diagnoses or management options, moderate complexity and amount of data to be reviewed, a moderate amount and/or complexity of data to be reviewed; and a moderate risk of significant complications, morbidity, and/or mortality. High complexity decision-making includes an extensive number of diagnoses or management options, an extensive amount and/or complexity of data to be reviewed, and high risk of significant complications, morbidity, and/or mortality (See Evaluation and Management Services Guide, Centers for Medicare & Medicaid Services, December 2010.) We propose that the post-discharge transitional care HCPCS code (GXXX1) would be payable only once in the 30 days following a discharge, per patient per discharge, to a single community physician or qualified nonphysician practitioner (or group practice) who assumes responsibility for the patient's post-discharge transitional care management. The service would be billable only at 30 days post discharge or thereafter. The post-discharge transitional care management service would be distinct from services furnished by the discharging physician or qualified nonphysician practitioner reporting CPT codes 99238 (Hospital discharge day management, 30 minutes or less); 99239 (Hospital discharge day management, more than 30 minutes); 99217 (Observation care discharge day management); or Observation or Inpatient Care services, CPT codes 99234–99236; as appropriate.

We propose to pay the first claim that we receive for the beneficiary at 30 days after discharge. Given the elements of the service and the short window of time following a discharge during which a physician or qualifying nonphysician practitioner will need to perform several tasks on behalf of a beneficiary, we believe it is unlikely that two or more physicians or practitioners would have had a face-to-face E/M contact with the beneficiary in the specified window of 30 days prior or 14 days post discharge and have furnished the proposed post-discharge transitional care management services listed above. Therefore, we do not believe it is necessary to take further steps to identify a beneficiary's community physician or qualified nonphysician practitioner who furnishes the post-discharge transitional care management services. We propose to pay only one claim for the post-discharge transitional care GXXX1 billed per beneficiary at the conclusion of the 30 day post-discharge period. Post-discharge transitional care management relating to any subsequent discharges for a beneficiary in the same 30-day period would be included in the single payment. Practitioners billing this post-discharge transitional care code accept responsibility for managing and coordinating the beneficiary's care over the first 30 days after discharge. Although we currently envision billing happening as it does for most services, after the conclusion of the service, we welcome comment on whether in this case there would be merit to allowing billing for the code to occur at the time the plan of care is established.

We have explicitly constructed this proposal as a payment for non face-to-face post-discharge transitional care management services separate from payment for E/M or other medical visits. However, we believe that it is important to ensure that the community physician or qualified nonphysician practitioner furnishing post-discharge transitional care management either have or establish a relationship with the patient. As such, we propose that the community physician or qualified nonphysician practitioner reporting post-discharge transitional care management GXXX1 should already have a relationship with the beneficiary, or establish one soon after discharge, prior to furnishing transitional care management and billing this code. Therefore, we propose that the community physician or qualified nonphysician practitioner reporting a transitional care management HCPCS G-code must have billed an E/M visit for that patient within 30 days prior to the hospital discharge (the start of post-discharge transitional care management period), or must conduct an E/M office/outpatient visit (99201 to 99215) within the first 14 days of the 30-day post-discharge period of transitional care management services. The E/M visit would be separately billed.

While we are proposing that the post-discharge transitional care management code would not include a face-to-face visit, and that physicians or qualified nonphysician practitioners would bill and be paid for this care management service separately from a medical visit, we are seeking comments about whether we should require a face-to-face visit when billing for the post-discharge transitional care management service. We are also seeking comments regarding how we might incorporate such a required visit on the same day into the payment for the proposed code. We considered several reasons for requiring a face-to-face visit on the same day. We wondered whether, with a face-to-face visit immediately after discharge, the plan of care would be more accurate given that the patient's medical or psychosocial condition may have changed from the time the practitioner last met with the patient and the practitioner could better develop a plan of care through an in-person visit and discussion. We also wondered whether beneficiaries would understand their coinsurance liability for the post-discharge transitional care service when they did not visit the physician's or qualified nonphysician practitioner's office. On the other hand, we have contemplated several scenarios where it is not possible for a beneficiary to get to the physician's or qualified nonphysician practitioner's office and welcome comment on whether an exception process would be appropriate if we were to finalize a same day face-to-face visit as a requirement for billing the post-discharge transitional care management code.

The proposed post-discharge transitional care HCPCS G-code would be described as follows:

GXXX1—Post-discharge transitional care management with the following required elements:

- Communication (direct contact, telephone, electronic) with the patient or caregiver within 2 business days of discharge.
- Medical decision making of moderate or high complexity during the service period.
- To be eligible to bill the service, physicians or qualified nonphysician practitioners must have had a face-to-face E/M visit with the patient in the 30 days prior to the transition in care or within 14 business days following the transition in care.

We contemplated establishing a requirement that post-discharge transitional care management be furnished by a physician or qualified nonphysician practitioner or other clinical staff in the practice who are qualified to assist beneficiaries in managing post-transition changes in

conditions and treatments. We welcome public comment on whether this would be an appropriate requirement for GXXX1.

We propose that a physician or qualified nonphysician practitioner who bills for discharge management during the time period covered by the transitional care management services code may not also bill for HCPCS code GXXX1. The CPT discharge management codes are 99217, 99234–99236, 99238–99239, 99281–99285, or 99315–99316, home health care plan oversight services (HCPCS code G0181), or hospice care plan oversight services (HCPCS code G0182) . We believe these codes describe care management services for which Medicare makes separate payment and should not be billed in conjunction with GXXX1, which is a comprehensive post-discharge transitional care management service. Further, we propose that a physician or qualified nonphysician practitioner billing for a procedure with a 10- or 90-day global period would not also bill HCPCS code GXXX1 in conjunction with that procedure because any follow-up care management would be included in the post-operative portion of the global period. Many of the global surgical packages include discharge management codes. We believe that any physician or qualified nonphysician practitioner billing separately for the discharge management code that also is the community physician or nonphysician practitioner for the beneficiary would be paid for post-discharge transitional care management through the discharge management code.

We are making this proposal to provide a separate reporting mechanism to the community physician for these services in the context of the broader HHS and CMS multi-year strategy to recognize and support primary care and care management. Should any of these discrete proposals, like this one, become final policy, they may be short-term payment strategies that would be modified and/or revised to be consistent with broader primary care and care management and coordination services if the agency decides to pursue payment for a broader set of management and coordination services in future rulemaking. We would also note that this proposal dovetails with our discussion under section III.J. of this proposed rule on the Value-based Payment Modifier and Physician Feedback Reporting Program which discusses hospital admission measures and a readmission measure as outcome measures for the proposed value-based payment modifier adjustment beginning in CY 2015.

c. Proposed Payment for Post-Discharge Transitional Care Management Service

To establish a physician work relative value unit (RVU) for the proposed post-discharge transitional care management, HCPCS code GXXX1, we compared GXXX1 with CPT code 99238 (Hospital discharge day management; 30 minutes or less) (work RVU = 1.28). We recognize that, unlike CPT code 99238, HCPCS code GXXX1 is not a face-to-face visit. However, we believe that the physician time and intensity involved in post-discharge community care management is most equivalent to CPT code 99238 which, like the proposed new G-code, involves a significant number of care management services. Therefore, we are proposing a work RVU of 1.28 for HCPCS code GXXX1 for CY 2013. We also are proposing the following physician times: 8 minutes pre-evaluation; 20 minutes intra-service; and 10 minutes immediate post-service. The physician time file associated with this PFS proposed rule is available on the CMS Web site in the Downloads section for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

In addition, we are proposing to crosswalk the clinical labor inputs from CPT code 99214 (Level 4 established patient office or other outpatient visit) to the post-discharge transitional care code. The proposed CY 2013 direct PE input database reflects these inputs and is available on the CMS Web site under the supporting data files for the CY 2013 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. The proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

For malpractice expense, we are proposing a malpractice crosswalk of CPT code 99214 for HCPCS code GXXX1 for CY 2013. We believe the malpractice risk factor for CPT code 99214 appropriately reflects the relative malpractice risk associated with furnishing HCPCS code GXXX1. The malpractice RVUs included in Addendum B to this proposed rule reflect the RVUs that result from the application of this proposal.

We note that as with other services paid under the PFS the 20 percent beneficiary coinsurance would apply to the post-discharge transitional care management service as would the Part B deductible.

For BN calculations, we estimated that physicians or qualified nonphysician practitioners would provide post-discharge transitional care management services for 10 million discharges in CY 2013. This number roughly considers the total number of hospital inpatient and SNF discharges, hospital outpatient observation services and partial hospitalization patients that may require with moderate to high complexity decision-making.

For purposes of the Primary Care Incentive Payment Program (PCIP), we are proposing to exclude the post discharge transitional care management services from the total allowed charges used in the denominator calculation to determine whether a physician is a primary care practitioner. Under section 1833(x) of the statute the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care practitioner. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435–73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, in order to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation.

We believe that the proposed transitional care management code should be treated in the same manner as those services for the purposes of PCIP because post-discharge transitional care management services are a complement in the community setting to the hospital-based discharge day management services already excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we are concerned that inclusion of the transitional care management code in the denominator of the primary care percentage calculation could produce unwarranted bias against ''true primary care practitioners'' who are involved in furnishing post-discharge care to their patients. Therefore, while physicians and qualified nonphysician practitioners who furnish transitional care management would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a ''primary care service'' for purposes of the PCIP), the allowed charges for transitional care

management would not be included in the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

2. Primary Care Services Furnished in Advanced Primary Care Practices

a. Background

As we have discussed above, we are committed to considering new options and developing future proposals for payment of primary care services under the MPFS. Such options would promote comprehensive and continuous assessment, care management, and attention to preventive services that constitute effective primary care by establishing appropriate payment when physicians furnish such services. One method for ensuring that any targeted payment for primary care services would constitute a minimum level of care coordination and continuous assessment under the MPFS would be to pay physicians for services furnished in an ''advanced primary care practice'' that has implemented a medical home model supporting patient-specific care. The medical home model has been the subject of extensive study in medical literature. Since 2007, the AMA, American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Osteopathic Association (AOA), and many other physician organizations have also endorsed ''Joint Principles of the Patient-Centered Medical Home.'' In February 2011, the AAFP, the AAP, the ACP, and AOA also published formal ''Guidelines for Patient-Centered Medical Home (PCMH) Recognition and Accreditation Programs'' to develop and promote the concept and practice of the PCMH. (These guidelines are available at *http://www.aafp.org/online/etc/medialib/aafp_org/documents/membership/pcmh/pcmhtools/pcmhguidelines.Par.0001.File.dat/GuidelinesPCMHRecognitionAccreditationPrograms.pdf.*) As we have discussed above, the Innovation Center has been conducting a several initiatives based on the medical home concept.

The medical home concept emphasizes establishing an extensive infrastructure requiring both capital investments and new staffing, along with sophisticated processes, to support continuous and coordinated care with an emphasis on prevention and early diagnosis and treatment. The literature, reports, and guidelines dealing with the medical home concept define the requisite elements or functions that constitute this infrastructure and processes in various ways. For example, the Innovation Center's CPC initiative identified a set of five ''comprehensive primary care functions,'' which form the service delivery model being tested and the required framework for practice transformation under the CPC initiative. We believe these five ''comprehensive primary care functions'' provide an appropriate starting point for discussing the incorporation of the comprehensive primary care services delivered in advanced primary care practices (practices implementing a medical home model) into the MPFS:

1. Risk-Stratified Care Management

One of the hallmarks of comprehensive primary care is the provision of intensive care management for high-risk, high-need, high-cost patients. Providers must provide routine, systematic assessment of all patients to identify and predict which patients need additional interventions. In consultation with their patients, they should create a plan of care to assure care that is provided is congruent with patient choices and values. Once patient needs, including social needs and functional deficits, have been identified, they should be systematically addressed. Markers of success include policies and procedures describing routine risk assessment and the presence of appropriate care plans informed by the risk assessment.

2. Access and Continuity

Health providers who know the patient should be accessible when a patient needs care. Providers must have access to patient data even when the office is closed so they can continue to participate in care decisions with their patients. Patients need access to the patient care team 24/7. Every patient is assigned to a designated provider or care team with whom they are able to get successive appointments. Markers of success include care continuity and availability of the EHR when the office is closed.

3. Planned Care for Chronic Conditions and Preventive Care

Primary care must be proactive. Practitioners must systematically assess all patients to determine his or her needs (one way would be through the annual wellness visit [2]) and provide proactive, appropriate care based on that assessment. Pharmaceutical management, including medication reconciliation and review of adherence and potential interactions, and oversight of patient self-management of medications for diabetes, anti-coagulation management or warfarin therapy, and other chronic conditions, should be a routine part of all patient assessments. Markers of success include completion of the Annual Wellness Visit and documentation of medication reconciliation.

4. Patient and Caregiver Engagement

Truly patient-centered care assumes the mantra ''nothing about me without me.'' Providers should establish systems of care that include the patient in goal setting and decision making, creating opportunities for patient engagement throughout the care delivery process. Markers of success include policies and procedures designed to ensure that patient preferences are sought and incorporated into treatment decisions.

5. Coordination of Care Across the Medical Neighborhood

The ''medical neighborhood'' is the totality of providers, related non-health services and patients in an area, and the ways in which they work together.[3] Primary care can be seen as the hub of the neighborhood and must take the lead in coordinating care. In particular, primary care providers must move towards leadership of health teams both within and outside their practice's walls. Providers must have the ability to access a single medical record shared by the whole team; the content of this record can be leveraged to manage communication and information flow in support of referrals to other clinicians, and to support safe and effective transitions from the hospital and skilled nursing facilities back to the community. The primary care practice must also include personnel who are qualified to assist patients to manage post transition changes in conditions and treatments required to support patients' health and reduce their need for readmission. Markers of success include the presence of standard processes and documents for communicating key information during care transitions or upon referral to other providers.

[2] The Affordable Care Act (ACA) covered an annual wellness visit for Medicare beneficiaries through which they are to receive a personalized prevention plan. The ACA also ensured preventive services would be covered without cost if they are recommended by the US Preventive Services Taskforce and meet certain other conditions.

[3] ''Coordinating Care in the Medical Neighborhood'' White Paper. Agency for Healthcare Research and Quality, June 2011.

b. Advanced Primary Care Practices Accreditation and Infrastructure

1. Accreditation Utilizing Nationally Recognized Organizations

In the event that we were to establish an enhanced payment for primary care services furnished to Medicare beneficiaries in an advanced primary care practice environment, we would need to establish a set of parameters to determine whether or not a clinical practice could be considered an advanced primary care practice (medical home). The foundation for our assessment could be whether the practice has the capacity to deliver comprehensive primary care services that mirror the five functions of the CPC initiative. However, we would need to identify explicit criteria in the form of documented processes and quantifiable practice attributes, such as the availability and capacity of electronic health records, to assess the presence of these five functions.

We could make our determination that a practice has implemented all identified functions and is, therefore, an advanced primary care practice, by recognizing one or more of the nationally available accreditation programs currently in use by major organizations that provide accreditation for advanced primary care practices, frequently credentialed as ''PCMHs''. Having established recognition of accreditation by one of several national accreditation organizations, we might require that a provider document through the enrollment process (PECOS) that the practice meets the definition of an Advanced Primary Care Practice to furnish comprehensive primary care services. We have identified four national models that provide accreditation for organizations wishing to become an advanced primary care practice; the Accreditation Association for Ambulatory Health, The Joint Commission, the NCQA, and the Utilization Review Accreditation Commission (URAC). While there are similarities between all four of the national models for PCMH accreditation, each model has different standards and areas of emphasis in its review and approval of organizational capacity and function as a PCMH. For instance, according to a report prepared for CMS by the Urban Institute entitled, ''Patient-Centered Medical Home Recognition Tools: A Comparison of Ten Surveys' Content and Operational Details'' released in March of 2012, the NCQA places a heavier emphasis on Health IT than the other accrediting bodies in their measurement standards. This report can be viewed at the following link: *http://www.urban.org/uploadedpdf/412338-patient-centered-medical-home-rec-tools.pdf*.

We believe that basing our determination on accreditation as a PCMH by a national accreditation organization would offer a number of benefits, including that their accreditation tools, which review specific aspects of practice including information systems and organizational processes already are well known, widely used, and well respected. Level 3 NCQA accreditation, URAC, the Accreditation Association for Ambulatory Health and Joint Commission accreditation standards are, despite their differences, very similar to the concepts of the comprehensive primary care services, and CMS could consider accepting accreditation from any of these as documentation that a group practice is an advanced primary care practice. Other payers currently recognize PCMH accreditation by these organizations for payment. A publication from the Medical Group Management Association (MGMA) ''The Patient Centered Medical Home Guidelines: A Tool to Compare National Programs'' found that all four of the national accreditation programs met the guidelines set forth by the AAFP, the AAP, the ACP, and AOA in their 2011 guidelines. The MGMA report can be downloaded from the following Web site: *http://www.mgma.com/Books/Patient-Centered-Medical-Home-Guidelines/*. However, we recognize that the cost to a practice to acquire accreditation from one of these accrediting organizations could be significant. In addition, the processes to receive accreditation as an advanced primary care practice under these guidelines can be lengthy. We also are concerned that some parts of the accreditation processes for these accrediting organizations would be considered proprietary. We believe that Medicare payment should rely whenever feasible on criteria and tools that are in the public domain. We also recognize that it could be challenging for us to address how we could rely on a set of standards from a private accrediting body while still retaining responsibility for accreditation outcomes. It is unclear at this time how we would balance the proprietary interests of these private organizations in their accreditation models with our responsibility to establish and maintain appropriate transparency in our decision-making processes.

If we were to move forward with a process that would use the accreditation standards from a private sector organization to make determinations as to whether a practice is an advanced primary care practice, we would need to determine whether to recognize one, some, or all of the available and established accreditation models. As we stated above, because each accreditation tool has different standards and emphasizes different criteria, we are concerned that there could be consistency issues if we were to recognize accreditation from all four organizations as evidence of certification to provide advanced primary care. It would be important to ensure that any of the accreditation tool(s) we selected met the goals of our policy. We specifically invite comments regarding the processes that we should consider for application, confirmation that recognized accreditation standards are met, and notification of recognition as a PCMH if we were to recognize practices as advanced primary care practices based on accreditation as a PCMH by one or more of the national accreditation organizations.

2. CMS-Developed Advanced Primary Care Accreditation Criteria

Alternatively, we could develop our own criteria using, for example, the five functions of comprehensive primary care used in the CPC initiative and described above, to determine what constitutes advanced primary care for purposes of Medicare payment. We would then need to develop a process for determining whether specific physician practices meet the criteria for advanced primary care. This could include creating our own criteria and processes for review or could include using existing accrediting bodies to measure compliance against advanced primary care criteria determined by CMS. This would create more consistent standards for identifying advanced primary care practices and provide greater transparency in the certification process. If CMS was able to determine the validity of an organization's application to be recognized to be an advanced primary care practice, this could reduce the cost to the physician practice for accreditation. However, practices would still need to invest in organizational process and infrastructure to meet advanced primary care criteria. Implementing an internal process to accredit practices as advanced primary care for purposes of Medicare payment could involve significant administrative cost. The amount of cost likely would depend on the rigor of the required criteria, and the amount of documentation and review required prior to approval as an advanced primary care practice.

If we established our own criteria in order to resolve the lack of standardization between the standards adopted by the various national accreditation organizations for PCMH, it is possible that the accrediting bodies would then be able to assist us in determining compliance with the CMS criteria. Depending on the nature of the criteria, the CMS criteria may cost less to implement but would likely require a practice to incur the cost for an accrediting body to review the practice's compliance. We invite public comment on the potential approaches we could use to identify advanced primary care practices for purposes of Medicare payment, including the possible use of one or more national accrediting organizations (and whether meaningful use of certified electronic health record technology should be required for such accreditation) as part of a Medicare approval process, as well as any other potential approaches to accrediting advanced primary care practices that we have not discussed here.

c. Beneficiary Attribution for Purposes of Payment

One potential issue surrounding comprehensive primary care services delivered in an advanced primary care practice is attribution of a beneficiary to an advanced primary care practice. We would not expect that there would be more than one practice functioning as an advanced primary care practice for a beneficiary at any given time. However, in a fee-for-service environment we would need to determine which practice is currently serving as the advanced primary care practice for the beneficiary in order to ensure appropriate payment. One method of attribution could be that each beneficiary prospectively chooses an advanced primary care practice. We seek comment on how such a choice might be documented and incorporated into the fee-for-service environment. Other attribution methodologies might examine the quantity and type of E/M or other designated services furnished to that beneficiary by the practice. We welcome input on the most appropriate approach to the issue of how to best determine the practice that is functioning as the advanced primary care practice for each beneficiary. We are not considering proposals that would restrict a beneficiary's free choice of practitioners.

In summary, we believe that targeting primary care management payments to advanced primary care practices would have many merits including ensuring a basic level of care coordination and care management. We recognize that the advanced primary care model has demonstrated efficacy in improving the value of health care in several contexts, and we are exploring whether we can achieve these outcomes for the Medicare population through several demonstration projects. Careful analysis of the outcomes of these demonstration projects will inform our understanding of how this model of care affects the Medicare population and of potential PFS payment mechanisms for these services. At the same time, we also believe that there are many policy and operational issues to be considered when nationally implementing such a program within the PFS. Therefore, we generally invite broad public comment on the accreditation and attribution issues discussed above and any other aspect, including payment, of integrating an advanced primary care model in to the PFS.

I. Payment for Molecular Pathology Services

For CY 2012, the AMA CPT Editorial Panel began creating new CPT codes to replace the current codes used to bill for molecular pathology services. The new codes describe distinct molecular pathology tests and test methods. CPT divided these new molecular pathology codes into Tiers. Tier 1 codes describe common gene-specific and genomic procedures. Tier 2 codes capture reporting for less common tests and each Tier 2 code represents a group of tests that involve similar technical resources and interpretive work. For CY 2012, CPT created 101 new molecular pathology codes; 92 new Tier 1 codes for individual tests and nine Tier 2 codes for common groups of tests. These codes appear in Table 21. We anticipate that CPT will create additional molecular pathology codes for CY 2013.

We stated in our notice for the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting (to be held July 16–17, 2012 at CMS headquarters in Baltimore, Maryland, more information at *https://www.cms.gov//Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Public_Meetings.html*) that we are following our process to determine the appropriate basis and payment amounts for new clinical diagnostic laboratory tests, including the molecular pathology tests, under the CLFS for CY 2013. However, we also stated that we understand stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the CLFS or the PFS. Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We stated that we believe we would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests that should be paid under the CLFS or whether they are physicians' services that should be paid under the PFS. Therefore, we said that we intend to solicit comment on this issue in this proposed rule, as well as public comment on pricing policies for these tests under the CLFS at the Annual Public Meeting. This section first discusses and requests comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, and then discusses our proposal to address payment for these CPT codes on the PFS, pending public comment on the first question. This proposal is parallel to the invitation to discuss at the CLFS Annual Public Meeting, the appropriate basis for establishing a payment amount for the molecular pathology CPT codes as clinical diagnostic laboratory tests under the CLFS.

As detailed in section II.B.1. of this proposed rule, Medicare establishes payment under the PFS by setting RVUs for physician work, practice expense (PE), and malpractice expense for services that ordinarily require physician work. To establish RVUs for physician work, we conduct a clinical review of the relative physician work (time by intensity) required for each PFS service. This clinical review includes the review of RVUs recommended by the American Medical Association Relative Value Scale Update Committee (AMA RUC) and others. The AMA RUC-recommended physician work RVUs typically are based in part on results of a survey conducted by the relevant specialty society for a service. CMS establishes RVUs for PE under a resource-based PE methodology that considers the cost of direct inputs, as well as indirect PE costs. The AMA RUC, through the Practice Expense Subcommittee, recommends direct PE inputs to CMS, and the relevant specialty societies provide pricing information for those direct inputs to CMS. After we determine the appropriate direct PE inputs, the PE methodology is used to develop proposed PE RVUs. Physician work and PE RVUs for each CPT code are constructed to reflect the typical case; that is, they reflect the service as it is furnished in greater than 50 percent of Medicare cases. CMS establishes resource-based malpractice expense RVUs using weighted specialty-specific malpractice insurance premium data collected from commercial and

physician-owned insurers in CY 2010 (74 FR 61758). For most services paid under the PFS, beneficiary cost-sharing is 20 percent of the payment amount.

CMS establishes a payment rate for new clinical diagnostic laboratory tests under the CLFS by either crosswalking or gap-filling. Crosswalking is used when a new test code is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. Under this methodology, the new test code is assigned the local fee schedule amounts and the national limitation amount (NLA) of the existing test, with payment made at the lesser of the local fee schedule amount or the NLA. Gap-filling is used when no comparable test exists on the CLFS. In the first year, carrier-specific amounts are established for the new test code using the following sources of information: Charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. For the second year, the NLA is calculated, which is the median of the carrier-specific amounts. See § 414.508. Services paid under the CLFS do not include any physician work, although tests paid under the CLFS can involve interpretation by a laboratory technician, a chemist, or a geneticist—none of which are occupations that meet the statutory definition of a physician. While payments can vary geographically due to contractor discretion across locality areas (which are the same localities used for the GPCIs under the PFS), payments cannot exceed a NLA nor can they be adjusted once rates are determined. In the CY 2008 PFS final rule with comment period, we adopted a prospective reconsideration process for new tests paid under the CLFS, allowing a single year for Medicare and stakeholders to review pricing for new tests after the payment is initially established (72 FR 66275 through 66279, 66401 through 66402). Finally, the statute waives beneficiary cost-sharing for clinical laboratory diagnostic tests paid on the CLFS.

For a handful of clinical laboratory services paid under the CLFS, we allow an additional payment under the PFS for the professional services of a pathologist when they meet the requirements for clinical consultation service as defined in § 415.130. The PFS pays for services that ordinarily require the work of a physician and, with regard to pathology services, explicitly pays for both the professional and technical component of the services of a pathologist as defined in § 415.130 including surgical pathology, cytopathology, hematology, certain blood banking services, clinical consultations, and interpretive clinical laboratory services.

Molecular pathology tests are currently billed using combinations of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called ''stacking'' because different ''stacks'' of codes are billed depending on the components of the furnished test. Currently, all of the stacking codes are paid through the CLFS. One stacking code, CPT code 83912 (molecular diagnostics; interpretation and report) is paid on both the CLFS and the PFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using the professional component (PC, or 26) of CPT code 83912 (83912–26). Payment for the interpretation and report of a molecular pathology test when furnished by non-physician laboratory staff is made under the CLFS using CPT code 83912.

Since the creation of new molecular pathology CPT codes, there has been significant debate in the stakeholder community regarding whether these new molecular pathology codes describe physicians' services that ordinarily require physician work and would be paid under the PFS, or whether they describe clinical diagnostic laboratory tests that would be paid on the CLFS. The AMA RUC reviewed the 101 new molecular pathology CPT codes and concluded that 79 of 101 new molecular pathology codes include work furnished by a physician. The American Clinical Laboratory Association (ACLA) has indicated that 32 of the 101 new molecular pathology codes are interpreted by a physician and that a physician may perform the technical component associated with 2 of the 101 CPT codes. Only 15 of the 101 new codes appear on both the AMA RUC and ACLA list of codes that each believe include work furnished by a physician. Additionally, some stakeholders have suggested that all molecular pathology tests require physician interpretation and report. Other stakeholders have suggested that the interpretation and report of a molecular pathology test is not ordinarily required because the majority of the molecular pathology tests are clearly negative so interpretation and reporting generally are not necessary. In addition, some stakeholders have argued that molecular pathology tests are becoming more and more automated, and therefore generally do not require interpretation by a physician.

In the CY 2012 PFS final rule (76 FR 73190), we stated that for CY 2012, Medicare would continue to use the existing stacking codes for the reporting and payment of these molecular pathology services, and that the 101 new CPT codes would not be valid for payment for CY 2012. We did this because we were concerned that we did not have sufficient information to know whether these new molecular pathology CPT codes describe clinical diagnostic laboratory tests or services that ordinarily require physician work. For CY 2013, we continue to have many of the same concerns that led us not to recognize the 101 molecular pathology CPT codes for payment for CY 2012. Specifically, we acknowledge that we are lacking definitive answers to the following questions:

- Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician?
- Do each of these molecular pathology CPT codes ordinarily require interpretation and report?
- What is the nature of that interpretation and does it typically require physician work?
- Who furnishes interpretation services and how frequently?

We are seeking public comment on these questions and the broader issue of whether the new molecular pathology codes describe physicians' services that should be paid under the PFS, or if they describe clinical diagnostic laboratory tests that should be paid under the CLFS.

As we continue to consider public comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, we want to ensure that there is a payment mechanism in place to pay for these CPT codes for CY 2013. We propose to price all of the 101 new molecular pathology codes through a single fee schedule, either the CLFS or the PFS. After meeting with stakeholders and reviewing each CPT code, we believe that there is little variation in the laboratory methodologies, as all of them employ gene sequencing processes. However, there are very different processes for establishing payment rates under the PFS and the CLFS. As discussed above, Medicare sets payment under the CLFS by either crosswalking or gap-filling and, after the prospective reconsideration process, currently cannot adjust the payment amount

further. In contrast, Medicare sets payment under the PFS through a set of resource-based methodologies for physician work, PE, and malpractice expense, and payment can be reviewed and adjusted as the resources required to furnish a service change. We are concerned that establishing different prices for comparable laboratory services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement. We are also concerned that the differences in prices would become more pronounced over time as the PFS continues to review the values for physician work and PE inputs relative to established CLFS prices. Therefore, because of the homogeneity of the laboratory methodologies behind these procedure test codes, we believe that it is appropriate for all 101 new molecular pathology CPT codes to be priced on the same fee schedule using the same methodology. We invite public comment on this proposal.

In our effort to determine the appropriate Medicare payment for these new molecular pathology codes, stakeholders will have the opportunity to discuss the CLFS payment basis for establishing payment amounts for the molecular pathology codes discussed above at the CLFS Annual Public Meeting in July 2012. Section 1833(h)(8)(A) of the Act, which discusses the CLFS, requires the Secretary to ''establish by regulation procedures for determining the basis for, and amount of, payment [under the CLFS] for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.'' Clauses (i) and (ii) of section 1833(h)(8)(B) of the Act requires the Secretary to: 1) Make ''available to the public (through an Internet Web site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount * * * is being considered for a year;'' and, ''on the same day such list is made available, causes to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis * * * for establishing payment amounts for the tests on such list.'' Because we believe that these molecular pathology codes may be clinical diagnostic laboratory tests payable on the CLFS, comments and recommendations from the public on the appropriate basis for establishing payment amounts on the CLFS will be discussed at the CY 2013 CLFS Annual Public Meeting. More information on the CLFS Annual Public Meeting is available in the **Federal Register** at 77 FR 31620 through 31622 and on the CMS Web site at *http://www.cms.hhs.gov/ClinicalLabFeeSched*.

As a parallel to our invitation to discuss these molecular pathology codes as clinical diagnostic laboratory tests at the CLFS Annual Public Meeting in July 2012, we also propose payment amounts for these codes under the PFS for CY 2013. The AMA RUC provided CMS with recommendations for physician work RVUs and PE inputs for the 79 CPT codes it believes include physician work. At our request, CAP provided CMS with direct PE input recommendations for 15 of the remaining 22 CPT codes to the best of their ability. We do not have recommendations on physician work RVUs or direct PE inputs for 7 of 101 codes which represent tests that are patented, and therefore the methodology used to furnish the service is proprietary and has been unavailable to the AMA RUC or CMS to support developing appropriate direct PE inputs. For the 79 CPT codes, the AMA RUC-recommended physician work RVUs range from 0.13 to 2.35, with a median work RVU of 0.45. The AMA RUC-recommended physician intra-service times (which, for these codes, equals the total times) range from 7 minutes to 80 minutes, with a median intra-service time of 18 minutes. We would note that the physician work RVU for CPT code 83912–26 and all but one of the other clinical diagnostic laboratory services for which CMS recognizes payment for clinical interpretation is 0.37. Table 21 lists AMA RUC-recommended physician work RVUs and times for these services.

Molecular pathology tests can be furnished in laboratories of different types and sizes (for example a large commercial laboratory or a pathologist's office), and tests may be furnished in small or large batches. The methodologies used and resources involved in furnishing a specific test can vary from laboratory to laboratory. When developing direct PE input recommendations for CMS, CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical direct PE inputs for each service. Given that many of these services are furnished by private laboratories, providing recommendations on the typical inputs was challenging for many services, and not possible for other services. The AMA RUC and CAP-recommended direct PE inputs are available on the CMS Web site in the files supporting this CY 2013 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. We appreciate all of the effort CAP has made to develop national pricing inputs. However, we agree with its view that, in many cases, there is no established protocol for executing many of these tests and that the potential means to execute these tests can vary considerably.

In addition to recommendations on physician work and direct PE inputs, the AMA RUC provided CMS with recommended utilization crosswalks for the 79 molecular pathology services it believes are typically furnished by a physician. When there are coding changes, the utilization crosswalk tracks Medicare utilization from an existing code to a new code. The existing code utilization figures are drawn from Medicare claims data. We use utilization crosswalk assumptions to ensure PFS BN and to create PE RVUs through the PE methodology. Currently, payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using CPT code 83912–26. Because CPT created the new molecular pathology codes to replace the current stacking codes, when recommending utilization crosswalks, the AMA RUC started with the total utilization for CPT code 83912–26, and divided that utilization among the 79 CPT codes. CAP has indicated that it distributed the utilization based, in part, on ICD–9 diagnosis data. Table 22 lists the AMA RUC-recommended utilization crosswalks for these services.

We are concerned that the RUC-recommended utilization is too low because it is based on the utilization of CPT code 83912–26 only. Instead, we believe that the utilization assumptions for the technical component of the 101 new CPT codes should be based on the utilization of the corresponding CPT codes currently billed on the CLFS. Several laboratories provided us with a list of the molecular pathology tests that they perform, and identified the stacking codes that are currently used to bill for each test and the new CPT code that would be billed for each test. However, because the same molecular pathology test may be billed using different stacks, and the same stack may be billed for different tests, it is not possible to determine which stacks match which new CPT codes for all Medicare claims. Additionally, if a beneficiary has more than one test on the same date of service and both stacks

are billed on the same Medicare claim, it is not possible to determine which stacking codes on the claim make up each stack. Furthermore, some tests described by the new CPT codes are currently billed using general ''not otherwise classified'' (NOC) pathology CPT codes that capture a range of services and not just the molecular pathology tests described by the new CPT codes. Given these factors, it is difficult to estimate the utilization of the 101 new molecular pathology codes based on the Medicare billing of the current stacking and NOC codes.

If we were to finalize payment for molecular pathology services under the PFS, we do not believe that we could propose national payment rates at this time. Many outstanding questions remain including:

- If these services are furnished by a physician, what are the appropriate physician work RVUs and times relative to other similar services?
- Where and how are each of these services typically furnished—for example, what is the typical laboratory setting and batch size?
- What is the correct projected utilization for each of these services?

Given these major areas of uncertainty, if CMS determined that new molecular pathology CPT codes should be paid under the PFS for CY 2013, we are proposing to allow the Medicare contractors to price these codes because we do not believe we have sufficient information to engage in accurate national pricing and because the price of tests can vary locally. As previously discussed, this proposal is a parallel to the invitation to discuss at the CLFS Annual Public Meeting the appropriate basis for establishing a payment amount for these molecular pathology tests as clinical diagnostic laboratory tests under the CLFS. If we decide to finalize payment for these new codes under the PFS, we would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services.

After reviewing comments received on the proposals contained within this CY 2013 PFS proposed rule, and after hearing the discussion at the CLFS Annual Public Meeting, we will determine the appropriate basis for establishing payment amounts for the new molecular pathology codes. We intend to publish our final decision in the CY 2013 PFS final rule with comment period and, at the same time that rule is published, as stated in the CLFS Public Meeting Notice, to post final payment determinations, if any, for the molecular pathology tests that will be paid under the CLFS.

TABLE 21—AMA RUC–RECOMMENDED PHYSICIAN WORK RVUS AND TIMES FOR NEW MOLECULAR PATHOLOGY CPT CODES

CPT Code	Short descriptor	AMA RUC–Recommended physician work RVU	AMA RUC–Recommended physician intra-service time (minutes)
81206	Bcr/abl1 gene major bp	0.37	15
81207	Bcr/abl1 gene minor bp	0.15	11
81208	Bcr/abl1 gene other bp	0.46	18
81210	Braf gene	0.37	15
81220	Cftr gene com variants	0.15	10
81221	Cftr gene known fam variants	0.40	20
81222	Cftr gene dup/delet variants	0.22	13
81223	Cftr gene full sequence	0.40	20
81224	Cftr gene intron poly t	0.15	10
81225	Cyp2c19 gene com variants	0.37	13
81226	Cyp2d6 gene com variants	0.43	15
81227	Cyp2c9 gene com variants	0.38	14
81240	F2 gene	0.13	7
81241	F5 gene	0.13	8
81243	Fmr1 gene detection	0.37	15
81244	Fmr1 gene characterization	0.51	20
81245	Flt3 gene	0.37	15
81256	Hfe gene	0.13	7
81257	Hba1/hba2 gene	0.50	20
81261	Igh gene rearrange amp meth	0.52	21
81262	Igh gene rearrang dir probe	0.61	20
81263	Igh vari regional mutation	0.52	23
81264	Igk rearrangeabn clonal pop	0.58	22
81265	Str markers specimen anal	0.40	17
81266	Str markers spec anal addl	0.41	15
81267	Chimerism anal no cell selec	0.45	18
81268	Chimerism anal w/cell select	0.51	20
81270	Jak2 gene	0.15	10
81275	Kras gene	0.50	20
81291	Mthfr gene	0.15	10
81292	Mlh1 gene full seq	1.40	60
81293	Mlh1 gene known variants	0.52	28
81294	Mlh1 gene dup/delete variant	0.80	30
81295	Msh2 gene full seq	1.40	60
81296	Msh2 gene known variants	0.52	28
81297	Msh2 gene dup/delete variant	0.80	30
81298	Msh6 gene full seq	0.80	30
81299	Msh6 gene known variants	0.52	28
81300	Msh6 gene dup/delete variant	0.65	30
81301	Microsatellite instability	0.50	20

TABLE 21—AMA RUC–RECOMMENDED PHYSICIAN WORK RVUS AND TIMES FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

CPT Code	Short descriptor	AMA RUC–Recommended physician work RVU	AMA RUC–Recommended physician intra-service time (minutes)
81302	Mecp2 gene full seq	0.65	30
81303	Mecp2 gene known variant	0.52	28
81304	Mecp2 gene dup/delet variant	0.52	28
81310	Npm1 gene	0.39	19
81315	Pml/raralpha com breakpoints	0.37	15
81316	Pml/raralpha 1 breakpoint	0.22	12
81317	Pms2 gene full seq analysis	1.40	60
81318	Pms2 known familial variants	0.52	28
81319	Pms2 gene dup/delet variants	0.80	30
81331	Snrpn/ube3a gene	0.39	15
81332	Serpina1 gene	0.40	15
81340	Trb@ gene rearrange amplify	0.63	25
81341	Trb@ gene rearrange dirprobe	0.45	19
81342	Trg gene rearrangement anal	0.57	25
81350	Ugt1a1 gene	0.37	15
81355	Vkorc1 gene	0.38	15
81370	Hla i & ii typing lr	0.54	15
81371	Hla i & ii type verify lr	0.60	30
81372	Hla i typing complete lr	0.52	15
81373	Hla i typing 1 locus lr	0.37	15
81374	Hla i typing 1 antigen lr	0.34	13
81375	Hla ii typing ag equiv lr	0.60	15
81376	Hla ii typing 1 locus lr	0.50	15
81377	Hla ii type 1 ag equiv lr	0.43	15
81378	Hla i & ii typing hr	0.45	20
81379	Hla i typing complete hr	0.45	15
81380	Hla i typing 1 locus hr	0.45	15
81381	Hla i typing 1 allele hr	0.45	12
81382	Hla ii typing 1 loc hr	0.45	15
81383	Hla ii typing 1 allele hr	0.45	15
81400	Mopath procedure level 1	0.32	10
81401	Mopath procedure level 2	0.40	15
81402	Mopath procedure level 3	0.50	20
81403	Mopath procedure level 4	0.52	28
81404	Mopath procedure level 5	0.65	30
81405	Mopath procedure level 6	0.80	30
81406	Mopath procedure level 7	1.40	60
81407	Mopath procedure level 8	1.85	60
81408	Mopath procedure level 9	2.35	80

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES

Source	Destination	Analytic ratio*
83912 26	81206	0.116
83912 26	81207	0.003
83912 26	81208	0.003
83912 26	81210	0.020
83912 26	81220	0.017
83912 26	81221	0.003
83912 26	81222	0.003
83912 26	81223	0.003
83912 26	81224	0.003
83912 26	81225	0.006
83912 26	81226	0.006
83912 26	81227	0.011
83912 26	81240	0.073
83912 26	81241	0.110
83912 26	81243	0.003
83912 26	81244	0.000
83912 26	81245	0.014
83912 26	81256	0.050

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81257	0.014
83912 26	81261	0.014
83912 26	81262	0.002
83912 26	81263	0.001
83912 26	81264	0.011
83912 26	81265	0.043
83912 26	81266	0.001
83912 26	81267	0.006
83912 26	81268	0.001
83912 26	81270	0.050
83912 26	81275	0.050
83912 26	81291	0.017
83912 26	81292	0.003
83912 26	81293	0.001
83912 26	81294	0.002
83912 26	81295	0.003
83912 26	81296	0.001
83912 26	81297	0.002

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81298	0.001
83912 26	81299	0.002
83912 26	81300	0.001
83912 26	81301	0.003
83912 26	81302	0.001
83912 26	81303	0.000
83912 26	81304	0.000
83912 26	81310	0.014
83912 26	81315	0.017
83912 26	81316	0.003
83912 26	81317	0.002
83912 26	81318	0.001
83912 26	81319	0.001
83912 26	81331	0.001
83912 26	81332	0.003
83912 26	81340	0.011
83912 26	81341	0.003
83912 26	81342	0.017

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81350	0.002
83912 26	81355	0.011
83912 26	81370	0.043
83912 26	81371	0.029
83912 26	81372	0.011
83912 26	81373	0.011
83912 26	81374	0.029
83912 26	81375	0.006
83912 26	81376	0.006
83912 26	81377	0.006
83912 26	81378	0.006
83912 26	81379	0.003
83912 26	81380	0.003
83912 26	81381	0.003
83912 26	81382	0.003
83912 26	81383	0.003
83912 26	81400	0.007
83912 26	81401	0.007
83912 26	81402	0.007
83912 26	81403	0.007
83912 26	81404	0.007
83912 26	81405	0.007
83912 26	81406	0.003
83912 26	81407	0.003
83912 26	81408	0.003

*Percentage of source code utilization transferred to the destination code

J. Payment for New Preventive Service HCPCS G-Codes

Under section 1861(ddd) of the Act, as amended by Section 4105 of the Affordable Care Act, CMS is authorized to add coverage of ''additional preventive services'' if certain statutory criteria are met as determined through the national coverage determination (NCD) process, including that the service meets all of the following criteria: (1) They must be reasonable and necessary for the prevention or early detection of illness or disability, (2) they must be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) they must be appropriate for individuals entitled to benefits under Part A or enrolled under Part B. After reviewing the USPSTF recommendations for the preventive services, conducting evidence reviews, and considering public comments under the NCD process, we determined that the above criteria were met for the services listed in Table 23. Medicare now covers each of the following preventive services:

- Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse, effective October 14, 2011;
- Screening for Depression in Adults, effective October 14, 2011;
- Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs, effective November 8, 2011;
- Intensive Behavioral Therapy for Cardiovascular Disease, effective November 8, 2011; and
- Intensive Behavioral Therapy for Obesity, effective November 29, 2011.

Table 23 lists the HCPCS G-codes created for reporting and payment of these services. The Medicare PFS payment rates for these services are discussed below. The NCD process establishing coverage of these preventive services was not complete at the time of publication of the CY 2012 PFS final rule in early November, so we could not indicate interim RVUs for these preventive services in our final rule addenda. However, we were able to include HCPCS G-codes and national payment amounts for these services in the CY 2012 PFS national relative value files, which became available at the end of the year and were effective January 1, 2012. From the effective date of each service to December 31, 2011, the payment amount for these codes was established by the Medicare Administrative Contractors.

TABLE 23—NEW PREVENTIVE SERVICE HCPCS G-CODES

HCPCS Code	HCPCS Code long descriptor	CMS National Coverage Determination (NCD)	CMS Change Request (CR)
G0442	Annual alcohol misuse screening, 15 minutes	Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes.	Screening Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0444	Annual Depression Screening, 15 minutes	Screening for Depression in Adults (NCD 210.9)	CR7637
G0445	High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes.	Screening for Sexually Transmitted infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to prevent STIs (NCD 210.10).	CR7610
G0446	Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes.	Intensive Behavioral Therapy for Cardiovascular Disease (NCD 210.11).	CR7636
G0447	Face-to-face behavioral counseling for obesity, 15 minutes.	Intensive Behavioral Therapy for Obesity (NCD 210.12).	CR7641

Two new HCPCS codes, G0442 (Annual alcohol misuse screening, 15 minutes), and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes), were created for the reporting and payment of screening and behavioral counseling interventions in primary care to reduce alcohol misuse.

We believe that the screening service described by HCPCS code G0442 requires similar physician work as CPT code 99211 (Level 1 office or other outpatient visit, established patient), that may not require the presence of a physician. CPT code 99211 has a work RVU of 0.18 and we believe HCPCS code G0442 should be valued similarly. As such, we are proposing a work RVU of 0.18 for HCPCS code G0442 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0442, which are the same as the current (CY 2012) values for this service.

We believe that the behavioral counseling service described by HCPCS

code G0443 requires similar physician work to CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes) (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0443 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0443, which are the same as the current (CY 2012) values for this service.

HCPCS code G0444 (Annual Depression Screening, 15 minutes) was created for the reporting and payment of screening for depression in adults.

We believe that the screening service described by HCPCS code G0444 requires similar physician work as CPT code 99211 (work RVU = 0.18) and should be valued similarly. As such, we are proposing a work RVU of 0.18 for HCPCS code G0444 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0444, which are the same as the current (CY 2012) values for this service.

HCPCS code G0445 (high-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes) was created for the reporting and payment of HIBC to prevent STIs.

We believe that the behavioral counseling service described by HCPCS code G0445 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0445 for CY 2013. For physician time, we are proposing 30 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0445, which are the same as the current (CY 2012) values for this service.

HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for cardiovascular disease.

We believe that the behavioral therapy service described by HCPCS code G0446 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0446 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0446, which are the same as the current (CY 2012) values for this service.

HCPCS G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for obesity.

We believe that the behavioral counseling service described by HCPCS code G0447 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0447 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0447, which are the same as the current (CY 2012) values for this service.

K. Certified Registered Nurse Anesthetists and Chronic Pain Management Services

The benefit category for services furnished by a certified registered nurse anesthetist (CRNA) was added to Medicare by section 9320 of the Omnibus Budget Reconciliation Act (OBRA) 1986. Since this benefit was implemented on January 1, 1989, CRNAs have been eligible to bill Medicare directly for the specified services. Section 1861(bb)(2) of the Act defines a CRNA as ''a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists.''

Section 410.69(b) defines a CRNA as a registered nurse who: (1) Is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to nonphysician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets one of the following criteria: (i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

Section 1861(bb)(1) of the Act defines services of a CRNA as ''anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished''. CRNAs are paid at the same rate as physicians for furnishing such services to Medicare beneficiaries. Payment for services

furnished by CRNAs only differs from physicians in that payment to CRNAs is made only on an assignment-related basis (§ 414.60) and supervision requirements apply in certain circumstances.

At the time that the Medicare benefit for CRNA services was established, CRNA practice largely occurred in the surgical setting and services other than anesthesia (medical and surgical) were furnished in the immediate pre- and post-surgery timeframe. The scope of ''anesthesia services and related care'' as delineated in section 1861(bb)(1) of the Act reflected that practice standard. As CRNAs have moved into other practice settings, questions have arisen regarding what services are encompassed under the ''related care'' aspect of the benefit category. Specifically, some CRNAs now offer chronic pain management services that are separate and distinct from a surgical procedure. Changes in CRNA practice have prompted questions as to whether these services fall within the scope of section 1861(bb)(1) of the Act. Medicare Administrative Contractors (MACs) have reached different conclusions as to whether the statutory description of ''anesthesia services and related care'' encompasses the chronic pain management services delivered by CRNAs. As a result, we have been asked to address whether or not chronic pain management is included within the scope of the statutory benefit for CRNA services.

To determine whether chronic pain management is included in the statutory benefit for CRNA services, we reviewed our current regulations and subregulatory guidance. We found that the existing guidance does not specifically address chronic pain management. In the Internet Only Manual (Pub 100–04, Ch 12, Sec 140.4.3), we discuss the medical or surgical services that fall under the ''related care'' language stating, ''These may include the insertion of Swan Ganz catheters, central venous pressure lines, pain management, emergency intubation, and the pre-anesthetic examination and evaluation of a patient who does not undergo surgery.'' Some have interpreted the reference to ''pain management'' in this language as authorizing direct payment to CRNAs for chronic pain management services, while others have taken the view that the services highlighted in the manual language are services furnished in the perioperative setting and refer only to acute pain management associated with the surgical procedure.

Since existing guidance was not determinative, we assessed the issue of CRNA practice of chronic pain management more broadly. We found that chronic pain management is an emerging field. The Institute of Medicine (IOM) issued a report entitled ''Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research'' on June 29, 2011, discussing the importance of pain management and focusing on the many challenges in delivering effective chronic pain management. The available interventions to treat chronic pain have been expanding. In addition to the use of medications and a variety of diagnostic tests, techniques include neural blocks, neuromodulatory techniques, and implanted pain management devices. The healthcare community continues to examine the appropriateness and effectiveness of these many and varied treatment techniques and modalities. As part of this evolution, Medicare established a physician specialty code for interventional pain management in 2003.

The healthcare community continues to debate whether CRNAs are qualified to provide chronic pain management. Some have stated that interventional pain management for beneficiaries with chronic pain is the practice of medicine, that CRNAs do not receive the sufficient education on chronic pain management, and that CRNAs do not have the skills required to furnish chronic pain management services. Others have stated that both acute and chronic pain management and treatment are within the CRNA professional scope and are comparable services, and that CRNAs receive the clinical training and experience necessary to furnish both acute and chronic pain management services. Recently, several State legislatures have debated the scope of CRNA practice, including those in the States of California, Colorado, Missouri, South Carolina, Nevada, and Virginia.

In the context of Medicare, some have pointed to Medicare policies allowing other advanced practice nurses such as nurse practitioners or clinical nurse specialists to furnish and bill for physicians' services as support for recognizing a broader interpretation of the scope of CRNA practice. We would note that the statutory benefit category definition for CRNAs substantively differs from that for other advanced practice nurses. Section 1861(s)(2)(K) of the Act authorizes certain nonphysician practitioners (NPPs) to bill Medicare directly for services they are legally authorized to perform under State law, and ''which would be physicians' services if furnished by a physician.'' With certain conditions (such as physician supervision or collaboration), the statute allows these NPPs to bill Medicare for physicians' services that fall within their State scope of practice.

Since State governments regulate the licensure and practice of specific types of health care professionals, we have looked to the State scope of practice laws to determine if chronic pain management was within the scope of practice for CRNAs. State scope of practice laws vary with regard to the range of services that CRNAs may perform, and some include chronic pain management. As discussed earlier, several States are debating whether to include chronic pain management services within the CRNA scope of practice.

After assessing the information available to us, we have concluded that chronic pain management is an evolving field, and we recognize that certain States have determined that the scope of practice for a CRNA should include chronic pain management in order to meet health care needs of their residents and ensure their health and safety. Therefore, we propose to revise our regulations at § 410.69(b) to define the statutory description of CRNA services. Specifically, we propose to add the following language: ''Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the State in which the services are furnished.'' This proposed definition would set a Medicare standard for the services that can be furnished and billed by CRNAs while allowing appropriate flexibility to meet the unique needs of each State. The proposal also dovetails with the language in section 1861(bb)(1) of the Act requiring the State's legal authorization to perform CRNA services as a key component of the CRNA benefit category. Finally, the proposed definition is also consistent with our policy to recognize State scope of practice as one parameter defining the services that can be furnished and billed by other NPPs.

Simply because the State allows a certain type of health care professional to furnish certain services does not mean that all members of that profession are adequately trained to provide the service. In the case of chronic pain management, the IOM report specifically noted that many practitioners lack the skills needed to help patients with the day-to-day self-management that is required to properly serve individuals with chronic pain. As with all practitioners who furnish services to Medicare beneficiaries, CRNAs practicing in States that allow them to furnish chronic pain

management services are responsible for obtaining the necessary training for any and all services furnished to Medicare beneficiaries.

L. Ordering of Portable X-Ray Services

Portable x-ray suppliers provide diagnostic imaging services at a patient's location. These services are most often furnished in residences, including private homes and group living facilities (for example, nursing homes) rather than in a traditional clinical setting (for example, a doctor's office or hospital). The supplier transports mobile diagnostic imaging equipment to the patient's location, sets up the equipment, and administers the test onsite. The supplier may interpret the results itself or it may provide the results to an outside physician for interpretation. Portable x-ray services may avoid the need for expensive ambulance transport of frail patients to a radiology facility or hospital.

In the Medicare Conditions for Coverage regulations established in 1969, § 486.106(a), requires that ''portable x-ray examinations are performed only on the order of a doctor of medicine (MD) or doctor of osteopathy (DO) licensed to practice in the State * * *'' With the exception of portable x-ray services, Medicare payment regulations at § 410.32 allow physicians, including limited-license practitioners such as doctors of podiatry and optometry, and most nonphysician practitioners who furnish physicians' services to order diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests so long as those nonphysician practitioners are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit.

Nonphysician practitioners have become an increasingly important component of clinical care, and we believe that delivery systems should take full advantage of all members of a healthcare team, including nonphysician practitioners.

Although current Medicare regulations limit ordering of portable x-ray services to a MD or a DO, the Office of the Inspector General (OIG) in its December 2011 report entitled ''*Questionable Billing Patterns of Portable X-Ray Suppliers''* (OEI–12–10–00190) found that Medicare was paying for portable x-ray services ordered by physicians other than MDs and DOs, including podiatrists and chiropractors, and by nonphysician practitioners. We issued a special education article on January 20, 2012, through the Medicare Learning Network (MLN) ''*Important Reminder for Providers and Suppliers Who Provide Services and Items Ordered or Referred by Other Providers and Suppliers,''* reiterating our current policy that portable x-ray services can only be ordered by a MD or DO. The article is available at *http://www.cms.gov/MLNMattersArticles/downloads/SE1201.pdf* on the CMS Web site. Since the publication of the above mentioned article, several stakeholders have told us that members of the healthcare community fail to distinguish ordering for portable x-ray services from ordering for other diagnostic services where our general policy is to allow nonphysician practitioners and physicians other than MDs and DOs to order diagnostic tests within the scope of their authority under State law and their Medicare statutory benefit. They report finding the different requirements confusing.

We propose to revise our current regulations, which limit ordering of portable x-ray services to only a MD or DO, to allow other physicians and nonphysician practitioners acting within the scope of their Medicare benefit and State law to order portable x-ray services. Specifically, we propose revisions to the Conditions for Coverage at § 486.106(a) and § 486.106(b) to permit portable x-ray services to be ordered by a physician or nonphysician practitioner in accordance with the ordering policies for other diagnostic services under § 410.32(a).

This proposed change would allow a MD or DO, as well as an nurse practitioner, clinical nurse specialist, physician assistant, certified nurse-midwife, doctor of optometry, doctor of dental surgery and doctor of dental medicine, doctor of podiatric medicine, clinical psychologist, and clinical social worker to order portable x-ray services within their State scope of practice and the scope of their Medicare benefit. Although all of these physicians and nonphysician practitioners are authorized to order diagnostic services in accordance with § 410.32(a), their Medicare benefit delimits the services that they can provide.

We also propose to revise the language included in § 410.32(c) to recognize the same authority for physicians and nonphysician practitioners to order diagnostic tests as is prescribed for other diagnostic services in § 410.32(a). Finally, we are proposing two technical corrections. One is to § 410.32(d)(2), where we currently cite to subsection (a)(3) for the definition of qualified nonphysician practitioner. The definition of qualified nonphysician practitioner is in paragraph (a)(2) and paragraph (a)(3) does not exist; therefore, we are changing the citation to the correct citation. The second technical correction is § 410.32(b)(2)(iii) to better reflect statutory authority to provide neuropsychological testing in addition to psychological testing.

Although we believe that this proposal is appropriate given overall changes in practice patterns since the beginning of the Medicare program, we remain concerned about the OIG's recent findings. The OIG observed questionable billing patterns for portable x-ray services in addition to ordering by nonphysician practitioners. Of specific note was the observation that some portable x-ray suppliers are delivering services on the same day that the patient also receives services in a clinical setting, such as the physician office or hospital. Under our current regulation at § 486.106(a)(2), the order for portable x-ray services must include a statement concerning the condition of the patient which indicates why portable x-ray services are necessary. If the patient was able, on the same day that a portable x-ray service was furnished, to travel safely to a clinical setting, the statement of need for portable x-ray services could be questionable. We also are concerned that the OIG observed some portable x-ray suppliers billing for multiple trips to a facility. Medicare makes a single payment for each trip the portable x-ray supplier makes to a particular location. We make available multiple modifiers to allow the portable x-ray supplier to indicate the number of patients served on a single trip to a facility. We expect portable x-ray suppliers to use those modifiers and not to bill multiple trips to the same facility when only one trip was made. Additionally, we strongly encourage portable x-ray suppliers to make efficient use of resources and consolidate trips rather than making multiple trips on the same day as clinically appropriate.

In conjunction with our proposal to expand the scope of physicians and nonphysician practitioners who can order portable x-ray services, we intend to develop, as needed, monitoring standards predicated by these and other OIG findings. In addition, we will be conducting data analysis of ordering patterns for portable x-ray and other diagnostic services to determine if additional claims edits, provider audits, or fraud investigations are required to prevent abuse of this service and to allow for the collection of any potential overpayments. We encourage providers, as with any diagnostic test, to proactively determine and document the medical necessity for this testing.

We are also considering whether to make other revisions to the current regulations at 42 CFR, Part 486, Subpart C—Conditions for Coverage: Portable X-Ray Services through future rulemaking, as we are aware stakeholders have suggested regulatory changes to consider since the last update of this regulation. The last time this regulation was updated was in 2008, but many of the sections in Part 486, Subpart C have not been updated since 1995. Since we are proposing to update part of Part 486, Subpart C in this proposed rule, we are using this opportunity to seek public comment on suggestions for updating in the future the rest of the regulations at Part 486, Subpart C. We are open to all suggestions for updates; therefore we did not pose specific questions for response by the public.

We are specifically seeking public comment on suggestions for updating Subpart C—Conditions for Coverage: Portable X-Ray Services; noting that any regulatory changes would be addressed through separate notice-and-comment rulemaking.

III. Other Provisions of the Proposed Regulation

A. Ambulance Fee Schedule

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. In the CY 2011 PFS final rule (75 FR 73385 and 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the MMEA again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2011 and before January 1, 2012. In the CY 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) final rule (76 FR 70228, 70284 through 70285, 70315), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. However, in doing so, paragraphs (c)(1)(ii)(A) and (B) were inadvertently deleted from the Code of Federal Regulations. Therefore, we propose to reinstate paragraphs (c)(1)(ii)(A) and (B), as further revised below to conform to subsequent legislation.

Subsequently, section 306 (a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) (TPTCCA) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through February 29, 2012; and section 3007(a) of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) (MCTRJCA) further amended section 1834(l)(13)(A) to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. Accordingly, we are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements. These statutory requirements are self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. This section originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385 through 86, 73625 through 26), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. In the CY 2012 ESRD PPS final rule (76 FR 70284 through 70285, 70315), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 306 (b) of the TPTCCA amended section 146(b)(1) of MIPPA to extend this provision through February 29, 2012; and section 3007(b) of the MCTRJCA further amended section 146(b)(1) of MIPPA to extend this provision through December 31, 2012. Therefore, we are proposing to revise § 414.610(h) to conform the regulations to these statutory requirements. These statutory requirements are self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through December 31, 2012.

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added paragraph (12) to section 1834(l) of the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA,

this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area''; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385 through 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA again amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284 through 70285, 70315), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 306 (c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2012 and before January 1, 2013 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS supplied ZIP Code File.

Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to the statutory requirements set forth at section 306(c) of the TPTCCA and section 3007(c) of the MCTRJCA. These statutory requirements are self-implementing. Together, these provisions require a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2012, and does not require any substantive exercise of discretion on the part of the Secretary.

B. Part B Drug Payment: Average Sales Price (ASP) Issues

Section 1847A of the Act requires use of the average sales price (ASP) payment methodology 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 applies to most drugs furnished incident to a physician's service, many drugs furnished under the DME benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

1. Widely Available Market Price (WAMP)/Average Manufacturer Price (AMP) Price Substitution

For a drug or biological that is found to have exceeded the WAMP of AMP by a threshold percentage, section 1847A(d)(3)(C) of the Act authorizes the Secretary to substitute, the lesser of—

- The widely available market price for the drug or biological, or
- 103 percent of the average manufacturer price as determined under section 1927(k)(1) of the Act.''

The applicable threshold percentage is specified in section 1847A(d)(3)(B)(i) of the Act as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B)(ii) of the Act authorizes the Secretary to specify the threshold percentage for the WAMP or the AMP, or both. In the CY 2006 (70 FR 70222), CY 2007 (71 FR69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904) PFS final rules with comment period, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the fact that data was too limited to support an adjustment to the 5 percent threshold. Beginning in CY 2011, we treated the WAMP and AMP based adjustments to the applicable threshold percentages separately.

a. WAMP Threshold and Price Substitution

After soliciting and reviewing comments, we finalized proposals to continue the 5 percent WAMP threshold for CY 2011 (75 FR 73469), and CY 2012 (76 FR 73287). For CY 2013, we again have no additional information from OIG studies or other sources that leads us to consider an alternative threshold. When making comparisons to the WAMP, we propose that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we propose to update § 414.904(d)(3)(iv) accordingly. As mentioned above, the threshold has remained at 5 percent since 2005. Our proposal will eliminate the need for annual rulemaking until a change is warranted.

We are not proposing to make any WAMP based price substitutions at this time. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73470) and reiterated in CY 2012 (76 FR 73287), we understand that there are complicated operational issues associated with the WAMP based substitution policy, and we continue to proceed cautiously in this area. We remain committed to providing stakeholders, including providers and manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

b. AMP Threshold

Like the WAMP threshold, for CY 2013, we have no information that leads us to believe that the 5 percent threshold percentage for AMP-based price substitution is inappropriate or should be changed. We propose that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we propose to update § 414.904(d)(3)(iii) accordingly. The AMP threshold has remained at 5 percent since 2005. Our proposal will eliminate the need for annual rulemaking until a change is warranted.

c. AMP Price Substitution-Additional Condition

In the CY 2012 PFS rule, we specified that the substitution of AMP for ASP will be made only when the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter, and that matching sets of NDCs had to be used in the comparison (76FR 73289 through 73295). The value of the AMP based price substation must also be less than the ASP payment limit that is calculated for the quarter in which the substitution is applied.

We did not apply the price substitution policy in April 2012 because access concerns led us to reconsider whether it was prudent to proceed with price substitution during a developing situation that was related to a drug shortage that had not met the definition of a public health emergency under section 1847A(e) of the Act. In light of recent concerns about drug shortages, the resulting impact on patient care, beneficiary and provider access, as well as the potential for

shortages to suddenly affect drug prices for the provider, under the authority in section 1847A(d)(3)(C) of the Act, we propose adding § 414.904(d)(3)(ii)(C) that would prevent the AMP price substitution policy from taking effect if the drug and dosage form represented by the HCPCS code are reported by the FDA on their Current Drug Shortage list (or other FDA reporting tool that identifies shortages of critical or medically necessary drugs) to be in short supply at the time that ASP payment limits are being finalized for the next quarter. Further, we also would like to clarify that this proposal to add to the safeguards finalized in CY 2012 only applies to calculations under the AMP-based price substitution policy. Our proposal is intended to continue the cautious approach described in previous rules and to strike a balance between operational requirements associated with receiving manufacturers' ASP reports, calculating the payment limits, and posting stable payment limits that will be used to pay claims. We believe that this proposal also addresses concerns about access to care, known program issues identified by the OIG, and provides an opportunity for some modest program savings. At this time, we are not proposing any other changes to the safeguards, timing, or notification that identifies the codes that will be substituted each quarter. We welcome comments on our approach as well as comments regarding additional specific safeguards for the AMP price substitution policy.

2. Billing for Part B Drugs Administered Incident to Physicians' Services

In this section, we propose to clarify payment policies regarding billing for certain drugs under Medicare Part B. In 2010 and 2011, we issued two change requests (CRs 7109 and 7397) that summarized a number of longstanding drug payment policy and billing requirements. We considered these CRs to be merely clarifying, rather than changing, our policy. However, one item in the CRs, which stated that pharmacies may not bill for drugs that are used incident to physicians' service, has caused some concern. Specifically, we understand that some nonphysician suppliers—operating in part on the basis of guidance from a Medicare contractor—have been submitting claims for drugs that they have shipped to physicians' offices for use in refilling implanted intrathecal pumps. In light of concern over its potential effect on suppliers, we delayed implementation of the most recently updated CR (CR 7397 Transmittal 2437, April 4, 2012) until January 1, 2013 so that we could undertake rulemaking, evaluate public comments on this issue, and determine whether CR 7397 should be implemented as planned, revised, or rescinded.

Implanted pumps may qualify as Durable Medical Equipment (DME); however, unlike external pumps used to administer drugs, implanted pumps are typically refilled in a physician's office. The implanted intrathecal pump is refilled by injecting the drug into a pump's reservoir, which lies below the patient's skin. The reservoir is connected to the pump, which delivers the drug to the intrathecal space through a tunneled catheter. The procedure of refilling an intrathecal pain pump is a service that is typically performed by the physician because of risk and complexity.

To be covered by Medicare, an item or service must fall within one or more benefit categories within Part A or Part B, and must not be otherwise excluded from coverage. Drugs and biologicals paid under Medicare part B drugs fall into three basic categories as follows:

- *Drugs furnished ''incident to'' a physician's services:* These are typically injectable drugs that are bought by the physician, administered in the physician's office and then billed by the physician to the Medicare Administrative Contractor (MAC).
- *Drugs administered through a covered item of DME:* These drugs are supplies necessary for the effective use of DME and are typically furnished to the beneficiary by suppliers that are either pharmacies (or general DME suppliers that utilize licensed pharmacists) for administration in a setting other than the physician's office. Most DME drugs are billed to the DME MAC.
- *Drugs specified by the statute:* Include a variety of drugs, such as oral immunosuppressives and certain vaccines.

Drugs used to refill an implanted intrathecal pump can be considered to be within either the ''incident to'' or the DME benefit category. The CMS Benefit Policy Manual (100–02 Chapter 15 Section 50.3) states that drugs paid under the ''incident to'' provision are of a form that is not usually self-administered; are furnished by a physician; and are administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. In what we believe is a typical situation, when physicians' services are used to refill an intrathecal pump, the ''incident to'' requirements can be met because, consistent with our guidance and longstanding policy, the physician or other professional employed by his or her office performs a procedure to inject the drug into the implanted pump's reservoir (that is, the drug is not self-administered) and the drug represents a cost to the physician because he or she has purchased it.

Conversely, we believe that in the typical situation, payment to a pharmacy or other nonphysician supplier under the DME benefit for a drug dispensed for use in the physician's office is both inappropriate and inconsistent with existing guidance. For example, DME prosthetics, orthotics, and supplies (POS) policy does not permit payment for prosthetics dispensed prior to a procedure. Moreover, in the case of prescription drugs used in conjunction with DME, our guidance is clear that the entity that dispenses the drug needs to furnish it directly to the patient for whom a prescription is written. We do not believe that an arrangement whereby a pharmacy (or supplier) ships a drug to a physician's office for administration to a patient constitutes furnishing the drug directly to the patient.

We note that payment to pharmacies (or suppliers) for drugs used to refill an implanted pump can be made under the DME benefit category where the drug is dispensed to a patient and the implanted pump is refilled without a physician's service. However, it is our understanding that implanted pumps are rarely refilled without utilizing the service of a physician.

We are concerned about stakeholders' reports that, due to guidance from a contractor, Medicare payment policy on this issue has been applied in an inconsistent manner. We consider the contractor's guidance to be erroneous. This inconsistency has permitted supplier claims for drugs dispensed by pharmacies to physicians' offices to be paid in some jurisdictions and has denied such payment in others. We understand that the inconsistent application of our payment policy has influenced the business and professional practices of pharmacies/DME suppliers that prepare drugs for implanted pumps. However, we do not believe that payment for drugs used to refill implanted DME should continue to be made because such action is not supported under long standing policy and, as discussed above, is not appropriate.

We therefore propose to clarify that we consider drugs used by a physician to refill an implantable item of DME to be within the ''incident to'' benefit category and not the DME benefit category. Therefore, the physician must buy and bill for the drug, and a non-

physician supplier that has shipped the drug to the physician's office may not do so (except as may be permitted pursuant to a valid reassignment). We welcome comments on this proposal and its potential impact on beneficiaries and providers.

C. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

1. Background

Sections 1832, 1834, and 1861 of the Act establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for specified covered items, that payment may only be made under section 1834(a) of the Act if a physician has communicated to the supplier a written order for the item, before delivery of the item. Section 1834(h)(3) of the Act states that section 1834(a)(11) applies to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of durable medical equipment (DME). In a December 7, 1992 final rule (57 FR 57675), we implemented this provision in § 410.38(g), for DME items and § 410.36(b) for prosthetic devices, orthotics, and prosthetics. Both of these sections state that as a requirement for payment, CMS, a carrier, or, more recently, a Medicare Administrative Contractor (MAC) may determine that an item of DME requires a written physician order before delivery. In addition to our regulations at § 410.38(g) and § 410.36(b), we have stated in Chapter 5, Section 5.2.3.1 of the Program Integrity Manual, that the following items require a written order prior to delivery: (1) Pressure reducing pads, mattress overlays, mattresses, and beds; (2) seatlift mechanisms; (3) transcutaneous electrical nerve stimulation (TENS) units; (4) power operated vehicles (POVs) and power wheelchairs.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act. It added language that requires a written order for certain items of DME, which under section 1834(h)(3) of the Act also could include prosthetic devices, orthotics, and prosthetics, to be issued per a physician documenting that a physician, a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary. The encounter must occur during the 6 months prior to the written order for each item or during such other reasonable timeframe as specified by the Secretary.

2. Provisions of the Proposed Regulations

a. DME Face-to-Face Encounters

(1) General Requirements

We are proposing to first revise § 410.38(g) to require, as a condition of payment for certain covered items of DME, that a physician must have documented and communicated to the DME supplier that the physician or a PA, an NP, or a CNS has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

We make this proposal because we believe that a face-to-face encounter that occurs within 90 days prior to the written order for DME should be relevant to the reason for the beneficiary's need for the item of DME, and therefore, this face-to-face encounter should substantiate that the beneficiary's condition warrants the covered item of DME and be sufficient to meet the goals of this statutory requirement. However, we recognize that there may be circumstances when it may not be possible to meet this general requirement of ''prior to the written order,'' and that in such cases, beneficiary access to needed items must be protected. If a face-to-face encounter occurs within 90 days of the written order, but is not related to the condition warranting the need for the item of DME, or if the beneficiary has not seen the physician or PA, NP, or CNS within the 90 days prior to the written order, we propose to allow a face-to-face encounter up to and including 30 days after the order is written in order to ensure access to needed items.

During the face-to-face encounter the physician, a PA, a, NP, or a CNS must have evaluated the beneficiary, conducted a needs assessment for the beneficiary or treated the beneficiary for the medical condition that supports the need for each covered item of DME. As a matter of practice, this information would be part of the beneficiary's medical record, which identifies the practitioner who provided the face-to-face assessment. We believe that requiring a face-to-face encounter that supports the need for the covered item of DME would reduce the risk of fraud, waste, and abuse since these visits would help ensure that a beneficiary's condition warrants the covered item of DME.

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 6407(b) of the Affordable Care Act states that a physician must document that the physician, a PA, a NP, or a CNS has had a face-to-face encounter (other than with respect to encounters that are incident to services involved) with the beneficiary. Incident to services are defined in section 1861(s)(2)(A) of the Act. Likewise, for the purpose of this regulation, a face-to-face encounter must be documented by a physician and any encounter that is covered as an ''incident to'' service does not satisfy the requirements of this regulation.

We note that a face-to-face encounter may be accomplished via a telehealth encounter if all Medicare telehealth requirements as defined under section 1834(m) of the Act and the implementing regulations in § 410.78 and § 414.65 are met. Specifically, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. The requirements in this proposed rule do not supersede the requirements of telehealth and merely apply to the telehealth benefit where applicable. In general, originating sites must be located in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). The practitioner at the distant site may be a physician, PA, NP, or CNS, and the encounter must be reported with a healthcare procedure common coding system (HCPCS) code for a service on the list of approved Medicare telehealth services for the applicable year. In the May 5, 2010 **Federal Register** (76 FR 25550), we published a final rule that revised the conditions of participation (CoPs) for hospitals and critical access hospitals (CAHs). These revisions implement a new credentialing and privileging process for physicians and other practitioners providing telemedicine services. We refer readers to the CMS Web site for more information regarding telehealth services at *http://www.cms.gov/Telehealth/*.

A single face-to-face encounter, including those facilitated through the appropriate use of telehealth, can support the need for multiple covered items of DME as long as it is clearly documented in the pertinent medical record that the beneficiary was evaluated or treated for a condition that supports the need for each covered item of DME, during the specified period of time.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud, and abuse, we propose that as a condition of payment a written order must include: (1) The

beneficiary name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; (5) the date of the order; (6) the diagnosis; and (7) necessary proper usage instructions, as applicable. Examples of necessary proper usage instruction could include duration of use, method of utilization, and correct positioning. We recognize that standards of practice may require that orders contain additional information. However, for purposes of this proposed rule, which is focused on implementing section 1834(a)(11)(B) of the Act and reducing fraud, waste, and abuse, an order without these minimum elements would be considered incomplete and would not support a claim for payment. We believe including this information on the written order would be a safeguard against waste, fraud, and abuse by promoting authenticity and comprehensiveness of the order by the practitioner.

Based on our commitment to the general principles of the President's Executive Order entitled ''Improving Regulation and Regulatory Review'' (released January 18, 2011) and to be consistent with other provisions in the amendments made by section 6407(a) of the Affordable Care Act and the provisions of section 6407 (d) of the Affordable Care Act as discussed above, we are proposing to require that the face-to-face encounter occur no earlier than 90 days prior to each written order for a covered item of DME or within 30 days after the order is written. This proposal is consistent with the Medicare and Medicaid home health face-to-face requirement which increases physician accountability and specifies a timeframe within the discretion of the Secretary. (For more information on the Medicare and Medicaid home health face-to-face requirements see the November 17, 2010 final rule (75 FR 70372) and the July 12, 2011 proposed rule (76 FR 41032) for Medicare and Medicaid respectively.) We have exercised our discretion to set a timeframe other than 6 months because we believe that our proposal strikes an appropriate balance among several factors: (1) The potential for fraud, waste, abuse associated with certain DME items; (2) the potential inconvenience and cost to practitioners and beneficiaries; and (3) potential health benefits to beneficiaries from increased practitioner involvement and more periodic reviews of their status and progress.

We perform ongoing education on many topics including the requirements of the other face-to-face provisions. This education includes, but is not limited to, various Medicare Learning Network® products such as MLN Matters® articles, brochures, fact sheets, Web-based training courses, and podcasts; Open Door forums; and national provider conference calls. Medicare is already working proactively with home health agencies, physicians, and other providers to educate them on implementing the face-to-face requirement. We plan to conduct similar provider education and outreach in implementing the DME face-to-face requirement.

As noted previously, section 1834(h)(3) of the Act adds prosthetic devices, orthotics, and prosthetics to the items encompassed by section 1834(a)(11)(B) of the Act. At this time, we are not proposing changes to § 410.36(b) to require documentation of a face-to-face encounter for prosthetic devices, orthotics, and prosthetics that, according to § 410.36(b), require a written order before delivery in this proposed rule. We intend to use future rulemaking to determine which prosthetic devices, orthotics, and prosthetics, require, as a condition of payment, a written order before delivery supported by documentation of a face-to-face encounter with the beneficiary consistent with section 1834(a)(11)(B)(ii) of the Act. We welcome comments on including prosthetic devices, orthotics, and prosthetics in future rulemaking, including any criteria that should be used for determining what items should require a written order before delivery supported by documentation of a face-to-face encounter.

This proposed requirement does not supersede any regulatory requirements that more specifically address a face-to-face encounter requirement for a particular item of DME. For example, § 410.38(c), which implemented section 1834(a)(1)(E)(iv) of the Act, specifically addresses prescription and face-to-face encounter requirements for power mobility devices (PMDs) and uses a 45-day period between the date of the face-to-face encounter and the date of the written order. That requirement is specific to the unique factors, including equipment expense and complex medical necessity determinations that affect PMDs.

(2) Physician Documentation

The statute requires that a physician document that the physician or a PA, NP or CNS has had a face-to-face encounter with the beneficiary. We propose that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record, containing sufficient information to document that the face-to-face encounter meets our requirements, would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. Some examples of pertinent parts of the beneficiary's medical record that can demonstrate that a face-to-face encounter has occurred can include: history; physical examination; diagnostic tests; summary of findings; diagnoses; treatment plans; or other information as appropriate. As an alternative, we are requesting comments on a second option for physicians to document the face-to-face encounter when it is performed by the physician, by requiring this physician documentation to be identical to what is required for a PA, a NP, or a CNS as discussed later in this section. We strive to find the option that strikes a balance between minimizing the effect on physicians, while still meeting the statutory objective to limit fraud, waste, and abuse.

(3) Physician Documentation of Face-to-Face Encounters Performed by a Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist

We are considering the following proposed options for physician documentation of a face-to-face encounter performed by a PA, NP, or CNS. We are reserving judgment as to which of these proposed options best accomplishes our goals until the final regulation and have not provided language reflecting these options in the proposed regulations text. The options are as follows:

- *Option 1:* Attestation stating: ''I, Doctor (Name) (NPI number) have reviewed the medical record and attest that (PA, NP or CNS) has performed a face-to-face encounter with (beneficiary) on (date) and evaluated the need for (the item of DME).'' (Sign) (Date). This option would provide all the needed information to document that a face-to-face encounter has occurred between the PA, NP or CNS and the beneficiary in a standardized manner. However, this attestation would not eliminate the need for the medical record to support the medical necessity of the ordered item. The attestation serves only as physician documentation of the face-to-face encounter.
- *Option 2:* The physician signs or cosigns the pertinent portion of the medical record, for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service. This option

would provide evidence that the physician has reviewed the relevant documentation to support that a face-to-face encounter occurred for that date of service. A signed order by the physician alone would not satisfy the requirement described in this option that the physician ''sign/cosign the pertinent portion of the medical record.''

• *Option 3:* The physician specifically initials the history and physical examination for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service. This option would provide evidence that the physician has reviewed the relevant documentation to support that a face-to-face encounter occurred for that date of service. A signed order would not satisfy the requirement described in this option that the physician ''initial the history and physical examination for the beneficiary for the date of the face-to-face encounter''.

We welcome comment on how physician documentation requirements should be handled when the face-to-face encounter with the beneficiary is conducted by a PA, a NP, or a CNS. We are looking for the alternative that best accomplishes the objective of reducing waste, fraud, and abuse by having a physician document the face-to-face encounter if it is performed by a PA, NP, or CNS without creating undue impact.

(4) Supplier Notification

Since the supplier submits the claims for the covered items of DME, the supplier must have access to the documentation of the face-to-face encounter. We welcome comment on the type of communication that should occur between the physician or PA, NP, or CNS, and the supplier. All documentation to support the appropriateness of the item of DME ordered including documentation of the face-to-face encounter, must be available to the supplier. As with all items and services, we require both the ordering practitioner and the supplier to maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to us upon our request or at the request of our contractors.

We are considering adding one of the following proposed options on how documentation of the face-to-face encounter must be delivered to the supplier. We are reserving judgment on these proposed options until the final regulation. The options are as follows:

• *Option 1:* Require the practitioner who wrote the order to provide the physician documentation of the face-to-face encounter directly to the DME supplier. This option may increase practitioner accountability, since it requires practitioners to submit the required documentation to the supplier.

• *Option 2:* Require the physician who completes the documentation of the face-to-face encounter to provide that documentation directly to the DME supplier. This option is consistent with current policies where the entity who submits the claims collects the necessary documentation even if it comes from multiple sources. For example, the supplier must have access to all documentation necessary to support the claim upon request.

• *Option 3:* Require that the documentation, no matter who completes it, be provided to the DME supplier through the same process as the written order for the covered item of DME. The option ensures that the same pathway followed for the order is also followed for the face-to-face documentation. In most circumstances, we would expect the order and the face-to-face documentation to travel together, the exception being those circumstances where the face-to-face encounter was conducted after the order.

• *Option 4:* Require a physician to provide a copy of the face-to-face documentation to the beneficiary for the beneficiary to deliver to the DME supplier of his or her choice. This would ensure that the supplier receives the documentation of the face-to-face encounter directly and limits the supplier's need to rely on the PA, NP, or CNS to receive this documentation completed by the physician.

We welcome comment on these options in order to facilitate open communication and enhanced coordination of documentation of a face-to-face encounter between the supplier, physician or when applicable, the PA, NP or CNS.

b. Covered Items

Section 1834(a)(11)(B)(i) of the Act (as redesignated by the Affordable Care Act authorizes us to specify covered items that require a written order prior to delivery of the item. Under section 1834(a)(11)(B)(ii) of the Act, these orders must be written pursuant to a physician documenting that a face-to-face encounter has occurred. Accordingly, to reduce the risk of fraud, waste, and abuse, we are proposing a list of Specified Covered Items that would require a written order prior to delivery. Our proposed list of Specified Covered Items is below. In future years, updates to this list would appear annually in the **Federal Register** and the full updated list would be available on the CMS Web site.

As highlighted in the January 2007 Government Accountability Office (GAO) report entitled, ''Improvements Needed to Address Improper Payments for Medical Equipment and Supplies'' it is estimated that there were $700 million in improper payments across the spectrum of DMEPOS from April 1, 2005, through March 31, 2006. GAO did not specifically recommend the use of DME face-to-face encounters as a remedial action in its report. However, the GAO did recommend making improvements to address improper payments in the DMEPOS arena. This proposed rule is one way in which we are working to prevent improper payments.

Though we initially considered making all items encompassed by section 1834(a)(11)(B) of the Act (including prosthetic and orthotic items described in section 1834(h)(3) of the Act) subject to a face-to-face encounter requirement, we have first proposed a more limited criteria driven list to balance what we believe to be broad statutory intent to establish a face-to-face requirement to prevent waste, fraud, and abuse with concerns that including all items could have an undue negative effect on practitioners and suppliers. We welcome comment on limiting the associated burden of this proposed rule by refining the number of items subject to a face-to-face encounter, while still protecting the Medicare Trust Funds.

In this section of the proposed rule, we describe our proposed criteria, as well as the reasons we selected these criteria. We first note that our proposed list of Specified Covered Items contains DME items only. We intend to use future rulemaking to apply section 1834(a)(11)(B)(ii) of the Act to prosthetics and orthotics. We believe that our proposed current focus on DME items is an appropriate way of balancing our goals of reducing waste, fraud, and abuse and limiting burden on beneficiaries and the supplier community.

We propose to focus initially on DME items for several reasons. First, these items are often marketed directly to beneficiaries and requiring a face-to-face encounter would help ensure that a practitioner has met with the beneficiary and considered whether the item is appropriate. Additionally, requiring a face-to-face encounter would help ensure that practitioners who order DME items are familiar with the beneficiary's medical condition, that

this condition is documented, and that the item is reasonable and necessary. Although we are also concerned about fraud, waste, and abuse associated with prosthetics and prosthetic devices, these items are, as stated in the Medicare Claims Processing Manual Chapter 20 (Section 10.1.2) ''devices that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.'' The body member that is being replaced by the prosthetic device can often be identified based on previous claims history. We will consider this separately as there may be different burden issues and other considerations that apply. Therefore we are not pursuing a face-to-face requirement on these items at this time. Further, since orthotics are treated in a manner similar to prosthetics for billing and coverage purposes, in order to apply consistent criteria these items will be considered together for future rulemaking.

We welcome comment on limiting the associated burden of this proposed regulation by refining the number of items subject to a face-to-face encounter, while still protecting the Medicare Trust Funds and also meeting the requirements of the statute.

The proposed list of Specified Covered Items contains items that meet at least one of the following four criteria: (1) Items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the DME MACs, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, Government Accountability Office or other oversight entities.

We are proposing to include items already listed in the Program Integrity Manual (PIM), Chapter 5, section 5.2.3.1. These items were added to the PIM originally since they were seen as posing vulnerabilities to the Medicare program that could be mitigated through requiring a written order prior to delivery. We believe that requiring a face-to-face encounter is consistent with our previous initiatives and strengthens our efforts to address this vulnerability.

We are also proposing to include any items of DME with a price ceiling greater than or equal to $1,000 in the price ceiling column on the DMEPOS Fee Schedule, which is updated annually and lists Medicare allowable pricing for DME. We believe that improper claims related to these high dollar items have a greater effect on the Medicare Trust Funds based on amounts paid by Medicare for these items. Therefore, any items that are $1,000 or greater would be added annually to the list of Specified Covered Items on a prospective basis. For administrative simplicity we would not annually adjust this value for inflation, any changes to this threshold will go through rulemaking. We see this price point as striking a balance between our responsibility to protect the Medicare Trust Funds and ensuring these requirements do not place an additional burden on beneficiaries, practitioners, and suppliers. Our objective is to minimize inappropriate use of high dollar DME items to help protect and preserve the Medicare Trust Funds.

The third criterion added items that we believe, based on our experience and recommendations from our DME Medicare MACs are particularly susceptible to fraud, waste, and abuse. Based on their experience, the DME MACs suggested items that warrant increased practitioner involvement because these items are often marketed directly to beneficiaries, thus highlighting the important role of the practitioner in conducting a needs assessment, evaluating, or treating the beneficiary to ensure that his/her condition warrants the item. The evaluations may assist in ensuring that the DME items are medically necessary for the beneficiary. Increasing the practitioner's role in evaluating the beneficiary's need for such items, would help ensure proper ordering of DME items, thereby minimizing the risk of waste, fraud, and abuse. The items recommended by the DME contractors were pressure reducing pads, mattress overlays, mattress, beds, seat lift mechanisms, TENS units, AEDs, external infusion pumps, glucose monitors, wheelchairs and wheelchair accessories, nebulizers, negative pressure wound therapy pumps, oxygen and oxygen equipment, pneumatic compression devices, positive airway pressure devices, respiratory assists devices, and cervical traction devices.

This criterion was also influenced by our experience with the Health Care Fraud and Prevention and Enforcement Action Teams (HEAT). These teams were established by HHS and the Department of Justice (DOJ) to investigate, among other things, fraudulent DME suppliers and have recovered millions of dollars in DME fraud. The HEAT strike force teams, which are now in nine cities nationwide, have assisted in investigating and prosecuting DME suppliers who were fraudulently seeking payment for DME items and services. HEAT investigations have resulted in indictments against DME suppliers relating to the following items: pressure reducing mattresses, oxygen equipment, manual wheelchairs, hospital beds, infusion supplies, and nebulizers. Further information about DME fraud by State is available at *www.stopmedicarefraud.gov*.

We are also proposing the inclusion of certain items of DME on the list of Specified Covered Items because OIG has expressed concerns (as expressed in DHHS–OIG reports since 1999) that these items are vulnerable to fraud, waste and abuse. These reports detailed vulnerabilities and called for CMS to address these issues. For example, in an OIG Report entitled ''Inappropriate Medicare Payments for Pressure Reducing Support Surfaces'' (OEI–02–07–00420), the OIG noted as a vulnerability the fact that the vast majority of pressure reducing pads that were billed failed to meet the coverage criteria. Home oxygen therapy was highlighted as a vulnerability in the OIG Report entitled ''Usage and Documentation of Home Oxygen Therapy'' (OEI–03–96–00090). Documentation and communication problems associated with negative pressure wound therapy pumps were highlighted in a report titled ''Comparison of Prices for Negative Pressure Wound Therapy Pumps'' (OEI–02–07–00660). As the OIG explained in that report, ''[s]uppliers are required to communicate with the beneficiary's treating clinician to assess wound healing progress and to determine whether the beneficiary continues to qualify for Medicare coverage of the pump * * * [S]uppliers reported not having contact with clinicians for almost one-quarter of the beneficiaries.''

Our proposed list of Specified Covered Items is in Table 24 of this proposed rule. We further propose to update this list of Specified Covered Items annually in order to add any new items that are described by a *HCPCS* code for the following types of DME:

- TENS unit
- Rollabout chair
- Manual Wheelchair accessories
- Oxygen and respiratory equipment
- Hospital beds and accessories
- Traction-cervical

Note that the proposed list does not include power mobility devices, which are subject to already existing face-to-face requirements, as previously discussed. In addition, we propose to add to the list any item of DME that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or

greater than $1,000. Items not included in one of the proposed automatic pathways would be added to the list of Specified Covered Items through notice and comment rulemaking.

Through updates in the **Federal Register**, we propose removing *HCPCS codes from the list* that are no longer covered by Medicare or that are discontinued HCPCS codes.

TABLE 24—DME LIST OF SPECIFIED COVERED ITEMS

HCPCS Code	Description
E0185	Gel or gel-like pressure mattress pad.
E0188	Synthetic sheepskin pad.
E0189	Lamb's wool sheepskin pad.
E0194	Air fluidized bed.
E0197	Air pressure pad for mattress standard length and width.
E0198	Water pressure pad for mattress standard length and width.
E0199	Dry pressure pad for mattress standard length and width.
E0250	Hospital bed fixed height with any type of side rails, mattress.
E0251	Hospital bed fixed height with any type side rails without mattress.
E0255	Hospital bed variable height with any type side rails with mattress.
E0256	Hospital bed variable height with any type side rails without mattress.
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress.
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress.
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress.
E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress.
E0290	Hospital bed fixed height without rails with mattress.
E0291	Hospital bed fixed height without rail without mattress.
E0292	Hospital bed variable height without rail without mattress.
E0293	Hospital bed variable height without rail with mattress.
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress.
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without mattress.
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress.
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress.
E0300	Pediatric crib, hospital grade, fully enclosed.
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350–600 lbs with any type of rail, without mattress.
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress.
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350–600 lbs with any type of rail, with mattress.
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress.
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing.
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing.
E0433	Portable liquid oxygen system.
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing.
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing.
E0441	Oxygen contents, gaseous (1 months supply).
E0442	Oxygen contents, liquid (1 months supply).
E0443	Portable Oxygen contents, gas (1 months supply).
E0444	Portable oxygen contents, liquid (1 months supply).
E0450	Volume control ventilator without pressure support used with invasive interface.
E0457	Chest shell.
E0459	Chest wrap.
E0460	Negative pressure ventilator portable or stationary.
E0461	Volume control ventilator without pressure support node for a noninvasive interface.
E0462	Rocking bed with or without side rail.
E0463	Pressure support ventilator with volume control mode used for invasive surfaces.
E0464	Pressure support vent with volume control mode used for noninvasive surfaces.
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface.
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface.
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface.
E0480	Percussor electric/pneumatic home model.
E0482	Cough stimulating device, alternating positive and negative airway pressure.
E0483	High Frequency chest wall oscillation air pulse generator system.
E0484	Oscillatory positive expiratory device, non-electric.
E0570	Nebulizer with compressor.
E0575	Nebulizer, ultrasonic, large volume.
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter.
E0585	Nebulizer with compressor & heater.
E0601	Continuous airway pressure device.
E0607	Home blood glucose monitor.
E0627	Seat lift mechanism incorporated lift-chair.
E0628	Separate seat lift mechanism for patient owned furniture electric.
E0629	Separate seat lift mechanism for patient owned furniture non-electric.
E0636	Multi positional patient support system, with integrated lift, patient accessible controls.
E0650	Pneumatic compressor non-segmental home model.
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure.
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure.
E0655	Non-segmental pneumatic appliance for use with pneumatic compressor on half arm.
E0656	Non-segmental pneumatic appliance for use with pneumatic compressor on trunk.
E0657	Non-segmental pneumatic appliance for use with pneumatic compressor chest.
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor on full leg.
E0665	Non-segmental pneumatic appliance for use with pneumatic compressor on full arm.
E0666	Non-segmental pneumatic appliance for use with pneumatic compressor on half leg.
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg.
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm.
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg.
E0671	Segmental gradient pressure pneumatic appliance full leg.

TABLE 24—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS Code	Description
E0672	Segmental gradient pressure pneumatic appliance full arm.
E0673	Segmental gradient pressure pneumatic appliance half leg.
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency.
E0692	Ultraviolet light therapy system panel treatment 4 foot panel.
E0693	Ultraviolet light therapy system panel treatment 6 foot panel.
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet.
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation.
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation.
E0731	Form fitting conductive garment for delivery of TENS or NMES.
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer.
E0744	Neuromuscular stimulator for scoliosis.
E0745	Neuromuscular stimulator electric shock unit.
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application.
E0749	Osteogenesis stimulator, electrical, surgically implanted.
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive.
E0762	Transcutaneous electrical joint stimulation system including all accessories.
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls.
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting.
E0782	Infusion pumps, implantable, Non-programmable.
E0783	Infusion pump, implantable, Programmable.
E0784	External ambulatory infusion pump.
E0786	Implantable programmable infusion pump, replacement.
E0840	Tract frame attach to headboard, cervical traction.
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible.
E0850	Traction stand, free standing, cervical traction.
E0855	Cervical traction equipment not requiring additional stand or frame.
E0856	Cervical traction device, cervical collar with inflatable air bladder.
E0958	Manual wheelchair accessory, one-arm drive attachment.
E0959	Manual wheelchair accessory-adapter for Amputee.

TABLE 24—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS Code	Description
E0960	Manual wheelchair accessory, shoulder harness/strap.
E0961	Manual wheelchair accessory wheel lock brake extension handle.
E0966	Manual wheelchair accessory, headrest extension.
E0967	Manual wheelchair accessory, hand rim with projections.
E0968	Commode seat, wheelchair.
E0969	Narrowing device wheelchair.
E0971	Manual wheelchair accessory anti-tipping device.
E0973	Manual wheelchair accessory, adjustable height, detachable armrest.
E0974	Manual wheelchair accessory anti-rollback device.
E0978	Manual wheelchair accessory positioning belt/safety belt/pelvic strap.
E0980	Manual wheelchair accessory safety vest.
E0981	Manual wheelchair accessory Seat upholstery, replacement only.
E0982	Manual wheelchair accessory, back upholstery, replacement only.
E0983	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control.
E0984	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control.
E0985	Wheelchair accessory, seat lift mechanism.
E0986	Manual wheelchair accessory, push activated power assist.
E0990	Manual wheelchair accessory, elevating leg rest.
E0992	Manual wheelchair accessory, elevating leg rest solid seat insert.
E0994	Arm rest.
E0995	Wheelchair accessory calf rest.
E1002	Wheelchair accessory Power seating system, tilt only.
E1003	Wheelchair accessory Power seating system, recline only without shear.
E1004	Wheelchair accessory Power seating system, recline only with mechanical shear.
E1005	Wheelchair accessory Power seating system, recline only with power shear.
E1006	Wheelchair accessory Power seating system, tilt and recline without shear.
E1007	Wheelchair accessory Power seating system, tilt and recline with mechanical shear.
E1008	Wheelchair accessory Power seating system, tilt and recline with power shear.
E1010	Wheelchair accessory, addition to power seating system, power leg elevation system, including leg rest pair.
E1014	Reclining back, addition to pediatric size wheelchair.

TABLE 24—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS Code	Description
E1015	Shock absorber for manual wheelchair.
E1020	Residual limb support system for wheelchair.
E1028	Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory.
E1029	Wheelchair accessory, ventilator tray.
E1030	Wheelchair accessory, ventilator tray, gimbaled.
E1031	Rollabout chair, any and all types with castors 5″ or greater.
E1035	Multi-positional patient transfer system with integrated seat operated by care giver.
E1036	Patient transfer system.
E1037	Transport chair, pediatric size.
E1038	Transport chair, adult size up to 300 lb.
E1039	Transport chair, adult size heavy duty >300 lb.
E1161	Manual Adult size wheelchair includes tilt in space.
E1227	Special height arm for wheelchair.
E1228	Special back height for wheelchair.
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system.
E1233	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system.
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system.
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system.
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system.
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system.
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system.
E1296	Special sized wheelchair seat height.
E1297	Special sized wheelchair seat depth by upholstery.
E1298	Special sized wheelchair seat depth and/or width by construction.
E1310	Whirlpool non-portable.
E2502	Speech Generating Devices prerecord messages between 8 and 20 minutes.
E2506	Speech Generating Devices prerecord messages over 40 minutes.
E2508	Speech Generating Devices message through spelling, manual type.
E2510	Speech Generating Devices synthesized with multiple message methods.
E2227	Rigid pediatric wheelchair adjustable.
K0001	Standard wheelchair.
K0002	Standard hemi (low seat) wheelchair.

TABLE 24—DME LIST OF SPECIFIED COVERED ITEMS—Continued

HCPCS Code	Description
K0003	Lightweight wheelchair.
K0004	High strength ltwt wheelchair.
K0005	Ultra Lightweight wheelchair.
K0006	Heavy duty wheelchair.
K0007	Extra heavy duty wheelchair.
K0009	Other manual wheelchair/base.
K0606	AED garment with electronic analysis.
K0730	Controlled dose inhalation drug delivery system.

c. Physician Payment

We understand that there is a burden associated with the requirement placed on the physician to document that a face-to-face encounter has occurred between a PA, a NP or a CNS, and the beneficiary. Accordingly, we are proposing the introduction of a G-code, estimated at $15, to compensate a physician who documented that a PA, a NP, or a CNS practitioner has performed a face-to-face encounter for the list of specified covered items above. This G-code would become effective when this provision becomes effective. We believe that the existing Evaluation and Management (E&M) codes are sufficient for practitioners performing face-to-face encounters. This new G-code would be specifically designed and mapped only for a physician who completes the documentation of the face-to-face encounter performed by a PA, a NP, or a CNS. Only a physician who does not bill an E&M code for the beneficiary in question would be eligible for this G-code. If multiple written orders for covered items of DME originate from one visit, the physician can receive the G-code payment only once for documenting that the face-to-face encounter has occurred. The G-code would be mapped so that only eligible DME items would be covered. Upon request, we will need to see documentation of the face-to-face encounter in order to verify the appropriateness of the G-code payment.

D. Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review (§ 421.500 Through § 421.505)

Medical review is the process performed by Medicare contractors to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act. We enter into contractual agreements with contractors to perform medical review functions. On December 8, 2003, the Congress enacted the MMA. Section 934 of the MMA amended section 1874A of the Act by adding a new subsection (h)—regarding random prepayment reviews and non-random prepayment complex medical reviews and requiring us to establish termination dates for non-random prepayment complex medical reviews. Although section 934 of the MMA set forth requirements for random prepayment review, our contractors do not perform random prepayment review. However, our contractors do perform non-random prepayment complex medical review.

On September 26, 2008, we published a final rule in the **Federal Register** (73 FR 55753) entitled, ''Medicare Program; Termination of Non-Random Prepayment Complex Medical Review'' that specified the criteria contractors would use for the termination of providers and suppliers from non-random prepayment complex medical review as required under the MMA. The final rule required contractors to terminate the non-random prepayment complex medical review of a provider or supplier no later than 1 year following the initiation of the complex medical review or when calculation of the error rate indicates the provider or supplier has reduced its initial error rate by 70 percent or more. (For more detailed information, see the September 26, 2008 final rule (73 FR 55753)).

On March 23, 2010, the Congress enacted the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) (together known as the Affordable Care Act). Section 1302 of the HCERA, repealed section 1874A(h) of the Act.

Section 1302 of the HCERA repealed section 1874A (h) of the Act, and therefore, removed the statutory basis for our regulation. Thus, we propose to remove the regulatory provisions in 42 CFR part 421, subpart F, that require contractors to terminate a provider or supplier from non-random prepayment complex medical review no later than 1 year following the initiation of the medical review or when the provider or supplier has reduced its initial error rate by 70 percent or more. As a result of this proposal, contractors would not be required to terminate non-random prepayment medical review by a prescribed time but would instead terminate each medical review when the provider or supplier has met all Medicare billing requirements as evidenced by an acceptable error rate as determined by the contractor.

E. Ambulance Coverage-Physician Certification Statement

We propose to revise § 410.40(d)(2) by incorporating nearly the same provision found at § 410.40(d)(3)(v) to clarify that a physician certification statement (PCS) does not, in and of itself, demonstrate that a nonemergency, scheduled, repetitive ambulance service is medically necessary for Medicare coverage. The Medicare ambulance benefit at section 1861(s)(7) of the Act allows for ''ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but * * * only to the extent provided in regulations.'' In other words, the definition of the benefit itself embodies the clinical medical necessity requirement that other forms of transportation must be contraindicated by a beneficiary's condition. Section 410.40(d) interprets the medical necessity requirement. Notably, even aside from the requirements of section 1861(s)(7), section 1862(a)(1)(A) of the Act dictates that any service that is not medically necessary under the Act and regulations is not a covered benefit.

Despite these statutory provisions and the language of the present regulation at section 410.40(d)(2) that we believe already requires both medical necessity and a PCS, some courts have recently concluded that § 410.40(d)(2) establishes that a sufficiently detailed and timely order from a beneficiary's physician, to the exclusion of any other medical necessity requirements, conclusively demonstrates medical necessity with respect to nonemergency, scheduled, repetitive ambulance services.

Absent explicit statutorily-based exceptions, we have consistently maintained that the Secretary is the final arbiter of whether a service is reasonable and necessary and qualifies for Medicare coverage. For example, in HCFA Ruling 93–1, we said ''[i]t is HCFA's ruling that no presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received. This information is available from the claims form and, when

necessary, the medical record which includes the physician's certification.''

Medical necessity is not just an integral requirement of Medicare's ambulance benefit in particular, but as we mentioned, section 1862(a)(1)(A) of the Act dictates that services must be reasonable and necessary to qualify for any Medicare coverage. Numerous U.S. Circuit Courts of Appeal have held that PCSs or certificates of medical necessity do not, in and of themselves, conclusively demonstrate medical necessity. The same applies in the context of nonemergency, scheduled, repetitive ambulance services—the PCS is not, in and of itself, the sole determinant of medical necessity, and, as we discuss below, we believe the existing regulation at § 410.40(d)(2) already demonstrates that. To erase any doubt, however, we propose a revision to § 410.40(d)(2) to explicitly clarify this principle.

Since being finalized in the February 27, 2002 **Federal Register** (67 FR 9100, 9132), § 410.40(d)(2) has stated that ''Medicare covers *medically necessary* nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.'' (emphasis added). Although a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. Indeed, the phrase ''medically necessary'' would have been surplus had we intended the PCS to be the sole determinant of medical necessity. Rather, as demonstrated by the fact that we did include that phrase, and by various other clarifying points, we made clear that a PCS, while necessary, does not on its own conclusively demonstrate the medical necessity of nonemergency, scheduled, repetitive ambulance services.

The preamble to the February 27, 2002 final rule (Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency ambulance Services (67 FR 9100)) and the 1999 final rule with comment (FRC) (Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements (64 FR 3637)) support this interpretation.

For example, in describing comments regarding medical necessity and physician certification in the 1999 FRC, we said: ''[t]wo ambulance suppliers commented that physicians are unaware of the coverage requirements for ambulance services and that their decisions to request ambulance services may be based on 'family preference or the inability to safely transport the beneficiary by other means rather than on the medical necessity requirement imposed by Medicare.''' We responded that section 1861(s)(7) of the Act allows coverage only under certain limited circumstances, and suggested that ''[t]o facilitate awareness of the Medicare rules as they relate to the ambulance service benefit, ambulance suppliers may need to educate the physician (or the physician's staff members) when making arrangements for the ambulance transportation of a beneficiary.'' We continued that ''[s]uppliers may wish to furnish an explanation of applicable medical necessity requirements, as well as requirements for physician certification, and to explain that the certification statement should indicate that the ambulance services being requested by the attending physician are medically necessary.'' (76 FR 3637, 3641) In light of our acknowledging a significant program vulnerability—that the physicians writing PCSs might not be fully cognizant of the Medicare ambulance benefit's medical necessity requirements—and encouraging suppliers themselves to help remedy that by educating physicians, it would have been irrational of us to (and we did not) abrogate the Secretary's judgment and vest exclusively in the PCS the authority to demonstrate an ambulance transport's medical necessity. We made a similar point in response to a separate comment: ''It is always the responsibility of the ambulance supplier to furnish complete and accurate documentation to demonstrate that the ambulance service being furnished meets the medical necessity criteria.'' (76 FR 3637, 3639).

In the section of the February 27, 2002 final rule preamble describing the PCS requirements, we said: ''[i]n all cases, the appropriate documentation must be kept on file and, upon request, presented to the carrier or intermediary. It is important to note that the presence of the signed physician certification statement does not necessarily demonstrate that the transport was medically necessary. The ambulance supplier must meet all coverage criteria for payment to be made.'' (67 FR 9100, 9111). Although we incorporated that passage into the final rule only at § 410.40(d)(3)(v), we intended, and we believe our intent is clear from the preamble narrative, that the principle apply equally to all nonemergency ambulance transports.

The OIG report titled ''Medicare Payments for Ambulance Transports'' (OEI–05–02–00590) (January 2006) also supports our position. Based on its analysis of a sample of calendar year 2002 claims, the OIG reported that ''27 percent of ambulance transports to or from dialysis facilities did not meet Medicare's coverage criteria.'' The OIG added ''the ongoing and repetitive nature of dialysis treatment makes transports to and from such treatment vulnerable to abuse. Although the condition of some patients warrants repetitive, scheduled ambulance transports for dialysis treatment, many dialysis transports do not meet coverage criteria.'' The OIG recommended that we instruct our contractors to implement prepayment edits with respect to dialysis transports and have them request wide-ranging documents when conducting postpayment medical review. The fact that we agreed with the OIG's recommendations demonstrated our belief that the PCS was not the sole determinant of medical necessity. Likewise, the fact that the OIG mentioned our ambulance coverage regulations, including the PCS requirement, but did not recommend altering or clarifying the regulations with respect to medical necessity demonstrated that we were of like mind; that, while a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary.

Accordingly, we propose to revise § 410.40(d)(2) to add nearly the same provision presently found at § 410.40(d)(3)(v), except without reference to a ''signed return receipt'' that does not pertain to nonemergency, scheduled, repetitive ambulance services. We propose to accomplish this by redesignating the current language as § 410.40(d)(2)(i), and adding the clarifying language to a new § 410.40(d)(2)(ii). The proposed § 410.40(d)(2)(ii) clarifies that a signed physician certification statement does not, in and of itself, demonstrate that an ambulance transport was reasonable and necessary. Rather, for all ambulance services, providers and suppliers must retain on file all appropriate documentation and present such documentation upon request to a Medicare contractor. A CMS contractor may use such documentation to assess, among other things, whether the service satisfied Medicare's medical necessity, eligibility, coverage, benefit category, or any other criteria necessary for Medicare payment to be made. For example, the patient's condition must

be such that other means of transportation would be contraindicated, and the expenses incurred must be reasonable and necessary for the diagnosis or treatment of illness or injury.

We also propose to fix the typographical error ''fro,'' which should be ''from'' in the existing § 410.40(c)(3)(ii).

F. Physician Compare Web Site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in the Physician Quality Reporting System under section 1848 of the Act.

We launched the first phase of the Physician Compare Internet Web site (*http://www.medicare.gov/find-a-doctor/provider-search.aspx*) on December 30, 2010. This initial phase included the posting of the names of eligible professionals that satisfactorily submitted quality data for the 2009 Physician Quality Reporting System, consistent with section 1848(m)(5)(G) of the Act. Since the initial launch of the Web site, we have continued to build and improve Physician Compare. Currently users can search by selecting a location and specialty for physicians or other healthcare professionals. Search results provide basic information about approved Medicare providers, such as primary and secondary specialties, practice locations, group practice affiliations, hospital affiliations, Medicare Assignment, education, languages spoken, and gender. As required by section 1848(m)(5)(G) of the Act, we have added the names of those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. As such, physician and other healthcare professional profile pages indicate if professionals satisfactorily participated in the Physician Quality Reporting System and/or are successful electronic prescribers under the eRx Incentive Program based on the most recent data available for these two quality initiatives.

2. Public Reporting of Physician Performance

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare, information on physician performance that provides comparable quality and patient experience measures. This plan is outlined below. To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable, and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare, which we seek to accomplish through rulemaking and focus groups. In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008.

We are required, under section 10331(f) of the Affordable Care Act, to submit a report to the Congress by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their health care, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize the Physician Compare Web site to publicly report physician performance results.

In implementing our plan to publicly report physician performance, we will use data reported under the existing Physician Quality Reporting System as an initial step for making physician ''measure performance'' information public on Physician Compare. By ''measure performance'' in relation to the Physician Quality Reporting System, we mean the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure. For measures requiring risk adjustment, ''measure performance'' refers to the risk adjusted percentage of times a particular outcome was attained.

We previously finalized a decision to make public on Physician Compare the performance rates of the quality measures that group practices submit under the 2012 Physician Quality Reporting System group practice

reporting option (GPRO) (76 FR 73417). Therefore, we anticipate, no earlier than 2013, posting performance information collected through the GPRO web interface for group practices participating in the Physician Quality Reporting System GPRO CY 2012 on Physician Compare. Specifically, we will make public performance information for measures included in the 2012 Physician Quality Reporting System that meet the minimum sample size, and that prove to be statistically valid and reliable. As we previously established, if the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate for that measure will be suppressed and not publicly reported. We previously established a minimum threshold of 25 patients for reporting performance information on the Physician Compare Web site (76 FR 73418). Although we considered keeping the threshold for reporting performance data on Physician Compare at 25 patients, we propose to change the minimum patient sample size, from 25 patients to 20 patients, beginning with data collected for services furnished in 2013, to align with the proposed minimum patient reporting thresholds for Physician Quality Reporting System measures group reporting for the 2013 and 2014 incentives, and the proposed reliability thresholds for the physician value-based payment modifier. We invite comment on the proposed new minimum patient sample size for Physician Compare, including whether or not we should retain the existing threshold of 25 patients.

Furthermore, in the Shared Savings Program final rule (76 FR 67948) as codified at § 425.308, we finalized ACO public reporting provisions in the interest of promoting greater transparency regarding the ACOs participating in the program. We finalized requirements for ACOs to publicly report certain data as well as data that we would publicly report. Because ACO providers/suppliers that are eligible professionals are considered to be group practices for purposes of qualifying for a Physician Quality Reporting System incentive under the Shared Savings Program, we indicated that performance on quality measures reported by ACOs at the ACO TIN level, on behalf of their ACO providers/suppliers who are eligible professionals, using the GPRO web interface would be reported on Physician Compare in the same way as for the groups that report under the Physician Quality Reporting System.

In April 2012, we added functionality to Physician Compare allowing users to search for group practices in preparation for the addition of 2012 Physician Quality Reporting System GPRO data. A full Web site redesign is slated for early 2013 to further prepare the site for the introduction of quality data. With each enhancement, we work to improve the usability and functionality of the site, providing consumers with more tools to help them make informed healthcare decisions.

In CY 2012, we intend to enhance the accuracy of ''administrative'' information displayed on the eligible professional's profile page, and to add additional data. By ''administrative'' data, we are referring to information about eligible professionals that is pulled from the Provider Enrollment, Chain, and Ownership System (PECOS) and other readily available external data sources. Specifically, we intend to add whether a physician/other health care professional is accepting new Medicare patients, board certification information, and to improve the foreign language and hospital affiliation data. We also intend to include the names of those eligible professionals who participated in the Medicare EHR Incentive Program and the names of those eligible professionals who satisfactorily participated under the Physician Quality Reporting System GPRO. We will continue to update the names of those eligible professionals and group practices who satisfactorily participated under the Physician Quality Reporting System, and those who are successful electronic prescribers under the eRx Incentive Program based on the most recent program year data available.

In support of the HHS-wide Million Hearts Initiative, we propose to post the names of the eligible professionals who report the Physician Quality Reporting System Cardiovascular Prevention measures group. This is consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in the Physician Quality Reporting System.

3. Future Development of Physician Compare

Consistent with Affordable Care Act requirements, we intend to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, if technically feasible. For our next phase, we propose to make public on Physician Compare, performance rates on the quality measures that group practices submit through the GPRO web interface under the 2013 Physician Quality Reporting System GPRO and the Medicare Shared Savings Program. We anticipate that the 2013 Physician Quality Reporting System GPRO web interface measures data would be posted no sooner than 2014. This data would include measure performance rates for measures included in the 2013 Physician Quality Reporting System GPRO web interface that meet the proposed minimum sample size of 20 patients, and that prove to be statistically valid and reliable.

When technically feasible, but no earlier than 2014, we propose to publicly report composite measures that reflect group performance across several related measures. As an initial step we intend to develop disease module level composite scores for Physician Quality Reporting System GPRO measures. Under the Medicare Shared Savings Program, ACOs are required to report on composite measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) (76 FR 67891). Accordingly, in an effort to align the PQRS GPRO measures with the GPRO measures under the Shared Savings Program, we have proposed in Table 35 of this proposed rule to add composite measures for DM and CAD into the Physician Quality Reporting System starting in 2013. We will also consider future development of composites for the remaining disease level modules within the GPRO web interface. As more data are added to Physician Compare over time, we will consider adding additional disease level composites across measure types as technically feasible and statistically valid.

Consistent with the requirement under section 10331(a)(2) under the Affordable Care Act to implement a plan to make publically available comparable information on patient experience of care measures, we propose to add patient experience survey-based measures such as, but not limited to, the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS). As discussed in section G.6.c. of this proposed rule, we propose to collect the following patient experience of care measures for group practices participating in the Physician Quality Reporting System GPRO;

- CAHPS: Getting Timely Care, Appointments, and Information
- CAHPS: How Well Your Doctors Communicate
- CAHPS: Patients' Rating of Doctor
- CAHPS: Access to Specialists
- CAHPS: Health Promotion and Education

These measures capture patients' experiences with clinicians and their staff, and patients' perception of care.

We propose, no earlier than 2014, to publicly report 2013 patient experience data for all group practices participating in the 2013 Physician Quality Reporting System GPRO, not limited to those groups participating via the GPRO web interface, on Physician Compare. At least for 2013, we intend to administer and collect patient experience survey data on a sample of the group practices' beneficiaries. As we intend to administer and collect the data for these surveys, we do not anticipate any notable burden on the groups.

For ACOs participating in the Shared Savings Program, consistent with the Physician Quality Reporting System proposal to publicly report patient experience measures on Physician Compare starting in 2013, we propose to publicly report patient experience data in addition to the measure data reported through the GPRO web interface. Specifically, the patient experience measures that would be reported for ACOs include the CAHPS measures in the Patient/Caregiver Experience domain finalized in the Shared Savings Program final rule (76 FR 67889):

- CAHPS: Getting Timely Care, Appointments, and Information
- CAHPS: How Well Your Doctors Communicate
- CAHPS: Patients' Rating of Doctor
- CAHPS: Access to Specialists
- CAHPS: Health Promotion and Education
- CAHPS: Shared Decision Making

For patient experience data reported under either the Physician Quality Reporting System GPRO or the Medicare Shared Savings Program, we also considered an alternative option of providing confidential feedback to group practices and ACOs using 2013 patient experience data before publicly reporting patient experience data on Physician Compare. In lieu of publicly reporting the patient experience data relating to 2013 Physician Quality Reporting System GPRO and ACOs participating in the Shared Savings Program, we considered using the 2013 results as a baseline to be shared confidentially with the group practices and ACOs, during which time the group practices and ACOs would have the opportunity to review their data, and implement changes to improve patient experience scores. Under this alternative option, program year 2014 patient experience data would be the first to be publicly reported on Physician Compare, and we would publicly report 2014 patient experience data for ACOs and group practices participating in the 2014 Physician Quality Reporting System GPRO on Physician Compare no earlier than 2015. We invite public comment on our proposal to begin publicly reporting patient experience data for program year 2013, and also the alternative option of delaying public reporting of patient experience of care data on Physician Compare until program year 2014 in order to give group practices and ACOs the opportunity to make changes to the processes used in their practices based on the review of their data from program year 2013.

As we continue to improve administrative and provider level data, we propose posting the names of those physicians who earned a Physician Quality Reporting System Maintenance of Certification Program incentive as data becomes available, but no sooner than 2014. Additionally, we are considering allowing measures that have been developed and collected by approved and vetted specialty societies to be reported on Physician Compare, as deemed appropriate, and as they are found to be scientifically sound and statistically valid. We propose including additional claims-based process, outcome and resource use measures on Physician Compare, and intend to align measure selection for Physician Compare with measures selected for the Value Based Modifier (section III.K).

As an initial step, we propose to include group level ambulatory care sensitive condition admission measures of potentially preventable hospitalizations developed by the HHS Agency for Healthcare Research and Quality (AHRQ) that meet the proposed minimum sample size of 20 patients, and that prove to be statistically valid and reliable (measure details are available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27275*). We propose reporting these measures on Physician Compare no earlier than 2015 for those group practices comprised of 2—99 eligible professionals participating in the proposed 2014 physician Quality Reporting System GPRO, and for ACOs. As our next step, we propose to publicly report performance rates on quality measures included in the 2015 Physician Quality Reporting System and value-based payment modifier for individual eligible professionals. Further details on what measures would be included in the 2015 reporting period will be addressed in future rule making. Public reporting of 2015 PQRS and administrative claims-based quality measures for individuals would occur no earlier than 2016. For all measures publicly reported on the Physician Compare Web site, we propose to post a standard of care, such as those endorsed by the National Quality Forum. Such information will serve as a standard for consumers to measure individual provider, and group level data.

We are committed to making Physician Compare a constructive tool for Medicare beneficiaries, successfully meeting the Affordable Care Act mandate, and in doing so, providing consumers with information needed to make informed healthcare decisions. CMS has developed a plan, and started to implement a phased approach to adding quality data to Physician Compare. We believe a staged approach to public reporting of physician information allows for the use of information currently available while we develop the infrastructure necessary to support the collection of additional types of measures and public reporting of individual physicians' quality measure performance results. Implementation of subsequent phases of the plan will need to be developed and addressed in future notice and comment rulemaking, as needed.

We invite comments regarding our proposals to: (1) Reduce the minimum reporting threshold from 25 patients to 20 patients for reporting on Physician Compare; (2) post the names of the eligible professionals who report the Physician Quality Reporting System Cardiovascular Prevention measures group for purposes of recognition and in support of the Million Hearts Initiative; (3) develop composite measures at the disease module level, initially with CY 2013 GPRO data, and incorporating additional measures; (4) to publicly report 2013 patient experience data for group practices participating in the 2013 Physician Quality Reporting System GPRO, or who are part of an ACO under the Medicare Shared Savings Program, on the Physician Compare Web site no earlier than 2014; (5) the alternative option of providing confidential feedback to group practices and ACOs on 2013 patient experience data to allow them to make necessary changes to their processes prior to publicly reporting of 2014 patient experience data on Physician Compare; (6) report names of participants who earn a 2013 Physician Quality Reporting System Maintenance of Certification Program Incentive no earlier than 2014; (7) allow measures that have been developed and collected by specialty societies to be reported on the Physician Compare Web site as deemed appropriate; (8) to report 2014 group level ambulatory care sensitive condition measures of potentially preventable hospitalizations developed by the AHRQ no earlier than 2015 for groups participating in the 2014 Physician Quality Reporting System and

ACOs, (measure details are available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27275*); (9) publicly report performance on 2015 Physician Quality Reporting System and value-based payment modifier quality measures for individuals. Public reporting of 2015 Physician Quality Reporting System and claims derived quality measures for individuals would occur no earlier than 2016; and (10) post a standard of care for measures posted on Physician Compare. For the above proposals, we note that we would only post data on Physician Compare if it is technically feasible; the data is available; the system is set up/adjusted to post information and the data is useful, sufficiently reliable, and accurate.

G. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

There are several healthcare quality improvement programs that affect physician payments under the Medicare PFS. The National Quality Strategy establishes three aims for quality improvement across the nation: better health, better healthcare, and lower costs. This strategy, the first of its kind, outlines a national vision for quality improvement and creates an opportunity for programs to align quality measurement and incentives across the continuum of care. CMS believes that this alignment is especially critical for programs involving physicians. The proposals that follow facilitate the alignment of programs, reporting systems, and quality measures to make this vision a reality. We believe that alignment of CMS quality improvement programs will decrease the burden of participation on physicians and allow them to spend more time and resources caring for beneficiaries. Furthermore, as the leaders of care teams and the healthcare systems, physicians and other clinicians serve beneficiaries both as frontline and system-wide change agents to improve quality. CMS believes, however, that in order to improve quality, physicians must first engage in quality measurement and reporting. It is CMS's intent that the following proposals will improve alignment of physician-focused quality improvement programs, decrease the burden of successful participation on physicians, increase engagement of physicians in quality improvement, and ultimately lead to higher quality care for beneficiaries.

This section contains our proposals related to the Physician Quality Reporting System (PQRS). The PQRS, as set forth in section 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. We note that, in developing these proposals, it was our goal to align program requirements between these quality reporting programs, such as the eRx Incentive Program, EHR Incentive Program, Medicare Shared Savings Program, and value-based payment modifier, wherever possible. We believe that alignment of these quality reporting programs will lead to greater overall participation in these programs, as well as minimize the reporting burden on eligible professionals.

For example, we have aligned the definition of group practice under the eRx Incentive Program with PQRS' definition of group practice. Our proposals with respect to reporting as a group practice for the eRx Incentive Program are intended to conform to our proposals for reporting as a group practice for PQRS.

With respect to integration with the EHR Incentive Program, section 1848(m)(7) of the Act requires us to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements under the EHR Incentive Program. We began integrating requirements for these two programs in 2012 with the alignment of reporting requirements via the Physician Quality Reporting System—Medicare EHR Incentive Pilot (76 FR 73422) and the alignment of reportable EHR measures (76 FR 73364). Our proposals in this section are intended to move the PQRS and EHR Incentive Program towards greater alignment, benefiting those eligible professionals who wish to participate in both programs. The vision is to report once for multiple programs on a set of measures aligned across programs and with the National Quality Strategy.

With respect to integration with the value-based payment modifier, we note that we began our efforts to integrate our program requirements with the value-based payment modifier in the CY 2012 Medicare PFS final rule, when CY 2013 was established as the reporting period for the 2015 PQRS payment adjustment (76 FR 73391) and the initial performance period for the application of the value modifier (76 FR 73435). Our proposals in this section, particularly as they relate to the proposed requirements for satisfactory reporting for the PQRS payment adjustments, are intended to align with the proposals for the application of the value modifier.

The regulation governing the PQRS is located at § 414.90. The program requirements for years 2007–2012 of the PQRS that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. Please also note that in this proposed rule, we are proposing to make technical changes to § 414.90 to aid in the readability of the regulation.

1. Methods of Participation

There are two ways an eligible professional can participate in the PQRS: (1) as in individual or (2) as part of a group practice participating in the PQRS group practice reporting option (GPRO).

a. Participation as an Individual Eligible Professional

(1) Participation for the 2013 and 2014 Incentives

As defined at § 414.90(b) the term ''eligible professional'' means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist. For more information on which professionals are eligible to participate in the Physician Quality Reporting System, we refer readers to the ''List of Eligible Professionals'' download located in the ''How to Get Started'' section of the PQRS CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/How_To_Get_Started.html*. There is no requirement to self-nominate to participate in PQRS as an individual eligible professional for the incentive or to use the claims, registry, or EHR reporting mechanisms.

(2) Proposed Requirement for Eligible Professionals and Group Practices Electing To Use the Administrative Claims-based Reporting Mechanism for the 2015 and 2016 Payment Adjustments

Unlike using the traditional PQRS reporting mechanisms (claims, registry, EHRs) to satisfy the reporting requirements for the 2015 and 2016 payment adjustments, we propose that eligible professionals and group practices wishing to use the administrative claims reporting mechanism, which is discussed in section K, and available for the 2015 and/or 2016 payment adjustments, must

elect to use the administrative claims reporting mechanism (please note that since the same proposed requirements would apply to both individual eligible professionals and group practices, we address both in this discussion). We believe this election requirement is necessary because CMS must be notified that CMS must analyze and calculate data from an eligible professional or group practice's claims. This election requirement is not necessary for eligible professionals and group practices using traditional PQRS reporting mechanisms because, for these traditional reporting mechanisms, CMS is not involved with analyzing claims data to determine whether a clinical quality action related to a quality measure was performed.

For eligible professionals, we propose that this election process would consist of a registration statement that includes: the eligible professional's name and practice name, the eligible professional's TIN and NPI for analytical purposes, and the eligible professional's contact information. For group practices, we propose that this election process would also consist of a registration statement that includes: The group practice's business name and contact information, the group practice's TIN, and contact information of the group practice's contact(s) who will be contacted for program, clinical, and/or technical purposes. With respect to the method of submitting this registration statement, we propose the following options:

—If technically feasible, submission of this statement via the Web and

—If technically feasible, submission of an eligible professional's or group practice's intent to register to use the administrative claims-based reporting mechanism by placing a G-code on at least 1 Medicare Part B claim.

In the event the two proposed options are not technically feasible, we also considered allowing for submission of the registration statement by submitting a mailed letter to CMS at Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850a. However, we note that using this mailing option would be a more burdensome and time-intensive process for CMS. We invite public comment on this considered option.

The eligible professional would be required to complete this election process by January 31 of the applicable payment adjustment reporting period (for example, by January 31, 2015 for the 2015 payment adjustment). However, we note that we propose that we may extend this deadline based on the submission method that is finalized. For example, because processing mailed letters would take the longest to process (out of the 3 methods), we anticipate that if we were to include the option of mailed letters the deadline for submitting a mailed registration letter would be January 31 of the applicable payment adjustment reporting period. Since it would be more efficient to process registration statements received via the Web or via a G-code on a claim, we anticipate that we would be able to extend the registration deadline to as late as December 31 of the applicable payment adjustment reporting period. Once an eligible professional makes an election to participate in PQRS using the administrative claims-based reporting mechanism for the PQRS payment adjustments, the eligible professional would be assessed under the administrative claims-based reporting mechanism.

For group practices participating in the GPRO, we propose that these group practices would use the 2 methods described above (mailed letter, Web, or G-code submission) and have the same deadline as eligible professionals wishing to elect to use the administrative claims-based reporting mechanism for an applicable payment adjustment. In the alternative, we propose that a group practice participating in the GPRO would be required to elect to use the administrative claims-based reporting mechanism in its self-nomination statement. We are proposing to provide less time for group practices to elect to use the administrative claims-based reporting mechanism because it is necessary for CMS to receive this information in the beginning of the applicable reporting period to indicate to CMS how these group practices should be analyzed throughout the reporting period. This early notification is especially important for large group practices, which may have hundreds or thousands of eligible professionals to track as a group practice. Therefore, we feel it is appropriate to request that a group practice elect to use the administrative claims-based reporting mechanism when the group practice self-nominates.

We further propose that an eligible professional or group practice would be required to make this election for each payment adjustment year the eligible professional or group practice seeks to be analyzed under this mechanism. For example, if the eligible professional seeks to report under the administrative claims mechanism for the 2015 and 2016 payment adjustments, the eligible professional would be required to make this election by the applicable deadline, for the 2015 payment adjustment and again by the applicable deadline, for the 2016 payment adjustment. We invite public comment on the proposed election requirement for eligible professionals and group practices electing to participate in the 2015 and 2016 payment adjustments using the administrative claims-based reporting mechanism.

b. Participation as a Group Practice in the GPRO

(1) Proposed Definition of Group Practice

We propose to modify § 414.90(b) to define group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN.'' We are proposing to change the number of eligible professionals comprising a PQRS group practice from 25 or more to 2 or more to allow all groups of smaller sizes to participate in the GPRO. We believe that expanding the scope of group practices eligible to participate under the program will lead to greater program participation. To participate in the GPRO, a group practice would be required to meet this proposed definition at all times during the reporting period for the program year in which the group practice is selected to participate in the GPRO. We invite public comment on the proposed definition of group practice.

(2) Proposed Election Requirement for Group Practices Selected To Participate in the GPRO

We established the process for group practices to be selected to participate in the GPRO in the CY 2012 PFS final rule with comment period (76 FR 73316). However, this section contains additional processes with respect to a group practice's self-nomination statement that we are proposing for group practices selected to participate in the GPRO for 2013 and beyond. With respect to the requirement that group practices wishing to participate in the GPRO submit a self-nomination statement (76 FR 73316), for 2012, we accepted these self-nomination statements via a letter accompanied by an electronic file submitted in a format specified by CMS because it was not operationally feasible to receive self-nomination statements via the Web at that time. In the CY 2012 Medicare PFS final rule with comment period, we

noted that we anticipated that CMS would have the ability to collect self-nomination statements via the Web for the 2013 Physician Quality Reporting System. We are therefore proposing that, for 2013 and beyond, a group practice must submit its self-nomination statement via the Web.

We note that this Web-based functionality is still being developed by CMS. Therefore, in the event this Web-based functionality would not be available in time to accept self-nomination statements for the 2013 Physician Quality Reporting System, we propose that, in lieu of submitting self-nomination statements via the Web, a group practice would be required to submit its self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by CMS (such as a Microsoft excel file). We propose that this self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. If mailing the self-nomination statement, we would require that this self-nomination statement be received by no later than 5 p.m. Eastern Standard Time on January 31 of the year in which the group practice wishes to participate in the GPRO.

In the CY 2012 Medicare PFS final rule with comment period, we also established what information is required to be included in a group practice's self-nomination statement (76 FR 73316). In previous years, the group practice only had one reporting mechanism available on which to report data on PQRS quality measures: The GPRO web-interface. However, beginning 2013, we are proposing to allow group practices to report data on quality measures using the claims, registry, and EHR-based reporting mechanisms for the PQRS incentive and payment adjustment. Additionally, we are proposing to allow group practices to use the proposed administrative claims reporting option. We propose that a group practice wishing to participate in the GPRO for a program year would be required to indicate the reporting mechanism the group practice intends to use for the applicable reporting period in its self-nomination statement. Furthermore, once a group practice is selected to participate in the GPRO and indicates which reporting mechanism the group practice would use, we propose that the group practice would not be allowed to change its selection. Therefore, under this proposal, the reporting mechanism the group practice indicates it will use in its self-nomination statement for the applicable reporting period would be the only reporting mechanism under which CMS will analyze the group practice to determine whether the group practice has met the criteria for satisfactory reporting for the PQRS incentive and/or payment adjustment. We acknowledge that this proposal would depart from the way we analyze an individual eligible professional, as CMS analyzes an individual eligible professional (who is permitted to use multiple reporting mechanisms during a reporting period) under every reporting method the eligible professional uses. Unfortunately, due to the complexity of analyzing group practices under the GPRO, such as having to associate multiple NPIs under a single TIN, it is not technically feasible for us to allow group practices using the GPRO to use multiple reporting mechanisms or switch reporting mechanisms during the reporting period. We invite public comment on the proposed election requirement and the proposed restriction noted above for group practices under the GPRO for 2013 and beyond.

(3) Proposed GPRO Selection Process

Group practices must be selected by CMS to participate in the PQRS GPRO for a program year. Please note that if a group practice is selected to participate in the PQRS as a GPRO, the eligible professionals in the selected group practice cannot participate in the PQRS individually. When selecting group practices to participate in the GPRO, CMS bases its decision on the information the group practice provides in its self-nomination statement. We believe that changes in a group practice's size or TIN constitute such a significant change in the group practice's composition that it would cause CMS to reconsider its decision to allow the group practice to participate in the GPRO for the applicable program year. Specifically, we understand that a group practice's size may vary throughout the program year. For example, we understand that eligible professionals enter into and leave group practices throughout the year. Similarly, we understand that group practices may undergo business reorganizations during the program year. We note that size fluctuations may affect the criteria under which a group practice would use to report after being selected to participate in the GPRO. As indicated in section III.G.4., we are proposing that groups of varying sizes be subject to different criteria for satisfactory reporting for the 2013 and 2014 incentives, as well as for the payment adjustments. Therefore, we propose that, for analysis purposes, the size of the group practice must be established at the time the group practice is selected to participate in the GPRO. We invite public comment on this proposal.

We also understand that, for various reasons, a group practice may change TINs within a program year. For example, a group practice may undergo a mid-year reorganization that leads to the group practice changing its TIN mid-year. We propose that, if a group practice changes its TIN after the group practice is selected to participate in the GPRO, the group practice cannot continue participate in PQRS as a GPRO. We consider the changing of a group practice's TIN a significant change to the makeup of the group practice, as the group practice is evaluated under the TIN the group practice provided to CMS at the time the group is selected to participate in the GPRO for the applicable year. Therefore, we view a group practice that changes its TIN as an entirely new practice, associated with a new TIN. We understand that this proposal may pose a disadvantage for those group practices who find it beneficial to report PQRS quality measures using the GPRO. However, we note that eligible professionals in a group practice that has changed its TIN within a year may still participate as individuals. We invite public comment on this proposal.

We understand that a group practice may decide not to participate in PQRS using the GPRO after being selected. Therefore, we propose that group practices be provided with an opportunity to opt out of participation in the GPRO after selection. We note that it is necessary for a group practice to indicate to CMS the group practices' intent not to use the GPRO because, once a group practice is selected to participate in the GPRO for the applicable reporting period, CMS will not separately assess the NPIs associated with the group practice's TIN to see if they meet the criteria for satisfactory reporting for individual eligible professionals. Therefore, CMS must be notified of the group practice's decision not to participate in the GPRO so the eligible professionals within the group practice could be assessed at the individual TIN/NPI level. We propose that group practices have until April 1 of the year of the applicable reporting period (for example, by April 1, 2013 for reporting periods occurring in 2013) to opt out of participating in the GPRO. We invite public comment on the proposed selection process for group practices wishing to participate in the GPRO.

(4) Proposed Requirement for Group Practices Electing To Use the Administrative Claims-Based Reporting Mechanism for 2015 and 2016 Payment Adjustments

We propose an election requirement for group practices that elect to participate in the PQRS for the 2015 and 2016 payment adjustment using administrative claims-based reporting mechanism, which is discussed in full in section III.G.5. (which also addresses election requirements for eligible professionals). We seek comment on our proposal on election requirements for group practices that intend to report using the proposed administrative claims reporting option for the 2015 and 2016 payment adjustment.

2. Proposed Reporting Periods for the PQRS Payment Adjustments for 2016 and Beyond

For the PQRS incentives, we previously established 12 and 6-month reporting periods for satisfactorily reporting PQRS quality measures at § 414.90(f)(1). Under section 1848(a)(8)(C)(iii) of the Act, we are authorized to specify the quality reporting period (reporting period) with respect to a payment adjustment year. We propose to modify the regulation to establish the reporting periods for the PQRS payment adjustments for 2015 and beyond.

For the 2015 payment adjustment, in the CY 2012 Medicare PFS final rule, we established CY 2013 (that is, January 1, 2013 through December 31, 2013) as the reporting period for the 2015 payment adjustment (76 FR 73392). We established a 12-month reporting period occurring 2 years prior to the application of the payment adjustments for group practices and for individual eligible professionals to allow time to perform all reporting analysis prior to applying payment adjustments on eligible professionals' Medicare Part B PFS claims. However, we note that we might specify additional reporting periods for the 2015 payment adjustment. To coincide with the 6-month reporting period associated with the 2013 incentive for the reporting of measures groups via registry, we propose to modify the regulation at newly designated § 414.90(h) to add a 6-month reporting period occurring July 1, 2013—December 31, 2013, for the 2015 payment adjustment for the reporting of measures groups via registry.

For 2016 payment adjustments, to coincide with the reporting periods for the 2014 incentive, we propose to modify the regulation at newly designated § 414.90(h) to specify a 12-month (January 1, 2014—December 31, 2014) and, for individual eligible professionals reporting measures groups via registry only, a 6-month (July 1, 2014—December 31, 2014) reporting periods for the 2016 payment adjustments.

We believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on a 6-month reporting period. Therefore, it is our intention to move towards using solely a 12-month reporting period once the reporting periods for the 2013 and 2014 incentives conclude. Therefore, for payment adjustments occurring in 2017 and beyond, we propose to modify the regulation at newly designated § 414.90(h) to specify only a 12-month reporting period occurring January 1–December 31, that falls 2 years prior to the applicability of the respective payment adjustment (for example, January 1, 2015 through December 31, 2015, for the 2017 payment adjustment). We invite public comment on the proposed reporting periods for the PQRS payment adjustments for 2015 and beyond.

3. Proposed Requirements for the PQRS Reporting Mechanisms

This section contains our proposals for the following reporting mechanisms: Claims, registry, EHR (including direct EHR products and EHR data submission vendor products), GPRO web-interface, and administrative claims. We previously established at § 414.90(f)(2) that eligible professionals reporting individually may use the claims, registry, and EHR-based reporting mechanisms. We propose to modify § 414.90 to allow group practices comprised of 2–99 eligible professionals to use the claims, registry, and EHR-based reporting mechanisms as well, because we recognize the need to provide varied reporting criteria for smaller group practices, particularly since we are proposing to expand the definition of group practice. For example, we understand that a smaller group practice may not have a sufficiently varied practice to be able to meet the proposed satisfactory reporting criteria for the GPRO web-interface that would require a smaller group practice to report on all of the proposed PQRS quality measures specified in Table 35. These proposals are reflected in our proposed changes to § 414.90, which we are proposing to re-designate § 414.90(g) and § 414.90(h). We invite public comment on this proposal to make the claims, registry, and EHR-based reporting options applicable to group practices.

a. Claims-Based Reporting: Proposed Requirements for Using Claims-Based Reporting for 2013 and Beyond

Eligible professionals and group practices wishing to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. QDCs for the eligible professional's or group practice's selected PQRS (individual or measures groups) quality measures that are reported on claims may be submitted to CMS at any time during the reporting period for the respective program year. However, as required by section 1848(m)(1)(A) of the Act, all claims for services furnished during the reporting period, would need to be processed by no later than the last Friday occurring two months after the end of the reporting period, to be included in the program year's PQRS analysis. For example, all claims for services furnished during a reporting period that occurs during calendar year 2013 would need to be processed by no later than the last Friday of the second month after the end of the reporting period, that is, processed by February 28, 2014 for the reporting periods that end December 31, 2013. In addition, after a claim has been submitted and processed, we propose at re-designated § 414.90(g)(2)(i)(A) and newly added § 414.90(h)(2)(i)(A) to indicate that EPs cannot submit QDCs on claims that were previously submitted and processed (for example, for the sole purpose of adding a QDC for the PQRS). We invite public comment on our proposed requirements for using the claims-based reporting mechanism for the incentives and for the payment adjustments for 2013 and beyond.

b. Registry-Based Reporting

(1) Proposed Qualification Requirements for Registries for 2013 and Beyond

For 2013 and beyond, we propose that registries wishing to submit data on PQRS quality measures for a particular reporting period would be required to be qualified for each reporting period the registries wish to submit quality measures data. This qualification process is necessary to verify that registries are able to submit data on PQRS quality measures on behalf of eligible professionals and group practices to CMS. Registries who wish to become qualified to report PQRS quality measures for a reporting period undergo (1) a self-nomination process

and (2) a qualification process regardless of whether the registry was qualified the previous program year.

For the self-nomination process, we propose that the self-nomination process would consist of the submission of a self-nomination statement submitted via the web by January 31 of each year in which the registry seeks to submit data on PQRS quality measures on behalf of eligible professionals and group practices. For example, registries that wish to become qualified to report data in 2013 under the program, that is, to report during all of the reporting periods for the 2013 incentive and the 2015 payment adjustment, would be required to submit its self-nomination statement by January 31, 2013. We propose that the self-nomination statement contain all of the following information:

- The name of the registry.
- The reporting period start date the registry will cover.
- The measure numbers for the PQRS quality measures on which the registry is reporting.

We note that CMS is currently developing the functionality to accept registry self-nomination statements via the web and anticipate development of this functionality to be complete for registries to submit their self-nomination statements via the web in 2013. However, in the event that it is not technically feasible to collect this self-nomination statement via the web, we propose that registry vendors would submit its self-nomination statement via a mailed letter to CMS. The self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. We propose that these self-nomination statements must be received by CMS by 5 Eastern Standard Time on January 31 of the applicable year.

For the qualification process, we propose that all registries, regardless of whether or not they have been qualified to report PQRS quality measures in a prior program year, undergo a qualification process to verify that the registry is prepared to submit data on PQRS quality measures for the reporting period in which the registry seeks to be qualified. To become qualified for a particular reporting period, we propose that a registry would be required to:

- Be in existence as of January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified to submit data in 2013).
- Have at least 25 participants by January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified for the reporting periods occurring in 2013).
- Provide at least 1 feedback report to participating eligible professionals and group practices for each program year in which the registry submits data on PQRS quality measures on behalf of eligible professionals and group practices. This feedback reporting would be based on the data submitted by the registry to CMS for the applicable reporting period or periods occurring during the program year. For example, if a registry was qualified for the reporting periods occurring in 2013, the registry would be required to provide a feedback report to all participating eligible professionals and group practices based on all 12 and 6-month reporting periods for the 2013 incentive and the 12-month reporting period for 2015 payment adjustment. Although we propose to require that qualified registries provide at least 1 feedback report to all participating eligible professionals and group practices, we encourage registries to provide an additional, interim feedback report, if feasible, so that an eligible professional may determine what steps, if any, are needed to meet the criteria for satisfactory reporting.
- For purposes of distributing feedback reports to its participating eligible professionals and group practices, the registry must collect each participating eligible professional's email address and have documentation from each participating eligible professional authorizing the release of his or her email address.
- Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a qualified PQRS registry).
- Participate in all ongoing PQRS mandatory support conference calls and meetings hosted by CMS for the program year in which the registry seeks to be qualified. For example, a registry wishing to be qualified for reporting in 2013 would be required to participate in all mandatory support conference calls hosted by CMS related reporting in 2013 under the PQRS.
- Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures.
- Be able to calculate and submit measure-level reporting rates and/or, upon request, the data elements needed to calculate the reporting rates by TIN/NPI.
- Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome based on a calculation of the measure's numerator and denominator specifications) for each measure on which the eligible professional or group practice (as identified by the TIN/NPI) reports and/or, upon request, the Medicare beneficiary data elements needed to calculate the reporting rates.
- Be able to separate out and report on Medicare Part B FFS patients.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (reporting/performance numerator).
- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Report the number of reported instances, performance not met, meaning the quality action was not performed for any valid reason as defined by the measure specification. Please note that an eligible professional receives credit for reporting, not performance.
- Be able to transmit data on PQRS quality measures in a CMS-approved XML format.
- Comply with a CMS-specified secure method for data submission, such as submitting the registry's data in an XML file through an identity management system specified by CMS or another CMS-approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.
- Submit an acceptable ''validation strategy'' to CMS by March 31 of the reporting year the registry seeks qualification (for example, if a registry wishes to become qualified for reporting in 2013, this validation strategy would be required to be submitted to CMS by March 31, 2013). A validation strategy details how the registry will determine whether eligible professionals and group practices have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method.

• Perform the validation outlined in the strategy and send the results to CMS by June 30 of the year following the reporting period (for example, June 30, 2014, for data collected in the reporting periods occurring in 2013).

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry's receipt of patient-specific data from the eligible professionals and group practices, as well as the registry's disclosure of quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries on behalf of eligible professionals and group practices who wish to participate in the PQRS.

• Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the eligible professional signs up with the registry to submit PQRS quality measures data to the registry and would be required to meet any applicable laws, regulations, and contractual business associate agreements.

• Upon request and for oversight purposes, provide CMS access to review the Medicare beneficiary data on which PQRS registry-based submissions are founded or provide to CMS a copy of the actual data.

• Provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

• Use PQRS measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. We will provide registries a standard set of logic to calculate each measure and/or measures group they intend to report for each reporting period.

• Provide a calculated result using the CMS-supplied measure calculation logic and XML file format for each measure that the registry intends to calculate. The registries may be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format. The registries will be required to send in test files with fictitious data in the designated file format.

• Describe to CMS the cost for eligible professionals and group practices that the registry charges to submit PQRS and/or eRx Incentive Program data to CMS.

• Agree to verify the information and qualifications for the registry prior to posting (includes names, contact, measures, cost, etc.) and furnish/support all of the services listed for the registry on the CMS Web site.

• Agree that the registry's data for Medicare beneficiaries may be inspected or a copy requested by CMS and provided to CMS under our oversight authority.

• Be able to report consistent with the satisfactory reporting criteria requirements for the PQRS incentives and payment adjustments.

In addition to meeting all the requirements specified previously for the reporting of individual quality measures via registry, for registries that intend to report on PQRS measures groups, we propose that these registries, regardless of whether or not registries were qualified in previous years, would be required to:

• Indicate the reporting period chosen for each eligible professional who chooses to submit data on measures groups.

• Base reported information on measures groups only on patients to whom services were furnished during the relevant reporting period.

• If the registry is reporting using the measures group option for 20 patients, the registry on behalf of the eligible professional may include non-identifiable data for non-Medicare beneficiaries as long as these patients meet the denominator of the measure and the eligible professional includes a majority Medicare Part B patients in their cohort of 20 patients for the measures group.

We intend to post the final list of registries qualified for each reporting period by the Summer of each the year in which the reporting periods occur on the CMS Web site at *http://http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. For example, we intend to post the list of registries qualified for 2013 reporting periods by the Summer 2013. For each reporting period, the list of qualified registries would contain the following information: the registry name, registry contact information, the measures and/or measures group(s) the registry is qualified and intends to report for the respective reporting period.

This proposed registry qualification process is largely the same process we established to qualify registries for the reporting periods occurring in 2012. We are proposing a similar process to the 2012 qualification process because, registries are already familiar with this qualification process, so we believe there would be a greater likelihood that registries wishing to be qualified to report quality measures data for a particular reporting period would be able to pass the qualification process. We believe this will provide eligible professional with more qualified registry products from which to choose.

Lastly, in the CY 2012 Medicare PFS proposed rule, we raised the issue of disqualifying registries that submit inaccurate data (76 FR 42845). We did not adopt a disqualification process but noted the importance of such a process, as well as our intention to provide detailed information regarding a disqualification process in future rulemaking (76 FR 73322). In an effort to ensure that registries provide accurate reporting of quality measures data, we propose to modify § 414.90 to indicate that we would audit qualified registries. If, during the audit process, we find that a qualified registry has submitted grossly inaccurate data, we propose, under § 414.90, to indicate that we would disqualify such a registry from the subsequent year under the program, meaning that a registry would not be allowed to submit PQRS quality measures data on behalf of eligible professionals and group practices for the next year. Under this proposal, a disqualified registry would not be included in the list of qualified registries that is posted for the applicable reporting periods under which the registry attempted to qualify. For example, if a qualified registry submits quality measures data for the reporting periods occurring in 2013 but is then audited and later disqualified, the registry would not be allowed to submit PQRS quality measures data on behalf of participating eligible professionals and group practices to CMS for the reporting periods occurring in 2014 or later. One example of submitting grossly inaccurate data that CMS has encountered in the past is if a registry reports inaccurate TIN/NPIs on 5 percent or more of the registry's submission. As CMS calculates data on a TIN/NPI level, it is important for registries to provide correct TIN/NPI information. We invite public comment as to the threshold of grossly inaccurate data for the purpose of disqualifying a registry.

Under our proposal, our decision to disqualify would be final. We further

propose to post a registry's disqualification status on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

In proposing registry disqualification, we considered other alternatives, such as placing registries in a probationary status. However, we believe it is important for registries to submit correct data once it is qualified to submit data on behalf of its eligible professionals and therefore, find that immediate disqualification to be appropriate. This becomes especially important particularly as the program moves from the use of incentives to payment adjustments.

We invite public comment on our proposals regarding registry qualification and disqualification for 2013 and beyond.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a registry through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via registry for PQRS via NwHIN.

c. EHR-Based Reporting

(1) Proposed Requirements for a Vendor's Direct EHR Products for 2014 and Beyond

We are proposing to modify § 414.90(b) to define a direct electronic health record (EHR) product as ''an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS.'' Please note that the self-nomination and qualification requirements for a vendor's direct EHR products for 2012 and 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73323).

In lieu of continuing this process in future years of the program, we propose to no longer require qualification of EHR products in order to be used for reporting under the PQRS. Although we would still allow EHR vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. Although vendors and their products would no longer be required to undergo this testing or qualification process, we propose that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and
- In compliance with a CMS-specified secure method for data submission, such as submitting the direct EHR vendor's data (for testing) through an identity management system specified by CMS or another approved method.

In addition, upon request and for oversight purposes, we propose that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. CMS, however, would no longer be posting a list of qualified EHR vendors and their products on the CMS Web site. Therefore, eligible professionals would need to work with their respective EHR vendor to determine whether their specific EHR product has undergone any testing with the PQRS and/or whether their EHR product can produce and transmit the data in the CMS-specified format and manner. While we no longer believe that this process is necessary, we invite public comment as to whether CMS should continue to require that direct EHR products undergo self-nomination and qualification processes prior to being authorized to submit quality measures data to CMS for PQRS reporting purposes.

We are proposing to not to continue the qualification requirement (that is, no longer propose this process for future years of the program) because we believe adequate checks are in place to ensure that a direct EHR product is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program with respect to our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that a vendor's EHR system be certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). In future years, we anticipate that the ONC certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Tables 32 and 33, since we are proposing to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invite public comment as to whether, in lieu of qualification, CMS should require that direct EHR products that would be used to submit data on PQRS quality measures for a respective reporting period be classified as certified under the program established by ONC.

Please note that, regardless of whether the qualification process is in place and not withstanding any CEHRT requirements that may apply, we note that eligible professionals bear the burden of determining choosing a direct EHR product that is able to adequately submit PQRS quality measures data to CMS.

We also invite public comment on the above proposals related to the proposed requirements for direct EHR products.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a direct EHR product through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via an EHR for PQRS via NwHIN.

(2) Proposed Requirements for a Vendor's EHR Data Submission Vendor Products for 2013 and Beyond

The EHR data submission vendor reporting mechanism was a mechanism that was newly established in the CY 2012 Medicare PFS final rule (76 FR 73324). We indicated that these EHR data submission vendors, some of which included previous registries, were entities that are able to receive and transmit clinical quality data extracted from an EHR to CMS. We propose to modify § 414.90(b) to define an electronic health record (EHR) data submission vendor as ''an electronic health record vendor's product and version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice.''

Please note that the qualification requirements for a vendor's EHR data submission vendor products for 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73327). Specifically, we established that a qualification and testing process would occur in 2012 to qualify EHR data submission vendor products to submit PQRS quality measures data for reporting periods occurring in CY 2013.

Operationally, we were unable to establish a qualification and testing process in 2012 to qualify EHR data submission vendor products for reporting periods occurring in CY 2013. Therefore, we propose to perform, in 2013, the qualification and testing process established in the CY 2012 Medicare PFS final rule (76 FR 73327) that was supposed to occur in 2012. We invite public comment on this proposal.

As for 2014 and beyond, we propose to no longer qualify EHR data submission vendor products in order to use such products under the PQRS for the same reasons we have articulated in our proposal not to continue qualifying direct EHR products. Although we would still allow EHR data submission vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. Although EHR data submission vendor products would no longer be required to undergo this testing or qualification process, we propose that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and for EHR data submission vendors who intend to report for purposes of the proposed PQRS Medicare EHR Incentive Program pilot, if the aggregate data are transmitted in a CMS-approved XML format.
- In compliance with a CMS-specified secure method for data submission.

In addition, upon request and for oversight purposes, we propose that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. CMS, however, would no longer be posting a list of qualified EHR data submission vendors on the CMS Web site. Therefore, eligible professionals would need to work with their respective EHR data submission vendor to determine whether the vendor has undergone any testing with the PQRS and/or whether EHR data submission vendor can produce and transmit the data in the CMS-specified format and manner.

We invite public comment on our proposal to, beginning 2014, not require qualification of EHR data submission vendor products. We also invite public comment as to whether CMS should continue to require that EHR data submission vendor products undergo these self-nomination and qualification processes prior to being authorized to submit quality measure data to CMS on an eligible professional's behalf for PQRS reporting purposes.

We are proposing to not to continue the qualification requirement (that is, no longer propose this process for 2014 and future years of the program) because we believe adequate checks are in place to ensure that a direct EHR product is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program with respect to our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that a vendor's EHR system be certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). In future years, we anticipate that the ONC certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Tables 32 and 33, since we are proposing to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invite public comment as to whether, in lieu of qualification, CMS should require that EHR data submission vendor products wishing to submit data on PQRS quality measures for a respective reporting period be certified under the program established by ONC.

Please note that, if the qualification process is no longer required or we do not require that an EHR data submission vendor product be certified under ONC's program, we note that eligible professionals bear the burden of determining choosing an EHR data submission vendor product that is able to adequately submit PQRS quality measures data to CMS.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via an EHR data submission vendor through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via an EHR for PQRS via NwHIN.

d. GPRO Web-Interface: Proposed Requirements for Group Practices Using the GPRO Web-Interface for 2013 and Beyond

The GPRO web-interface is a reporting mechanism established by CMS that is used by group practices that are selected to participate in the GPRO. For 2013 and beyond, we propose to modify newly designated § 414.90(g) and § 414.90(h) to identify the GPRO web-interface as a reporting mechanism available for reporting under the PQRS by group practices comprised of 25 or more eligible professionals. Consistent with the GPRO satisfactory reporting criteria we established for the 2012 PQRS (76 FR 73338), as well as the GPRO satisfactory reporting criteria we are proposing for 2013 and beyond, we propose to limit reporting via the GPRO web-interface during a respective reporting period to group practices comprised of at least 25 eligible professionals (that is, this reporting option would not be available to group practices that contain 2–24 eligible professionals) and selected to participate in the GPRO for the year under which the reporting period occurs. For example, a group practice wishing to submit quality measure data via the GPRO web-interface for 2013 must be a group practice selected to participate in the GPRO for the 2013 program year. We believe it is necessary to limit use of the GPRO web-interface to group practices comprised of at least 25 eligible professionals selected to participate in the GPRO because the 17 measures that are proposed to be reportable via the GPRO web-interface (as specified in Table 35) reflect a variety of disease modules: patient/caregiver experience, care coordination/patient safety, preventive health, diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

We believe that the reporting of these 18 proposed measures spanning across various settings lends this reporting mechanism more ideal for larger group practices that are more likely to be multi-specialty practices (which are typically group practices consisting of larger than 25 eligible professionals). The GPRO web-interface was modeled after the CMS Physician Group Practice (PGP) demonstration, and this demonstration was originally intended for large group practices. From our experience with the PGP demonstration, we believe a group practice comprised of 25 eligible professionals is the smallest group practice that could benefit from use of the GPRO web-interface as a reporting mechanism. We

also do not believe that excluding group practices comprised of 2–24 eligible professionals from using the GPRO web-interface as a reporting mechanism would harm these smaller group practices as we are proposing to allow groups comprised of 2–99 eligible professionals to report using the claims, qualified registry, EHR, and administrative claims-based reporting mechanisms.

We propose to provide group practices that are selected to participate in the GPRO using GPRO web-interface reporting option with access to the GPRO web-interface by no later than the first quarter of the year following the end of the reporting period under which the group practice intends to report. For example, for group practices selected for the GPRO for the 2013 incentive using the GPRO web-interface tool, we propose to provide group practices selected to participate in the GPRO with access to the GPRO web-interface by no later than the first quarter of 2014 for purposes of reporting for the applicable 2013 reporting period for the incentive. In addition, should CMS encounter operational issues with using the GPRO web-interface, we reserve the right to use a similar tool for group practices to use in lieu of reporting via the GPRO web-interface. We invite public comment on our proposed requirements for group practices using the GPRO web-interface for 2013 and beyond.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via the GPRO web-interface through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via the GPRO web-interface for PQRS via NwHIN.

e. Administrative Claims

For purposes of reporting for the 2015 and 2016 PQRS payment adjustments only, we propose to modify § 414.90(h) to allow eligible professionals and group practices to use an administrative claims reporting mechanism. The administrative claims reporting mechanism builds off of the traditional PQRS claims-based reporting mechanism. Under the traditional PQRS claims-based reporting mechanism, eligible professionals and group practices wishing to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. Under the proposed administrative claims reporting mechanism, unlike the traditional claims-based reporting option, an eligible professional or group practice would not be required to submit QDCs on claims to CMS for analysis. Rather, CMS would analyze every eligible professional's or group practice's patient's Medicare claims to determine whether the eligible professional or group practice has performed any of the clinical quality actions indicated in the proposed PQRS quality measures in Table 63. We propose that, for purposes of assessing claims for quality measures under this option, all claims for services furnished that occurs during the 2015 and/or 2016 PQRS reporting period would need to be processed by no later than 60 days after the end of the respective 2015 and 2016 payment adjustment reporting periods (that is, December 31, 2013 and December 31, 2014). We invite public comment on our proposed requirements for using the administrative claims-based reporting mechanism for the 2015 and 2016 payment adjustments.

4. Proposed Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For 2013 and 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. This section contains our proposed criteria for satisfactory reporting for the 2013 and 2014 incentives, which are the last two incentives authorized under the PQRS.

a. Proposed Criteria for Satisfactory Reporting for Individual Eligible Professionals

Please note that, in large part, we are proposing many of the same criteria for satisfactory reporting for individual eligible professionals for the 2013 and 2014 incentives that we established for the 2012 incentive, as eligible professionals are already familiar with these reporting criteria.

(1) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Claims

According to the ''2010 Physician Quality Reporting System and eRx Reporting Experience and Trends,'' available for viewing in the ''downloads'' section of the main page the PQRS Web site (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*), reporting via the claims-based reporting mechanism was the most commonly used reporting method. We believe that this trend continues, so we anticipate that, with respect to the 2013 and 2014 incentives, the criteria for satisfactory reporting for the claims-based reporting mechanism will be the method most widely used by individual eligible professionals. So as not to change reporting criteria that a large number of individual eligible professionals are familiar with using, we established the same reporting criteria for the 2011 and 2012 incentives (76 FR 73330). Therefore, for the respective 12-month reporting periods for the 2013 and 2014 incentives, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting specified under the statute and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73330), we propose the following criteria for satisfactory reporting of PQRS individual measures for individual eligible professionals using the claims-based reporting mechanism: Report at least 3 measures, OR, if less than 3 measures apply to the eligible professional, report 1—2 measures, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 3 measures via the claims-based reporting mechanism, we propose that the eligible professional be subject to the Measures Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. We believe the MAV process is necessary to review whether there are other closely related measures (such as those that share a common diagnosis or those that are representative of services typically provided by a particular type of eligible professional). Under the MAV process, if an eligible professional who reports on fewer than 3 measures reports on a measure that is part of an identified cluster of closely related measures, then the eligible professional would not qualify as a satisfactory

reporter for the 2013 and/or 2014 incentives. We are proposing this MAV process for the claims-based reporting mechanism only because it is more likely for EPs to report on more than 3 measures under the registry and EHR-based reporting mechanisms, as a registry or EHR product will typically automatically report on all measures that apply to the eligible professional's practice. We note that, consistent with section 1848(m)(3)(A)(i) of the Act, this proposed claims-based reporting criteria is the only proposed criteria where an eligible professional may report on fewer than 3 measures. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via claims for the 2013 and 2014 incentives.

(2) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Registry

In addition, we note that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, with respect to registry-based reporting, we have largely followed these reporting criteria for the PQRS incentives. According to the ''2010 Physician Quality Reporting System and eRx Reporting Experience and Trends,'' eligible professionals are more likely to meet the requirements for a PQRS incentive using the satisfactory reporting criteria for the registry-based reporting mechanism than claims. In fact, in 2010, approximately 87 percent of the eligible professionals reporting individual PQRS quality measures via registry were eligible and met the criteria for satisfactory reporting for the 2010 incentive. Since eligible professionals have had success with using these satisfactory reporting criteria, we believe such criteria are appropriate and see no reason to change the criteria for satisfactory reporting via registry that has been in place since 2010. Therefore, for those reasons and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73331), we propose the following criteria for satisfactory reporting of PQRS individual measures for individual eligible professionals using the registry-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives, respectively: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via a registry for the 2013 and 2014 incentives.

(3) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via EHR

As stated previously, section 1848(m)(7) of the Act requires us to develop a plan to integrate reporting requirements for PQRS and the EHR Incentive Program. Therefore, with respect to EHR-based reporting, it is our main goal to align our EHR reporting requirements with the reporting requirements an eligible professional must meet in order to satisfy the clinical quality measure (CQM) component of meaningful use (MU) under the EHR Incentive Program. In the EHR Incentive Program—Stage 2 NPRM (77 FR 13698), we proposed the CQM reporting requirements for the EHR Incentive Program for 2013, 2014, 2015, and potentially subsequent years. For the EHR reporting periods in CY 2013, we proposed (77 FR 13745) to continue the CQM reporting requirements that were established for eligible professionals for CYs 2011 and 2012 in the EHR Incentive Program—Stage 1 final rule (75 FR 44398–44411). Therefore, to align with the reporting requirements for meeting the CQM component of meaningful use, and based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting identified under the statute, we propose the following criteria for the 12-month reporting period for the 2013 incentive:

- As required by the Stage 1 final rule, eligible professionals must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

Under this proposal, eligible professionals using these reporting criteria would be required to report on 6 measures. For the proposed PQRS EHR measures that are also Medicare EHR Incentive Program core, alternate core, or additional measures that the eligible professional reports (75 FR 44398 through 44411), an eligible professional would be required to report the applicable measure for 100 percent of the eligible professionals Medicare Part B FFS patients.

In addition, we note that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, for EHR-based reporting, we have largely kept these reporting criteria for the 2010—2012 incentives. As we have seen some eligible professionals succeed with these criteria, we are proposing the following similar criteria for the 12-month reporting period for the 2013 incentive: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

We note that the Medicare EHR Incentive Program has proposed options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (for more information on these options, please see 77 FR 13746—13748). To align our EHR-based reporting requirements with those proposed under the Medicare EHR Incentive Program, we are proposing the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains—(1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.
- Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1

menu clinical quality measure from Tables 32 and 33. It is our intention to finalize the reporting criteria that aligns with the criteria that will be established for meeting the CQM component of meaningful use beginning with CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, our intention is to align with the reporting criteria the EHR Incentive Program ultimately establishes. Therefore, eligible professionals who participate in both PQRS and the EHR Incentive Program would be able to use one reporting criterion, during overlapping reporting periods, to satisfy the satisfactory reporting criteria under PQRS and the CQM component of meaningful use under the Medicare EHR Incentive Program. We invite public comment on this considered proposal.

In addition to this proposed criterion, the Medicare EHR Incentive Program proposed that, beginning with CY 2014, eligible professionals who participate in both the Physician Quality Reporting System and the Medicare EHR Incentive Program may satisfy the CQM component of meaningful use if they submit and satisfactorily report Physician Quality Reporting System clinical quality measures under the Physician Quality Reporting System's EHR reporting option using Certified EHR Technology (77 FR 13748). Since this language suggests that the Medicare EHR Incentive Program may defer to the satisfactory reporting criteria for the EHR-based reporting mechanism that we will establish for 2014, we are proposing the following reporting criteria for the 12-month reporting period for the 2014 incentive that largely conform to the criteria set forth under section 1848(m)(3)(A)(ii) of the Act that we established for the 2012 incentive and that we are proposing for the 2013 incentive: report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted. We invite public comment on the proposed criteria for satisfactory reporting on PQRS measures via EHR.

(4) Proposed Criteria for Satisfactory Reporting on PQRS Measures Groups via Claims

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73335):

- Report at least 1 PQRS measures group, AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR
- Report at least 1 PQRS measures group, AND report each measures group for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FF patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we propose the following criteria for the satisfactory reporting PQRS measures groups for individual eligible professionals using the claims-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives: Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted.

We note that, in an effort to simplify the satisfactory reporting criteria, we are only proposing 1 option for meeting the criteria for satisfactory reporting using PQRS measures groups via claims. We invite public comment on the proposed criterion for satisfactory reporting of measures groups via claims for the 2013 and 2014 incentives.

(5) Proposed Criteria for Satisfactory Reporting on PQRS Measures Groups via Registry

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73337):

- Report at least 1 PQRS measures group AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR
- Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

In addition, we established the following criteria for satisfactorily reporting PQRS measures groups for the 6-month reporting period for the 2012 incentive (76 FR 73337): Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FF patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we propose the following criteria for satisfactory reporting of PQRS measures groups for individual eligible professionals using the registry-based reporting mechanism for the 2013 and 2014 incentives:

(1) For the 12-month reporting periods for the respective 2013 and 2014 incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(2) For the 6-month reporting period for the respective 2013 and 2014 incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures group containing a measure with a zero percent performance rate will not be counted. Please note that this is the same criterion established for the 12-month reporting period. We are proposing the same criterion for both reporting periods in an effort to simplify the reporting criterion for satisfactory reporting.

We note that, while we still are proposing to require that an eligible professional report on at least 20 patients, we understand that a patient's personal identification information may be stripped when data is collected via

a qualified registry. As such, we understand that it may be difficult to distinguish Medicare and non-Medicare patients. Given this difficulty and that the eligible professionals generally would be attempting to report data on Medicare patients, we believe the reporting of some non-Medicare patients could serve a proxy for the reporting of Medicare patients whose data is not easily distinguishable as data on Medicare patients under this reporting mechanism.

Finally, we note that these proposals would satisfy the requirement under section 1848(m)(5)(F) of the Act that we provide for alternative reporting periods and criteria for satisfactory reporting with regard to measures groups and registry-based reporting. We invite public comment on the proposed criteria for satisfactory reporting of measures groups by individual eligible professionals via registry for the 2013 and 2014 incentives.

Tables 25 and 26 provide a summary of our proposals for the satisfactory reporting of PQRS quality measures for the 2013 and 2014 incentives.

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Table 25: Proposed Criteria for Satisfactory Reporting by Individual Eligible Professionals of Data on PQRS Quality Measures for the 2013 Incentive

Reporting Period	Measure Type	Reporting Mechanism	Proposed Reporting Criteria
Jan 1, 2013—Dec 31, 2013*	Individual Measures	Claims	Report at least 3 measures, OR, If less than 3 measures apply to the eligible professional, report 1—2 measures*; AND Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013—Dec 31, 2013	Individual Measures	Qualified Registry	Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013—Dec 31, 2013	Individual Measures	Direct EHR Product	Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures. If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; AND Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013—Dec 31, 2013	Individual Measures	EHR Data Submission Vendor	Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures. If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; AND Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2013—Dec 31, 2013	Measures Groups	Claims	Report at least 1 measures group, AND Report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jan 1, 2013—Dec 31, 2013	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted
Jul 1, 2013—Dec 31, 2013	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted

* Subject to the measure applicability validation (MAV) process.

Table 26: Proposed Criteria for Satisfactory Reporting by Individual Eligible Professionals of Data on PQRS quality measures for the 2014 Incentive

Reporting Period	Measure Type	Reporting Mechanism	Proposed Reporting Criteria
Jan 1, 2014—Dec 31, 2014*	Individual Measures	Claims	Report at least 3 measures, OR, If less than 3 measures apply to the eligible professional, report 1—2 measures*; AND Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2014—Dec 31, 2014	Individual Measures	Qualified Registry	Report at least 3 measures, AND Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
Jan 1, 2014—Dec 31, 2014	Individual Measures	Direct EHR product	Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness. Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33plus 1 menu clinical quality measure from Tables 32 and 33. Option 2: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.
Jan 1, 2014—Dec 31, 2014	Individual Measures	EHR data submission vendor	Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness. Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33plus 1 menu clinical quality measure from Tables 32 and 33. Option 2: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.
Jan 1, 2014—Dec 31, 2014	Measures Groups	Claims	Report at least 1 measures group, AND Report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jan 1, 2014—Dec 31, 2014	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
Jul 1, 2014—Dec 31, 2014	Measures Groups	Qualified Registry	Report at least 1 measures group, AND Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

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b. Proposed Criteria for Satisfactory Reporting for Group Practices Selected To Participate in the GPRO

This section contains our proposed criteria for satisfactory reporting for group practices selected to participate in the GPRO for the 2013 and 2014 incentives, which are the last two incentives authorized under the Physician Quality Reporting System. Please note that, in addition to offering the GPRO web-interface tool that we've previously included under the program, we are proposing new criteria for group practices under the GPRO that allow group practices to use the claims, registry, and EHR-based reporting mechanisms. In prior program years, large group practices have been successful in reporting quality measures data via the GPRO web-interface. We are proposing new criteria under the claims, qualified registry, and EHR-based reporting mechanisms because we believe that smaller groups may benefit from different reporting criteria and also other reporting mechanisms. Since the introduction of smaller group practices comprised of 25–99 eligible professionals under the GPRO is fairly recent, and given that we are proposing to modify the definition for group practice such that the PQRS GPRO would include beginning in 2013 group practices comprised of 2–24 eligible professionals, we are proposing additional criteria for reporting because we believe it may be more practicable that smaller group practices report on PQRS quality measures via claims, qualified registry, or direct EHR or EHR data submission vendor versus the GPRO web-interface, which was designed for use by larger group practices.

(1) Proposed Criteria for Beneficiary Assignment Methodology and Satisfactory Reporting on PQRS Quality Measures via the GPRO Web-Interface

In order to populate the GPRO web-interface, we must first assign beneficiaries to each group practice and then from those assigned beneficiaries draw a sample of beneficiaries for the disease modules in the GPRO web interface. This assignment and sampling methodology is based on what we learned from the PGP demonstration. The PGP demonstration aims to encourage coordination of the care furnished to individuals under Medicare parts A and B by institutional and other providers, practitioners, and suppliers of health care items and services; encourage investment in administrative structures and processes to ensure efficient service delivery; and reward physicians for improving health outcomes and reducing the rate of growth in health care expenditures. In the PGP Transition demonstration, the goal of beneficiary assignment criteria is to identify Medicare beneficiaries that have a plurality of their allowed charges for office evaluation and management (E & M) services furnished at a participating PGP during the year. If they do not have any primary care physician visits, then they are assigned using plurality of allowed charges for all office E & M physician visits regardless of specialty.

In 2012, the beneficiaries that we assigned to group practices, for purposes of reporting on the PQRS quality measures via the GPRO web-interface, were limited to those Medicare Part B FFS beneficiaries with Medicare Parts A and B claims for whom Medicare is the primary payer. Assigned beneficiaries did not include Medicare Advantage enrollees. We assigned a beneficiary to the group practice if the practice provided the plurality of a beneficiary's office or other outpatient office evaluation and management allowed charges. Beneficiaries with only one office visit to the group practice were eliminated from the group practice's assigned patient population. Please note that, for the GPRO web-interface, similar to the PGP demonstration, also takes eligible professional services other than physician services when evaluating a group practice's office E & M services. We are proposing to continue using this assignment methodology for 2013 and subsequent years because it is already in place operationally. We believe the assignment methodology we are currently using adequately captures sufficient data to reflect the quality of care furnished by group practices reporting under the GPRO web-interface. We invite public comment on our proposal to continue to use this methodology for assigning beneficiaries.

We note that the Medicare Shared Savings Program uses a somewhat different assignment methodology. More information regarding the assignment methodology that is used in the Shared Savings Program be found on the program Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/*. However, we note that consistent with the requirements of section 1899(c) of the Act, the assignment methodology used in the Shared Savings Program (which involves a 2-step process) has a greater focus on physician-provided primary care services.

In order to more closely align with the Medicare Shared Savings Program, we considered proposing to modify the assignment method PQRS uses to assign beneficiaries to a group practice to be similar to the two-step assignment method specified in § 425.402 that is used under the Medicare Shared Savings Program to assign beneficiaries to an ACO. Consistent with that two-step methodology, in order for a beneficiary to be eligible for assignment to a group practice, the beneficiary must have received at least one primary care service from a physician (as defined in § 425.20) within the group practice during the reporting period. Accordingly, we would identify beneficiaries who received at least one primary care service from any group practice physician (regardless of specialty) participating in the group practice during the reporting period. Under the first assignment step, we would assign the beneficiary to the group practice if the beneficiary had at least one primary care service furnished by a primary care physician at the participating group practice, and more primary care services (measured by Medicare allowed charges) furnished by primary care physicians in the participating group practice than furnished by primary care physicians at any other group practice or non-group practice physician. The second step applies only for those beneficiaries who do not receive any primary care services from a primary care physician during the reporting period. We would assign the beneficiary to the participating group practice in this step if the beneficiary had at least one primary care service furnished by a group practice physician, regardless of specialty, and more primary care services were furnished by group practice professionals (including non-primary care physicians, nurse practitioners, physician assistants or clinical nurse specialists) (measured by Medicare allowed charges) at the participating group practice than at any other group practice or non-group practice physician. We would then pull samples of beneficiaries for the relevant measures/modules from this population of assigned beneficiaries to populate the GPRO web interface. We considered making this change to the assignment method beginning with the 2013 PQRS GPRO web-interface so that the rules used to assign beneficiaries to group practices participating in PQRS and ACOs participating in the Medicare Shared Savings Program would be

consistent. Since both group practices that are participating in the PQRS GPRO and ACOs participating in the Medicare Shared Savings Program would be using the same GPRO web interface to report the same set of quality measures to CMS, we believe that applying consistent assignment methods across the two programs would allow us to streamline our processes and could potentially reduce confusion among group practices considering participation in the PQRS GPRO or ACOs considering participation in the Medicare Shared Savings Program. We invite public comment on this alternative option of adopting a methodology similar to the one the Medicare Shared Savings Program uses to assign beneficiaries to ACOs to assign beneficiaries to group practices that report on PQRS quality measures via the GPRO web-interface beginning in 2013.

Consistent with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we propose the following criteria for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 12-month reporting periods for the 2013 and 2014 incentives, respectively, using the GPRO Web-interface for groups practices of 25–99 eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 218 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 218 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. In addition, we propose the following criteria for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 2013 and 2014 incentives, respectively, using groups practices of 100 or more eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.

The satisfactory criteria we proposed for the GPRO web-interface for large group practices for the 2013 and 2014 incentives is consistent with the reporting criteria we established for the 2012 PQRS incentive (76 FR 73339). The satisfactory criteria we proposed for groups of 25–99 eligible professionals are consistent with the reporting criteria we established for the 2012 PQRS incentive (76 FR 73339). We are proposing these same criteria because the thresholds proposed in these criteria are based on analysis performed on group reporting based on the PGP demonstration to determine reasonable thresholds for group practice reporting. Therefore, we believe the satisfactory reporting criteria that we have proposed for the GPRO web-interface for the 2013 and 2014 incentives are appropriate criteria and reasonable for groups to meet.

Furthermore, we propose using Medicare Part B claims data for dates of service on or after January 1 and submitted and processed by approximately the last Friday in October of the applicable 12-month reporting period under which the group practice participates in the GPRO to assign Medicare beneficiaries to each group practice. For example, for a group practice participating under the GPRO for the reporting periods occurring in 2013, for the sampling model, we propose that we would assign beneficiaries on which to report based on Medicare Part B claims with dates of service beginning January 1, 2013 and processed by October 25, 2013. We invite public comment on our proposal to continue to use this methodology for assigning beneficiaries.

(2) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Selected To Participate in the GPRO via Claims, Registry, and EHR

We are proposing to have the claims, registry, and EHR reporting mechanisms available for group practices of 2–99 eligible professionals to use to report PQRS quality measures. We note that we are not proposing to make the claims, registry, and EHR reporting mechanisms available to larger groups of 100 or more eligible professionals, because we believe that these larger group practices do not face the potential limitations that smaller group practices may face when using the GPRO web-interface. Although group practices of 100–249 were also only introduced to the GPRO web-interface in 2012, we note that we believe these practices are sufficiently large enough to account for the varied measures required for reporting under the GPRO web-interface. For example, the proposed criteria for satisfactory reporting on individual PQRS quality measures for group practices using the GPRO web-interface would require a group practice to report on all 18 measures that are indicated in Table 35. Larger group practices tend to have more varied practices, so it would be easier for larger groups to report on a measure set that covers multiple domains, such as the one proposed in Table 35, than smaller group practices that tend to be focused on a limited set of specialties. We certainly think this is the case for the smallest group practices comprised of 2–24 eligible professionals, which is the reason why we are not proposing that the GPRO web-interface be available for use for these smaller group practices. With respect to group practices comprised of 25–99 eligible professionals, we believe it is possible for these group practices to have a practice that is sufficiently varied to be able to report on measures that cut across multiple domains. However, we note that use of the GPRO web-interface as a reporting mechanism was only introduced to groups of 2–99 in 2012, so no data is available to determine the feasibility of groups of 25–99 using the GPRO web-interface. Therefore, in the event these groups feel that reporting using the GPRO web-interface would be difficult, we are proposing criteria alternative to that proposed under the GPRO web-interface for satisfactory reporting for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms that mirror the criteria we are proposing for individual reporting for the claims, registry, and EHR-based reporting mechanisms from the 2013 and 2014 incentives. We note that the criteria we are proposing for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms are similar to the criteria for individual reporting, because we believe smaller group practices are more akin to individuals with respect to practice scope. The larger the group practice, the more likely the group practice would benefit using the reporting options under the GPRO web-interface.

Therefore, based on our authority under section 1848(m)(3)(C) of the Act, we propose the following satisfactory reporting criteria via claims for group practices comprised of 2–99 eligible

professionals under the GPRO for the 2013 and 2014 incentives via claims: Report at least 3 measures AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

For those group practices that choose to report using a qualified registry, we propose the following satisfactory reporting criteria via qualified registry for group practices comprised of 2–99 eligible professionals under the GPRO for the 2013 and 2014 incentives: Report at least 3 measures AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted. Please note that we are only proposing these satisfactory reporting criteria for group practices comprised of 2–99 eligible professionals because we believe that larger group practices should have the technical capacity and resources to report on the more expansive measure set that is collected via the GPRO web-interface.

For group practices choosing to report PQRS quality measures via EHR, we propose the following 2 options for the satisfactory reporting criteria via a direct EHR product or EHR data submission vendor for group practices comprised of 2–99 eligible professionals under the GPRO for the 2013 incentive:

Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals reporting those CQMs (75 FR 44398 through 44411).

Option 2: Report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

We note that the Medicare EHR Incentive Program has proposed 2 options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (for more information on these options, please see 77 FR 13746–13748). To align our EHR-based reporting requirements with those proposed under the Medicare EHR Incentive Program, we are proposing the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- *Option 1a:* Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains—(1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.
- *Option 1b:* Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33. We propose to adopt the group reporting criteria that aligns with the criteria that will be established for meeting the CQM component under CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final group reporting criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, our intention is to align with the group reporting criteria the EHR Incentive Program ultimately establishes. We invite public comment on this proposal.

We also considered proposing the following satisfactory reporting criteria for the 2014 PQRS incentive for groups of 2–99 that was similar to the satisfactory reporting criteria being proposed for the 2013 PQRS incentive: report at least 3 measures, AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted. We invite public comment on this considered proposal.

We note that we believe these proposed criteria meets the requirements for group practice reporting specified in section 1848(m)(3)(C) of the Act. Section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We note that, although these criteria depart from the model used in the PGP demonstration, we believe that these criteria still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. Rather than CMS choosing which sample of patients the group practice must report, with these proposed criteria, the group practice decides on which sample of patients to report for either 50 percent, 80 percent, or 100 percent of its patients depending on the reporting mechanism the group practice chooses. For example, if a group practice who sees 100 patients during the 2013 incentive reporting period chooses to report PQRS quality measures using the claims-based reporting mechanism, for the 2013 incentive, the group practice would have to report at least 3 measures for 50 percent of the practice's patients. The group practice may pick which patients on which to report, as long as the group practice reports on at least 50 of the patients the practice sees in 2013. If the same group practice decides to report on PQRS quality measures using the Option 1 criteria for EHR-based reporting for the 2013 incentive, the group practice would report on all 100 patients. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the EHR measures apply. Therefore, even though a group practice would report on 100 percent of patients to which the measure applies, not all of the EHR measures would necessarily apply to all of the group practice's patients. Since the group practice is then only providing information on its applicable patients, we believe the proposed EHR reporting criteria would still meet the statistical sampling model requirement. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by group practices via claims, registry, or EHR for the 2013 and 2014 incentives.

A summary of the proposed criteria for satisfactory reporting for group practices selected to participate in the GPRO for the 2013 and 2014 incentives is specified in Tables 27 and 28:

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TABLE 27: Proposed Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO for the 2013 Incentive

Reporting Period	Reporting Mechanism	Group Practice Size	Proposed Reporting Criterion
12-month (Jan 1 — Dec 31)	GPRO Web-Interface	25-99 eligible professionals	Report on all measures included in the web interface in Table 35; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1 — Dec 31)	GPRO Web-Interface	100+ eligible professionals	Report on all measures included in the web interface in Table 35; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1 — Dec 31)*	Claims	2-99 eligible professionals	Report at least 3 measures, AND Report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	Qualified Registry	2-99 eligible professionals	Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	Direct EHR product	2-99 eligible professionals	Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals for reporting those CQMs (75 FR 44398 through 44411). Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	EHR data submission vendor	2-99 eligible professionals	Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals for reporting those CQMs (75 FR 44398 through 44411). Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

Table 28: Proposed Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO for the 2014 Incentive

Reporting Period	Reporting Mechanism	Group Practice Size	Proposed Reporting Criterion
12-month (Jan 1 — Dec 31)	GPRO Web-Interface	25-99 eligible professionals	Report on all measures included in the web interface in Table 35; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1 — Dec 31)	GPRO Web-Interface	100+ eligible professionals	Report on all measures included in the web interface in Table 35; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.
12-month (Jan 1 — Dec 31)*	Claims	2-99 eligible professionals	Report at least 3 measures, AND Report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	Qualified Registry	2-99 eligible professionals	Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	Direct EHR product	2-99 eligible professionals	Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness. Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33. Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	EHR data submission vendor	2-99 eligible professionals	Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness. Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33. Option 2: Report at least 3 measures, AND Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

* Subject to the measure applicability validation (MAV) process.

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c. Proposed Analysis of the Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For the proposed criteria for satisfactory reporting for the 2013 and 2014 incentives described in this section, we propose that eligible professionals and group practices may not combine different satisfactory reporting criteria under different reporting mechanisms to meet the requirements of satisfactory reporting for the 2013 and 2014 incentives. For example, an eligible professional may not meet the requirements for the 2013 incentive by reporting on 2 applicable PQRS quality measures via claims and 1 applicable PQRS quality measure via qualified registry, because the eligible professional did not meet the criteria for satisfactory reporting under at least one reporting mechanism. Similarly, a group practice would be required to select a single reporting mechanism for the entire group practice. For example, for a group practice consisting of 4 eligible professionals, the group practice would not be able to meet the requirements for the 2013 incentive by reporting 2 individual measures via claims and 1 measure via the direct EHR submission method.

For individual eligible professionals and group practices reporting on individual measures and/or measures groups, please note that, although an eligible professional or group practice could meet more than one criterion for satisfactory reporting, only one incentive payment will be made to the eligible professional or group practice. For example, if an eligible professional meets the criteria for satisfactory reporting of individual measures via claims and measures groups via claims for the 2013 incentive, the eligible professional would nonetheless only be entitled to one incentive payment. CMS would consider the eligible professional to be incentive eligible under whichever reporting criterion yields the greatest bonus. We invite public comment on our proposed analysis of the criteria for satisfactory reporting for the 2013 and 2014 incentives.

5. Proposed Criteria for Satisfactory Reporting for the Payment Adjustments

Section 1848(a)(8) of the Social Security Act, as added by section 3002(b) of the Affordable Care Act, provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. The applicable percent for 2015 is 98.5 percent. For 2016 and subsequent years, the applicable percent is 98.0 percent.

This section contains the proposed criteria for satisfactory reporting for purposes of the 2015 and 2016 payment adjustments for eligible professionals and group practices, as well as some discussion of what we are considering for the payment adjustments for 2017 and beyond.

As stated previously, the majority of eligible professionals currently are not participating in the PQRS. Yet, the payment adjustment will apply to all eligible professionals who are not satisfactory reporters during the reporting period for the year. Therefore, in implementing the PQRS payment adjustment, we seek to achieve two overarching policy goals. First, and foremost, we seek to increase participation in the PQRS and to implement the payment adjustment in a manner that will allow eligible professionals who have never participated in the program to familiarize themselves with the program. Second, we seek to align the reporting requirements under the PQRS with the quality reporting requirements being proposed for the physician value-based payment modifier discussed in section III.K of this proposed rule.

a. Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices Using the Claims, Registry, EHR, and GPRO Web-Interface Reporting Mechanisms

This section contains our proposals for the criteria for satisfactory reporting for the 2015 and 2016 payment adjustments using the claims, registry, EHR-based, and GPRO web-interface reporting mechanisms. First, we propose that for purposes of the 2015 and 2016 payment adjustments (which would be based on data reported during 12 and 6-month reporting periods that fall within 2013 and 2014, respectively), an eligible professional or group practice would meet the requirement to satisfactorily report data on quality measures for covered professional services for the 2015 and 2016 payment adjustments by meeting the requirement for satisfactory reporting for the 2013 and 2014 incentives respectively. That is, we are proposing the exact same criteria for satisfactory reporting for the 2015 and 2016 payment adjustments that we are proposing for the 2013 and 2014 incentives, described in Tables 25 and 26, with the exception of one additional alternative criterion. Since we have already proposed satisfactory reporting criteria for the 2013 and 2014 incentives and the reporting periods for the respective 2013 and 2014 incentives and 2015 and 2016 payment adjustments coincide, we believe it is appropriate that the proposed criteria for the 2013 and 2014 respective incentives apply to satisfy the satisfactory reporting requirements for the 2015 and 2016 payment adjustments, respectively. Please note that these proposed criteria for the 2013 and 2014 PQRS incentives are the only criteria we are proposing to establish for the respective 2015 and 2016 PQRS payment adjustments for group practices using the GPRO web-interface.

With respect to individual eligible professionals also participating in the EHR Incentive Program, it is our intention to align our proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments with the criteria for meeting the CQM component of meaningful use applicable during the 2015 and 2016 PQRS payment adjustment reporting periods. For eligible professionals participating in PQRS and the EHR Incentive Program using a direct EHR product or EHR data submission vendor that is CEHRT, please note that since we are proposing to align our proposed EHR criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives with the proposed criteria for meeting the CQM component of meaningful use for CYs 2013 and 2014, if these proposals are established and we meet our goal of aligning the two programs, we note that an eligible professional meeting the CQM component of meaningful use during the PQRS 2015 and 2016 payment adjustment reporting periods using a direct EHR product or EHR data submission vendor that is CEHRT would be able to meet the requirements for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments by submitting a single set of data.

As a result of the overarching goals we have articulated above about encouraging participation and concern about eligible professionals' familiarity and experience with the program, we propose the following alternative criteria for satisfactory reporting during the 12-month reporting periods for the 2015 and 2016 payment adjustments for eligible professionals and group practices: report 1 measure or measures group using the claims, registry, or EHR-

based reporting mechanisms. We understand that this particular proposed alternative criterion for satisfactory reporting are significantly less stringent that the satisfactory reporting criteria we have proposed for the 2013 and 2014 incentives. However, we stress that we are proposing less stringent criteria only to ease eligible professionals and group practices who have not previously participated in PQRS into reporting. We note that we are only proposing these criteria for the 2015 and 2016 payment adjustments. As indicated in section III.G.5.c., for 2017 and beyond, we anticipate eliminating these alternative proposed criteria and establishing criteria that more closely resembles the proposed satisfactory reporting criteria for the 2013 and 2014 incentives.

With respect to group practices, section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration, we note that this proposed reporting criteria meets this standard, as the group practice would decide on which sample of patients to report. In these proposed criteria, the group practice would select the sample number, meaning the group could choose to report on all applicable patients or a certain number of patients to which the particular measure applied. Please note that, although the group practice may choose the sample, we anticipate that the sample the group practice selects would represent a sufficient picture of the beneficiaries the group practice sees. We invite public comment on the proposed criteria for satisfactory reporting for the 2015 and 2016 payment adjustments for eligible professionals and group practices using the claims, registry, EHR-based reporting mechanisms.

b. Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices Using the Administrative Claims-Based Reporting Mechanism

(1) Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices Using the Administrative Claims-Based Reporting Mechanism

Unlike the traditional PQRS claims-based reporting mechanism, the proposed administrative claims-based reporting mechanism does not require an eligible professional to submit quality data codes (QDCs) on Medicare Part B claims. Rather, using the administrative claims-based reporting mechanism only requires that an eligible professional or group practice submit Medicare claims to CMS. Since CMS, rather than the eligible professional or group practice, is performing the analysis and collecting the data provided in an eligible professional's or group practice's Medicare claims for an eligible professional's or group practice's Medicare beneficiaries, we believe it is appropriate to propose a reporting threshold that is more stringent than that proposed for the 2013 and 2014 incentives that use traditional PQRS reporting mechanisms. Therefore, we propose the following criteria for satisfactory reporting for the 12-month reporting periods for the 2015 and 2016 payment adjustments for eligible professionals and group practices using the administrative claims-based reporting mechanism: Report ALL measures in Table 63 for 100 percent of the cases in which the measures apply.

Section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We note that, although these criteria depart from the model used in the PGP demonstration, similar to our arguments for the satisfactory reporting criteria we are proposing for group practices using the claims, registry, and EHR-based reporting mechanisms, we believe that these criteria still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. We understand that, with these proposed criteria, the group practice provides claims data to CMS on 100 percent of its patients for which the measure applies. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the administrative claims measures apply. Therefore, even though a group practice who sees 100 patients during the applicable PQRS payment adjustment reporting period would report on 100 percent of patients to which the measure applies, not all of the proposed administrative claims measures would necessarily apply to all of the group practice's patients. Since the group practice is then only providing information on its applicable patients, we believe these reporting criteria would still meet the statistical sampling model requirement. We invite public comment on these proposed criteria.

When considering proposals for reporting criteria for the 2015 and 2016 PQRS payment adjustments, we considered satisfactory reporting options that would encourage eligible professionals and group practices to report for the 2013 and/or 2014 incentives but, should eligible professionals or group practices come up shy of meeting the 2013 and/or 2014 incentive reporting criteria, would still allow an eligible professional to meet the criteria for satisfactory reporting for the 2015 and/or 2016 payment adjustments. In lieu or more lenient satisfactory reporting criteria we proposed for the 2015 and 2016 payment adjustment, e.g. to report at least 1 measure or measures group or to elect the administrative claims-based reporting option, we considered the option of defaulting those eligible professionals who report but fail to meet the criteria for satisfactory reporting using the proposed criteria for the 2013 and/or 2014 incentives to the administrative claims-based reporting option. We would therefore analyze the claims of all eligible professionals who report at least 1 measure under a traditional reporting method during the respective 2015 and 2016 payment adjustment reporting periods under the administrative claims-based reporting option. We considered this proposal because it is our intention to encourage eligible professionals to report PQRS measures using the proposed reporting criteria for the 2013 and 2014 PQRS incentives. However, given our concern about new eligible professionals' familiarity and experience with the program, we believe it is necessary to propose an alternative, less stringent reporting option. We invite public comment on this considered proposal.

c. Proposed Analysis of Eligible Professionals and Group Practices Who Will Be Assessed a PQRS Payment Adjustment

As noted in § 414.90(b), an eligible professional is assessed at the TIN/NPI level and a group practice selected to participate in the GPRO is assessed at the TIN level. As there is a 1-year lapse in time between the end of a proposed respective payment adjustment reporting period and when an eligible professional is expected to receive a PQRS payment adjustment for not meeting the requirements for satisfactory reporting for the respective payment adjustment, we understand that an eligible professional may change his or her TIN/NPIs during this lapse of time. Likewise, a group practice selected to participate in the GPRO may change its TIN during this lapse in time. We believe this raises issues with regard to the subsequent application of the payment adjustment and concerns about the potential for abuse (e.g., ''gaming the

system''). Accordingly, we invite public comment this issue, including what parameters, if any, CMS should impose regarding the changes in TIN/NPIs and compositions of group practices with regard to the payment adjustment.

d. Criteria for Satisfactory Reporting for the Payment Adjustments for 2017 and Beyond for Eligible Professionals and Group Practices

We have stressed the importance of allowing eligible professionals and group practices who are new to the program to gain familiarity with PQRS's reporting requirements. However, we note that, as we move towards the sole implementation of payment adjustments (which would serve as the reporting period for the 2017 payment adjustment), it is our intention that eligible professionals would be expected to meet reporting criteria that more closely align to the reporting criteria that we have proposed for the 2014 incentives above. It is our expectation that in two years' time, eligible professionals who are new to PQRS would have enough familiarity with the program that CMS could reasonably expect a majority of participating eligible professionals to meet the requirements that are identical or very similar to those that have been required for incentive payment purposes. We invite public comment on goals for future criteria for satisfactory reporting we may require under the program for the 2017 payment adjustment that are identical or similar to the criteria we have proposed for the 2014 incentive payments. We also invite commenters to provide alternative criteria for us to consider in future rulemaking for the payment adjustments for 2017 and beyond.

6. PQRS Quality Measures for 2013 and Beyond

a. Statutory Requirements for the Selection of Proposed PQRS Quality Measures for 2013 and Beyond

Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently, that is the National Quality Forum, or NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, ''the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.''

The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) (that is, the NQF) and are silent for how the measures that are submitted to the NQF for endorsement were developed. The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, as amended by adding section 3014 of the Patient Protection and Affordable Care Act (PPACA), requires that the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently that, is the NQF) establish a multi-stakeholder group that would provide for a transparent process for selecting quality measures, such as the quality measures selected for reporting under the PQRS. Pursuant to section 3014 of Affordable Care Act, the NQF created the Measure Applications Partnership. Section 1890(b)(7)(B) requires that the Secretary establish a pre-rulemaking process whereby the multi-stakeholder group will provide input to the Secretary on the selection of quality measures. To receive input from the Measures Applications Partnership, we submitted all the measures we are proposing in this section with the exception of the administrative claims measures that we are incorporating to align with the Value-Based Modifier and the measures that we are incorporating to align with the Medicare Shared Savings Program specified in Tables 29 through 62. The list of measures the Measures Application Partnership have considered for 2012 are available at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

b. Other Considerations for the Selection of Proposed PQRS Quality Measures for 2013 and Beyond

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- High impact on healthcare.
- Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.
- Measures that address gaps in the quality of care delivered to Medicare beneficiaries.
- Address Gaps in the PQRS measure set.
- Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal).
- Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.).
- Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals.
- Measures groups that reflect the services furnished to beneficiaries by a particular specialty.

On October 7, 2011, we ended a Call for Measures that solicited new measures for possible inclusion in the PQRS for 2013 and beyond. During the Call for Measures, we solicited measures that were either consistent with section 1848(k)(2)(C) of the Act or fell under the exception specified in section 1848(k)(2)(C)(ii) of the Act. Although the deadline to submit measures for consideration for the 2013 PQRS

program year has ended, we invite public comment on future considerations related to the selection of new PQRS quality measures.

c. Proposed PQRS Quality Measures

This section focuses on the proposed PQRS individual Measures available for reporting via claims, registry, and/or EHR-based reporting for 2013 and beyond. To align with the proposed measure domains provided in the EHR Incentive Program (77 FR 13743), we classify all proposed measures against six domains based on the National Quality Strategy's six priorities, as follows:

(1) *Patient and Family Engagement.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self care, activation, and understanding of their health condition and its effective management.

(2) *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

(3) *Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families in order to improve appropriate and timely patient and care team communication.

(4) *Population and Public Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are especially focused on the leading causes of mortality. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

(5) *Efficient Use of Healthcare Resources.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

(6) *Clinical Processes/Effectiveness.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2012, please note that detailed measure specifications, including the measure's title, for the proposed individual PQRS quality measures for 2013 and beyond may have been updated or modified during the NQF endorsement process or for other reasons. In addition, due to our desire to align measure titles with the measure titles that were proposed for 2013, 2014, 2015, and potentially subsequent years of the EHR Incentive Program, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program updates its measure titles to include version numbers (77 FR 13744), we intend to use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program. We will continue to work toward complete alignment of measure specifications across programs whenever possible.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org*. We would provide sufficient lead time for [insert applicable party; i.e. hospitals, LTCHs, etc.] to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF—endorsed [insert name of applicable program] measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

To receive more information on the proposed measures contained in this section, including the measure specifications for these proposed measures, please contact the respective measure owners. Contact information for the measure owners of these proposed PQRS measures is available at the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

(1) Proposed PQRS Individual Core Measures Available for Claims, Qualified Registry, and EHR-Based Reporting for 2013 and Beyond

In 2011, the Department of Health and Human Services (HHS) started the Million Hearts Initiative, which is an initiative to prevent 1 million heart attacks and strokes in five years. We are dedicated to this initiative and seek to encourage eligible professionals to join in this endeavor. Therefore, based on our desire to support the Million Hearts initiative and maintain our focus on cardiovascular disease prevention, we are proposing the following proposed individual PQRS Core Measures specified in Table 29 for 2013 and beyond. Please note that these measures are the same measures we finalized under the 2012 PQRS in the CY 2012 Medicare PFS final rule (76 FR 73345).

TABLE 29: Proposed PQRS Individual Core Measures for 2013 and Beyond

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0064/ 2		Clinical Process/ Effective-ness	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA	X	X	X		X	HITECH Million Hearts
0068/ 204		Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic	NCQA	X	X	X	X	X	HITECH ACO Million Hearts
0028/ 226		Population /Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	X	X	X	X	X	HITECH ACO Million Hearts
0018/ 236		Clinical Process/ Effective-ness	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA	X	X	X	X	X	HITECH ACO Million Hearts
0075/ 241		Clinical Process/	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low**	NCQA	X	X	X	X	X	HITECH ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Effective-ness	**Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)							Million Hearts
N/A/ 316		Clinical Process/ Effective-ness	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent 2. Moderate Level of Risk: Multiple (2+) Risk Factors 3. Lowest Level of Risk: 0 or 1 Risk Factor	CMS/ QIP			X			HITECH Million Hearts
N/A/ 317		Population /Public Health	**Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 and older who are screened for high blood pressure	CMS/ QIP	X	X	X	X	X	HITECH ACO Million Hearts

*Measures that can be reported using the GPRO web interface.

¥ Titles and descriptions in this table are aligned with the proposed 2013 Physician Quality Reporting System Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

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Please note that, although we are proposing that the measures in Table 29 serve as core PQRS quality measures, we are not proposing to require that

eligible professionals report on these proposed PQRS core measures. We invite public comment on the proposed PQRS core measures for 2013 and beyond.

(2) Proposed PQRS quality measures Available for Reporting via the Claims, Qualified Registry, EHR, and GPRO Web-Interface Reporting Mechanisms for 2013 and Beyond

This section contains our proposals for individual PQRS quality measures for 2013 and beyond. Please note that, in large part, we are proposing to retain most of the quality measures we finalized for reporting for the 2012 PQRS (76 FR 42865 through 42872). However, in 2013 and 2014, we are proposing to include new measures, as well as remove measures that were available for reporting under the 2012 PQRS (not re-propose certain measures for 2013 and beyond). Table 30 specifies the measures we are proposing to be available for reporting under the PQRS for 2013 and beyond.

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TABLE 30: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR and/or the GPRO Web-Interface for 2013 and Beyond That Were NOT Available for Reporting under the 2012 PQRS

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
TBD/ TBD	Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure):** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke who arrive at the hospital within 4.5 hours of time last known well who were considered for t-PA administration	AMA-PCPI	X	X				
TBD/ TBD	Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure):** Percentage of all patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA, for whom t-PA was initiated within three hours of time last known well	AMA-PCPI	X	X				
0729/ TBD	Clinical Process/ Effective-ness	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: A1c < 8.0%, LDL < 100 mg/dL, blood pressure < 140/90 mmHg, tobacco non-user and for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated	MNCM				X		ACO
0658/ TBD	Care Coordina-tion	**Endoscopy and Polyp Surveillance: Appropriate Follow-Up Interval for Normal**	AMA-PCPI	X	X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Colonoscopy in Average Risk Patients: Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report							
0493/ TBD	Care Coordina-tion	**Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry b. Data elements are applicable to consensus endorsed quality measures c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure.	CMS/ QIP	X	X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		f. Registry may provide feedback directly to the provider's local registry if one exists							
0670/ TBD	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), or cardiovascular magnetic resonance (CMR) performed in low risk surgery patients for preoperative evaluation	ACC		X				
0671/ TBD	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and stress echo performed routinely after percutaneous cardiology intervention (PCI), with reference to timing of test after PCI and symptom status	ACC		X				
0672/ TBD	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac	ACC		X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients for intial detection and risk assessment							
TBD/ TBD	Clinical Process/ Effective-ness	**Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up:** Percentage of medical records of patients aged 18 years and older with a diagnosis of MDD and a diagnosed co-morbid condition being treated by another physician with communication to the other physician treating the co-morbid condition	AMA-PCPI		X				
TBD/ TBD	Care Coordina-tion	**Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up (Paired Measure):** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a diagnosed co-morbid condition with communication to another physician treating the co-morbid condition who have a response from the other physician within 45 days of original communication OR who have a follow-up attempt within 60 days of original communication by the physician treating MDD to elicit a response from the other physician	AMA-PCPI		X				
1525/ TBD	Patient Safety	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation**	AMA	X	X				HITECH

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Therapy: Percentage of patients aged 18 and older with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification, who were presecribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period							
TBD/ TBD	Clinical Process/ Effective-ness	**Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of end-stage renal disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	AMA/ ASPN	X	X				
1667/ TBD	Clinical Process/ Effective-ness	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL	AMA	X	X				

*Measures that can be reported using the GPRO web interface.

†These measures can only be reported by participants using the GPRO. They are not available for reporting for individual Eligible Professionals using this reporting method.

¥ Titles and descriptions in this table may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

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Although we are proposing to add measures that were not available for reporting under the 2012 PQRS, we note that we are not proposing to retain

certain measures from the 2012 PQRS. For reference, in Table 31 we list 14 measures from the 2012 PQRS that we are not proposing for the 2013 PQRS.

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TABLE 31: Measures Included in the 2012 PQRSs Measure Set that are Not Proposed to be Included in the Physician Quality Reporting Program Measure Set for 2013 and Beyond

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	CMS-Selected EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0246/ 10	Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports:** Percentage of final reports for CT or MRI studies of the brain performed either: • In the hospital within 24 hours of arrival, OR • In an outpatient imaging center to confirm initial diagnosis of stroke, transient ischemic attack (TIA) or intracranial hemorrhage For patients aged 18 years and older with either a diagnosis of ischemic stroke, TIA or intracranial hemorrhage OR at least one documented symptom consistent with ischemic stroke, TIA or intracranial hemorrhage that includes documentation of the presence or absence of each of the following: hemorrhage, mass lesion and acute infarction	AMA-PCPI/ NCQA	X	X				HITECH
0094/ 57	Clinical Process/ Effective-ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with oxygen saturation documented and reviewed	AMA-PCPI/ NCQA	X	X			X	
0095/58	Clinical Process/ Effective-ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Mental Status:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial	AMA-PCPI/ NCQA	X	X			X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	CMS-Selected EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		pneumonia with mental status assessed							
AQA adopted/ 92	Clinical Process/ Effectiveness	**Acute Otitis Externa (AOE): Pain Assessment:** Percentage of patient visits for those patients aged 2 years and older with a diagnosis of AOE with assessment for auricular or periauricular pain	AMA-PCPI	X	X				
0488/ 124	Care Coordination	**Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR):** Documents whether provider has adopted and is using health information technology. To report this measure, the eligible professional must have adopted and be using a certified, Physician Quality Reporting System qualified or other acceptable EHR system	CMS/ QIP	X	X				
0466/ 158	Clinical Process/ Effectiveness	**Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectomy:** Percentage of patients aged 18 years and older undergoing conventional (non-eversion) carotid endarterectomy (CEA) who undergo patch closure of the arteriotomy	SVS	X	X				
AQA adopted/ 186	Clinical Process/ Effectiveness	**Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers:** Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who were prescribed compression therapy within the 12-month reporting period	AMA-PCPI/ NCQA	X	X				
N/A/ 189	Care Coordination	**Referral for Otologic Evaluation for Patients with History of Active Drainage from the Ear Within the Previous 90 Days:** Percentage of	AQC	X	X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	CMS-Selected EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		patients aged birth and older who have disease of the ear and mastoid processes referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a history of active drainage from the ear within the previous 90 days							
N/A/ 190	Care Coordination	**Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation immediately following an audiologic evaluation that verifies and documents sudden or rapidly progressive hearing loss	AQC	X	X				
0065/ 196	Clinical Process/ Effectiveness	**Coronary Artery Disease (CAD): Symptom and Activity Assessment:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period for whom there are documented results of an evaluation of level of activity AND an evaluation of presence or absence of anginal symptoms in the medical record	AMA-PCPI/ ACCF /AHA		X			X	
0082/ 199	Clinical Process/ Effectiveness	**Heart Failure: Patient Education:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior	CMS/ QIP				X		

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	CMS-Selected EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		changes during one or more visit(s) within 12 months							
0447/ 212	Care Coordination	**Functional Communication Measure - Motor Speech:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure	ASHA		X				
0017/ 235	Clinical Process/ Effectiveness	**Hypertension (HTN): Plan of Care:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN during which either systolic blood pressure ≥ 140 mmHg OR diastolic blood pressure ≥ 90mm Hg, with documented plan of care for hypertension	CMS/ QIP	X	X				
0502/ 253	Clinical Process/ Effectiveness	**Pregnancy Test for Female Abdominal Pain Patients:** Percentage of female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain for whom a pregnancy test ordered	ACEP	X	X				

*Measures that can be reported using the GPRO web interface.

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

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A summary of the measures we are proposing for 2013 and beyond are specified in Table 32. Table 32 specifies our proposals to propose all measures that were available for reporting in PQRS in 2012, with the exception of the measures listed in Table 31, as well as propose new measures specified in Table 30 not available for reporting under PQRS in prior years.

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TABLE 32: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR, or GRPO Web-Interface for 2013 and Beyond

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0059/ 1		Clinical Process/ Effective-ness	**Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQA	X	X	X	X	X	HITECH ACO
0064/ 2		Clinical Process/ Effective ness	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA	X	X	X		X	HITECH Million Hearts
0061/ 3		Clinical Process/ Effective-ness	**Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA	X	X	X		X	HITECH
0081/ 5		Clinical Process/ Effective-ness	**Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular**	AMA-PCPI/ ACCF/ AHA		X	X		X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy							
0067/ 6		Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel	AMA-PCPI/ ACCF/ AHA	X	X	X		X	
0070/ 7		Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI):** Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy	AMA-PCPI/ ACCF/ AHA		X	X			HITECH
0083/ 8		Clinical Process/ Effective-ness	**Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart	AMA-PCPI/ ACCF/ AHA		X	X	X	X	HITECH ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy							
0105/ 9		Clinical Process/ Effective-ness	**Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment:** The percentage of patients 18 years of age and older who were diagnosed with a new episode of major depression, treated with antidepressant medication, and who remained on an antidepressant medication treatment	NCQA	X	X	X			HITECH
0086/ 12		Clinical Process/ Effective-ness	**Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of POAG who have an optic nerve head evaluation during one or more office visits within 12 months	AMA-PCPI/ NCQA	X	X	X			HITECH
0087/ 14		Clinical Process/ Effective-ness	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			of AMD who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months							
0088/ 18		Clinical Process/ Effective-ness	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months	AMA-PCPI/ NCQA	X	X	X			HITECH
0089/ 19		Clinical Process/ Effective-ness	**Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care:** Percentage of patients aged 18 years and older	AMA-PCPI/ NCQA	X	X	X			HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the on-going care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months							
0270/ 20		Patient Safety	**Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA-PCPI/ NCQA	X	X			X	
0268/ 21		Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation**	AMA-PCPI/ NCQA	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis							
0271/ 22		Patient Safety	**Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time	AMA-PCPI/ NCQA	X	X			X	
0239/ 23		Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis**	AMA-PCPI/ NCQA	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			(When Indicated in ALL Patients): Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time							
0045/ 24		Care Coordina-tion	**Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			should be tested or treated for osteoporosis							
0092/ 28		Clinical Process/ Effective-ness	**Aspirin at Arrival for Acute Myocardial Infarction (AMI):** Percentage of patients, regardless of age, with an emergency department discharge diagnosis of AMI who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay	AMA-PCPI/ NCQA	X	X				
0269/ 30		Patient Safety	**Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics:** Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures with the indications for prophylactic parenteral antibiotics for whom administration of the prophylactic parenteral antibiotic ordered has been initiated within one hour (if fluoroquinolone or vancomycin, two hours) prior to the surgical	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			incision (or start of procedure when no incision is required)							
0240/ 31		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Deep Vein Thrombosis (DVT) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered DVT prophylaxis by end of hospital day two	AMA-PCPI/ NCQA	X	X				
0325/ 32		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) who were prescribed antithrombotic therapy at discharge	AMA-PCPI/ NCQA	X	X				
0241/ 33		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of	AMA-PCPI/ NCQA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge							
0243/ 35		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Screening for Dysphagia:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the institution in which the patient is receiving care	AMA-PCPI/ NCQA	X	X				
0244/ 36		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge							
0046/ 39		Clinical Process/ Effective-ness	**Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA-PCPI/ NCQA	X	X	X		X	
0048/ 40		Clinical Process/ Effective-ness	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			prescribed							
0049/ 41		Clinical Process/ Effective-ness	**Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months	AMA-PCPI/ NCQA	X	X				
0134/ 43		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery using an IMA graft	STS	X	X			X	
0236/ 44		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received a beta-blocker within 24 hours prior to surgical incision	CMS/ QIP	X	X			X	
0637/ 45		Patient Safety	**Perioperative Care: Discontinuation of**	AMA-PCPI/	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Prophylactic Antibiotics (Cardiac Procedures): Percentage of cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 48 hours of surgical end time	NCQA						
0097/ 46		Patient Safety	**Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented	AMA-PCPI/ NCQA	X	X		X		ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0326/47		Care Coordination	**Advanced Care Plan:** Percentage of patients aged 65 years and older who have an advanced care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advanced care plan	AMA-PCPI/ NCQA	X	X	X			
0098/ 48		Clinical Process/ Effectiveness	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	AMA-PCPI/ NCQA	X	X	X		X	
0099/ 49		Clinical Process/ Effectiveness	**Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			incontinence whose urinary incontinence was characterized at least once within 12 months							
0100/ 50		Patient and Family Engagement	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months	AMA-PCPI/ NCQA	X	X				
0091/ 51		Clinical Process/ Effective-ness	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA-PCPI	X	X			X	
0102/ 52		Clinical Process/ Effective-ness	**Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who	AMA-PCPI	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			were prescribed an inhaled bronchodilator							
0047/ 53		Clinical Process/ Effective-ness	**Asthma: Pharmacologic Therapy for Persistent Asthma:** Percentage of patients aged 5 through 50 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment	AMA-PCPI/ NCQA	X	X	X		X	
0090/ 54		Clinical Process/ Effective-ness	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain:** Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead ECG performed	AMA-PCPI/ NCQA	X	X				
0093/ 55		Clinical Process/ Effective-ness	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope:** Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			had a 12-lead ECG performed							
0232/ 56		Clinical Process/ Effective-ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Vital Signs:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with vital signs documented and reviewed	AMA-PCPI/ NCQA	X	X				
0096/ 59		Clinical Process/ Effective-ness	**Emergency Medicine: Community-Acquired Pneumonia (CAP): Empiric Antibiotic:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with an appropriate empiric antibiotic prescribed	AMA-PCPI/ NCQA	X	X				
0001/ 64		Clinical Process/ Effective-ness	**Asthma: Assessment of Asthma Control:** Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms	AMA-PCPI/ NCQA	X	X	X		X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0069/ 65		Efficient Use of Healthcare Resources	**Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use:** Percentage of children aged 3 months through 18 years with a diagnosis of URI who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service	NCQA	X	X				HITECH
0002/ 66		Efficient Use of Healthcare Resources	**Appropriate Testing for Children with Pharyngitis:** Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode	NCQA	X	X	X			HITECH
0377/ 67		Clinical Process/ Effective-ness	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia who had baseline	AMA-PCPI/ ASH	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			cytogenetic testing performed on bone marrow							
0378/ 68		Clinical Process/ Effective-ness	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy	AMA-PCPI/ ASH	X	X				
0380/ 69		Clinical Process/ Effective-ness	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period	AMA-PCPI/ ASH	X	X				
0379/ 70		Clinical Process/ Effective-ness	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry:** Percentage of	AMA-PCPI/ ASH	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			patients aged 18 years and older with a diagnosis of CLL who had baseline flow cytometry studies performed							
0387/ 71		Clinical Process/ Effective-ness	**Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN	X	X	X		X	HITECH
0385/ 72		Clinical Process/ Effective-ness	**Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients:** Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN	X	X	X		X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0464/ 76		Patient Safety	**Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol:** Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed	AMA-PCPI	X	X				
0323/ 81		Care Coordina-tion	**Adult Kidney Disease: Hemodialysis Adequacy: Solute:** Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week who have a spKt/V $\geq$ 1.2	AMA-PCPI		X				
0321/ 82		Care Coordina-tion	**Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients	AMA-PCPI		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months							
0393/ 83		Clinical Process/ Effective-ness	**Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed	AMA-PCPI		X				
0395/ 84		Clinical Process/ Effective-ness	**Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	AMA-PCPI	X	X			X	
0396/ 85		Clinical Process/ Effective-ness	**Hepatitis C: HCV Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years	AMA-PCPI	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment							
0397/ 86		Clinical Process/ Effective-ness	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period	AMA-PCPI	X	X			X	
0398/ 87		Clinical Process/ Effective-ness	**Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	AMA-PCPI	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0401/ 89		Clinical Process/ Effective-ness	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months	AMA-PCPI	X	X			X	
0394/ 90		Clinical Process/ Effective-ness	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment	AMA-PCPI	X	X			X	
0653/ 91		Clinical Process/ Effective-ness	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	AMA-PCPI	X	X				
0654/ 93		Care Coordina-tion	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of**	AMA-PCPI	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy							
0391/ 99		Clinical Process/ Effective-ness	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade	AMA-PCPI/ CAP	X	X				
0392/ 100		Clinical Process/ Effective-ness	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	AMA-PCPI/ CAP	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0389/ 102		Efficient Use of Healthcare Resources	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	AMA-PCPI	X	X	X			HITECH
0390/ 104		Clinical Process/ Effective-ness	**Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist)	AMA-PCPI	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0388/ 105		Patient Safety	**Prostate Cancer: Three Dimensional (3D) Radiotherapy:** Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT)	AMA-PCPI	X	X				
0103/ 106		Clinical Process/ Effective-ness	**Major Depressive Disorder (MDD): Diagnostic Evaluation:** Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who met the DSM-IV criteria during the visit in which the new diagnosis or recurrent episode was identified during the measurement period	AMA-PCPI	X	X				
0104/ 107		Clinical Process/ Effective-ness	**Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years	AMA-PCPI	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			and older with a new diagnosis or recurrent episode of MDD who had a suicide risk assessment completed at each visit during the measurement period							
0054/ 108		Clinical Process/ Effective-ness	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD	NCQA	X	X			X	
0050/ 109		Patient and Family Engagement	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with assessment for function and pain	AMA-PCPI	X	X				
0041/ 110		Population/ Public Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31)	AMA-PCPI	X	X	X	X	X	HITECH ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0043/ 111		Clinical Process/ Effective-ness	**Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA	X	X	X	X	X	HITECH ACO
0031/ 112		Clinical Process/ Effective-ness	**Preventive Care and Screening: Screening Mammography:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer	NCQA	X	X	X	X	X	HITECH ACO
0034/ 113		Clinical Process/ Effective-ness	**Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening	NCQA	X	X	X	X	X	HITECH ACO
0058/ 116		Efficient Use of Healthcare Resources	**Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use:** Percentage of adults aged 18 through 64 years with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service	NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0055/ 117		Clinical Process/ Effective-ness	**Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam	NCQA	X	X	X		X	HITECH
0066/ 118		Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior LVEF < 40% who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ ACCF/ AHA		X		X		ACO
0062/ 119		Clinical Process/ Effective-ness	**Diabetes: Urine Screening:** Percentage of patients aged 18 through 75 years with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy	NCQA	X	X	X		X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
AQA adopted/ 121		Clinical Process/ Effective-ness	**Adult Kidney: Disease Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	AMA-PCPI	X	X			X	
AQA adopted/ 122		Clinical Process/ Effective-ness	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care	AMA-PCPI	X	X			X	
AQA adopted/ 123		Clinical Process/ Effective-ness	**Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL:** Percentage of calendar months within a 12-month period during which a Hemoglobin level	AMA-PCPI	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			is measured for patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy AND have a Hemoglobin level > 12.0 g/dL							
0417/ 126		Clinical Process/ Effective-ness	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months	APMA	X	X				
0416/ 127		Clinical Process/ Effective-ness	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who	APMA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			were evaluated for proper footwear and sizing							
0421/ 128		Population/ Public Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18 – 64 years BMI ≥ 18.5 and < 25.	CMS/ QIP	X	X	X	X	X	HITECH ACO
0419/ 130		Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals,	CMS/ QIP	X	X			X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route							
0420/ 131		Population/ Public Health	**Pain Assessment and Follow-Up:** Percentage of patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	CMS/ QIP	X	X				
0418/ 134		Population/ Public Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool AND follow-up plan documented	CMS/ QIP	X	X		X		HITECH ACO
0650/ 137		Clinical Process/ Effective-ness	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose	AMA-PCPI/ NCQA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment							
0561/ 138		Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of patient age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis	AMA-PCPI/ NCQA		X				
0566/ 140		Clinical Process/ Effectiveness	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of AMD and/or their caregiver(s) who were counseled within 12	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD							
0563/ 141		Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of POAG whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months	AMA-PCPI/ NCQA	X	X				
0051/ 142		Clinical Process/ Effectiveness	**Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with an assessment	AMA-PCPI	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			for use of anti-inflammatory or analgesic OTC medications							
0384/ 143		Patient and Family Engagement	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA-PCPI		X			X	HITECH
0383/ 144		Patient and Family Engagement	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	AMA-PCPI		X			X	
0510/ 145		Patient Safety	**Radiology: Exposure Time Reported for Procedures Using Fluoroscopy:** Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0508/ 146		Efficient Use of Healthcare Resources	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign"	AMA-PCPI/ NCQA	X	X				
0511/ 147		Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	AMA-PCPI	X	X				
0322/ 148		Efficient Use of Healthcare Resources	**Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain	NCQA					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0319/ 149		Clinical Process/ Effective-ness	**Back Pain: Physical Exam:** Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain	NCQA					X	
0314/ 150		Clinical Process/ Effective-ness	**Back Pain: Advice for Normal Activities:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain	NCQA					X	
0313/ 151		Clinical Process/ Effective-ness	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain	NCQA					X	
AQA adopted/ 154		Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			with a history of falls who had a risk assessment for falls completed within 12 months							
AQA adopted/ 155		Care Coordina-tion	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	AMA-PCPI/ NCQA	X	X				
0382/ 156		Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues	AMA-PCPI	X	X				
0455/ 157		Patient Safety	**Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal Cancer Resection:** Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal	STS	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			cancer who had clinical staging provided prior to surgery							
0404/ 159		Clinical Process/ Effective-ness	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage:** Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months	AMA-PCPI/ NCQA		X			X	
0405/ 160		Clinical Process/ Effective-ness	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count	AMA-PCPI/ NCQA		X			X	HITECH
0406/ 161		Clinical Process/ Effective-ness	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+	AMA-PCPI/ NCQA		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			cell count below 350/mm3 or who have a history of an AIDS- defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy							
0407/ 162		Clinical Process/ Effective-ness	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care	AMA-PCPI/ NCQA		X			X	HITECH
0056/ 163		Clinical Process/ Effective-ness	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes	NCQA	X	X	X		X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			who had a foot examination							
0129/ 164		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require intubation > 24 hours	STS		X			X	
0130/ 165		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection (involving muscle, bone, and/or mediastinum requiring operative intervention)	STS		X			X	
0131/ 166		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood	STS		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			supply to the brain) that did not resolve within 24 hours							
0114/ 167		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	STS		X			X	
0115/ 168		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	STS		X			X	
0116/ 169		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older	STS		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			undergoing isolated CABG surgery who were discharged on antiplatelet medication							
0117/ 170		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers	STS		X			X	
0118/ 171		Clinical Process/ Effective-ness	**Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen	STS		X			X	
0259/ 172		Clinical Process/ Effective-ness	**Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula:** Percentage of patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5) or End Stage Renal Disease (ESRD) requiring	SVS	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			hemodialysis vascular access documented by surgeon to have received autogenous AV fistula							
AQA adopted/ 173		Population/ Public Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	AMA-PCPI	X	X	X		X	
AQA adopted/ 176		Clinical Process/ Effective-ness	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)	AMA-PCPI/ NCQA	X	X			X	
AQA adopted/ 177		Clinical Process/ Effective-ness	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an	AMA-PCPI/ NCQA	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			assessment and classification of disease activity within 12 months							
AQA adopted/ 178		Clinical Process/ Effective-ness	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	AMA-PCPI/ NCQA	X	X			X	
AQA adopted/ 179		Clinical Process/ Effective-ness	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	AMA-PCPI/ NCQA	X	X			X	
AQA adopted/ 180		Care Coordina-tion	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no	AMA-PCPI/ NCQA	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			change in disease activity, documentation of glucocorticoid management plan within 12 months							
AQA adopted/ 181		Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with documentation of a screen for elder maltreatment AND documented follow-up plan	CMS/ QIP	X	X				
AQA adopted/ 182		Care Coordina-tion	**Functional Outcome Assessment:** Percentage of patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool AND documentation of a care plan based on identified functional outcome deficiencies	CMS/ QIP	X	X				
0399/ 183		Population/ Public Health	**Hepatitis C: Hepatitis A Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented	AMA-PCPI	X	X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			immunity to hepatitis A							
0400/ 184		Population/ Public Health	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	AMA-PCPI	X	X			X	
0659/ 185		Care Coordina-tion	**Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy with a history of colonic polyp(s) in a previous colonoscopy, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report	AMA-PCPI/ NCQA	X	X				
0437/ 187		Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who	AHA/ ASA/TJC		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well							
N/A/ 188		Care Coordina-tion	**Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a congenital or traumatic deformity of the ear (internal or external)	AQC	X	X				
0565/ 191		Clinical Process/ Effective-ness	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery	AMA-PCPI/ NCQA		X			X	HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery							
0564/ 192		Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	AMA-PCPI/ NCQA		X			X	HITECH
0454/ 193		Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial	AMA-PCPI	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom *either* active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time							
0386/ 194		Clinical Process/ Effective-ness	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months	AMA-PCPI/ ASCO	X	X			X	
0507/ 195		Clinical Process/ Effective-ness	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for all patients, regardless	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			of age, for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement							
0074/ 197		Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin	AMA-PCPI/ ACCF/ AHA		X	X	X	X	ACO
0079/ 198		Clinical Process/ Effective-ness	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis	AMA-PCPI/ ACCF/ AHA		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			of heart failure for whom the quantitative or qualitative result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period							
0084/ 200		Clinical Process/ Effective-ness	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy	AMA-PCPI/ ACCF/ A HA			X			
0073/ 201		Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Blood Pressure Management Control:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA	X	X	X		X	HITECH
0068/ 204		Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with	NCQA	X	X	X	X	X	HITECH ACO Million Hearts

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			documented use of aspirin or other antithrombotic							
0409/ 205		Clinical Process/ Effective-ness	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection	AMA-PCPI/ NCQA		X			X	
0413/ 206		Clinical Process/ Effective-ness	**HIV/AIDS: Screening for High Risk Sexual Behaviors:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for high risk sexual behaviors at least once within 12 months	AMA-PCPI/ NCQA		X			X	
0415/ 207		Clinical Process/ Effective-ness	**HIV/AIDS: Screening for Injection Drug Use:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for injection drug use at least once within 12 months	AMA-PCPI/ NCQA		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0410/ 208		Clinical Process/ Effective-ness	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months	AMA-PCPI/ NCQA		X			X	
0445/ 209		Care Coordina-tion	**Functional Communication Measure - Spoken Language Comprehension:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Comprehension Functional Communication Measure	ASHA		X				
0449/ 210		Care Coordina-tion	**Functional Communication Measure – Attention:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure	ASHA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0448/ 211		Care Coordina-tion	**Functional Communication Measure – Memory:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure	ASHA		X				
0446/ 213		Care Coordina-tion	**Functional Communication Measure – Reading:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure	ASHA		X				
0444/ 214		Care Coordina-tion	**Functional Communication Measure - Spoken Language Expression:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Expression Functional Communication Measure	ASHA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0442/ 215		Care Coordination	**Functional Communication Measure – Writing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure	ASHA		X				
0443/ 216		Care Coordination	**Functional Communication Measure – Swallowing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure	ASHA		X				
0422/ 217		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0423/ 218		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0424/ 219		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0425/ 220		Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments:** Percentage	FOTO		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured							
0426/ 221		Care Coordina-tion	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk- Adjusted Functional Status is measured	FOTO		X				
0427/ 222		Care Coordina-tion	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their	FOTO		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Risk-Adjusted Functional Status is measured							
0428/ 223		Care Coordina-tion	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured	FOTO		X				
0562/ 224		Efficient Use of Healthcare Resources	**Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma, without signs or symptoms, seen for an office visit during the one-year measurement period, for whom no diagnostic	AMA-PCPI/ NCQA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			imaging studies were ordered							
0509/ 225		Care Coordination	**Radiology: Reminder System for Mammograms:** Percentage of patients aged 40 years and older undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram	AMA-PCPI/ NCQA	X	X				
0028/ 226		Population/ Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	X	X	X	X	X	HITECH ACO Million Hearts
N/A/ 228		Clinical Process/ Effectiveness	**Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with LVF testing performed during the measurement period for patients hospitalized with a principal diagnosis of HF during the reporting	CMS/ QIP		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			period							
N/A/ 231		Clinical Process/ Effective-ness	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period	AMA-PCPI/ NCQA	X	X			X	
N/A/ 232		Clinical Process/ Effective-ness	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period	AMA-PCPI/ NCQA	X	X			X	
0457/ 233		Clinical Process/	**Thoracic Surgery: Recording of**	STS		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Effective-ness	**Performance Status Prior to Lung or Esophageal Cancer Resection:** Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer who had performance status documented and reviewed within 2 weeks prior to surgery							
0458/ 234		Patient Safety	**Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy):** Percentage of thoracic surgical patients aged 18 years and older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy)	STS		X				
0018/ 236		Clinical Process/ Effective-ness	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension	NCQA	X	X	X	X	X	HITECH ACO Million Hearts

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			(HTN) and whose BP was adequately controlled (< 140/90 mmHg)							
0013/ 237		Clinical Process/ Effective-ness	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded	AMA-PCPI			X			
0022/ 238		Patient Safety	**Drugs to be Avoided in the Elderly:** Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly and/or two different drugs to be avoided in the elderly in the measurement period	NCQA			X			HITECH
0024/ 239		Population/ Public Health	**Weight Assessment and Counseling for Children and Adolescents:** Percentage of children 2 through 17 years of age who had an outpatient visit with a PCP or OB/GYN and who had evidence of BMI percentile documentation, counseling for nutrition and counseling for physical activity during the measurement period	NCQA			X			HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0038/ 240		Population/ Public Health	**Childhood Immunization Status:** The percentage of children two years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps, rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	NCQA			X			HITECH
0075/ 241		Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA	X	X	X	X	X	HITECH ACO Million Hearts
N/A/ 242		Clinical Process/	**Coronary Artery Disease (CAD): Symptom**	AMA-PCPI/		X			X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Effective-ness	**Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period and with results of an evaluation of level of activity AND an assessment for the presence *or* absence of anginal symptoms, with a plan of care to manage anginal symptoms, if present	ACCF/ AHA						
0643/ 243		Clinical Process/ Effective-ness	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the past 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program	ACCF-AHA		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			for the qualifying event/diagnosis who were referred to a CR program							
N/A/ 244		Clinical Process/ Effective-ness	**Hypertension: Blood Pressure Management:** Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti-hypertensive medications during the most recent office visit	AMA-PCPI/ ACCF/ AHA		X				
AQA adopted/ 245		Clinical Process/ Effective-ness	**Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without the use of a wound surface culture technique	AMA-PCPI/ NCQA	X	X				
AQA adopted/ 246		Clinical Process/ Effective-ness	**Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			chronic skin ulcer without a prescription or recommendation to use wet to dry dressings							
AQA adopted/ 247		Clinical Process/ Effective-ness	**Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12-month reporting period	AMA-PCPI/ NCQA	X	X				
AQA adopted/ 248		Clinical Process/ Effective-ness	**Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period	AMA-PCPI/ NCQA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 249		Clinical Process/ Effective-ness	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia	CAP	X	X				
N/A/ 250		Clinical Process/ Effective-ness	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status	CAP	X	X				
N/A/ 251		Clinical Process/ Effective-ness	**Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	CAP	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0503/ 252		Clinical Process/ Effective-ness	**Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus	ACEP	X	X				
0651/ 254		Clinical Process/ Effective-ness	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location	ACEP	X	X				
0652/ 255		Clinical Process/ Effective-ness	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-	ACEP	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Immunoglobulin (Rhogam) in the emergency department (ED)							
N/A/ 256		Care Coordination	**Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR):** Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR) who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status	SVS		X				
N/A/ 257		Clinical Process/ Effectiveness	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge	SVS		X				
N/A/ 258		Care Coordination	**Rate of Open Elective Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major**	SVS		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Complications (Discharged to Home by Post-Operative Day #7): Percent of patients undergoing open repair of small or moderate sized abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7)							
N/A/ 259		Care Coordina-tion	**Rate of Elective Endovascular Aortic Repair (EVAR) of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	SVS		X				
N/A/ 260		Care Coordina-tion	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home**	SVS		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Post-Operative Day #2): Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2							
N/A/ 261		Care Coordina-tion	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness	AQC	X	X				
N/A/ 262		Patient Safety	**Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion,	ASBS	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.							
N/A/ 263		Clinical Process/ Effective-ness	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method (excludes open/incisional biopsies)	ASBS	X	X				
N/A/ 264		Clinical Process/ Effective-ness	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure	ASBS		X				
0645/ 265		Care Coordina-tion	**Biopsy Follow-Up:** Percentage of patients whose biopsy results have	AAD		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			been reviewed and communicated to the primary care/referring physician and patient by the performing physician							
N/A/ 266		Clinical Process/ Effective-ness	**Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies):** Percentage of patient visits with a diagnosis of epilepsy who had the type(s) of seizure(s) and current seizure frequency(ies) for each seizure type documented in the medical record	AAN	X	X				
N/A/ 267		Clinical Process/ Effective-ness	**Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome:** All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic	AAN	X	X				
N/A/ 268		Clinical Process/ Effective-ness	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12-44 years old) diagnosed with epilepsy who were counseled about epilepsy	AAN	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			and how its treatment may affect contraception and pregnancy at least once a year							
N/A/ 269		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period	AGA					X	
N/A/ 270		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year	AGA					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 271		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year	AGA					X	
N/A/ 272		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year	AGA					X	
N/A/ 273		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal**	AGA					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received							
N/A/ 274		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA					X	
N/A/ 275		Clinical Process/ Effective-ness	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older	AGA					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy							
N/A/ 276		Clinical Process/ Effective-ness	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of symptoms, including presence or absence of snoring and daytime sleepiness	AMA-PCPI/ NCQA					X	
N/A/ 277		Clinical Process/ Effective-ness	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	AMA-PCPI/ NCQA					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 278		Clinical Process/ Effective-ness	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	AMA-PCPI/ NCQA					X	
N/A/ 279		Clinical Process/ Effective-ness	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	AMA-PCPI/ NCQA					X	
N/A/ 280		Care Coordina-tion	**Dementia: Staging of Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period	AMA-PCPI					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 281		Clinical Process/ Effective-ness	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	AMA-PCPI					X	HITECH
N/A/ 282		Clinical Process/ Effective-ness	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period	AMA-PCPI					X	
N/A/ 283		Clinical Process/ Effective-ness	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	AMA-PCPI					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 284		Clinical Process/ Effective-ness	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	AMA-PCPI					X	
N/A/ 285		Clinical Process/ Effective-ness	**Dementia: Screening for Depressive Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period	AMA-PCPI					X	
N/A/ 286		Patient Safety	**Dementia: Counseling Regarding Safety Concerns:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	AMA-PCPI					X	
N/A/ 287		Clinical Process/ Effective-ness	**Dementia: Counseling Regarding Risks of Driving:** Percentage of patients, regardless of age,	AMA-PCPI					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and driving alternatives within a 12 month period							
N/A/ 288		Clinical Process/ Effective-ness	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	AMA-PCPI					X	
N/A/ 289		Clinical Process/ Effective-ness	**Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review:** All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications than can produce Parkinson- like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease	AAN					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually							
N/A/ 290		Clinical Process/ Effective-ness	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	AAN					X	
N/A/ 291		Clinical Process/ Effective-ness	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually	AAN					X	
N/A/ 292		Clinical Process/ Effective-ness	**Parkinson's Disease: Querying about Sleep Disturbances:** All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about	AAN					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			sleep disturbances at least annually							
N/A/ 293		Clinical Process/ Effective-ness	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	AAN					X	
N/A/ 294		Clinical Process/ Effective-ness	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	AAN					X	
N/A/ 295		Clinical Process/ Effective-ness	**Hypertension: Appropriate Use of Aspirin or Other Antiplatelet or Anticoagulant Therapy:** Percentage of patients	ABIM					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			aged 15 through 90 years old with a diagnosis of hypertension who were prescribed aspirin or other anticoagulant/antiplatelet therapy							
N/A/ 296		Clinical Process/ Effective-ness	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 24 months	ABIM					X	
N/A/ 297		Clinical Process/ Effective-ness	**Hypertension: Urine Protein Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months	ABIM					X	
N/A/ 298		Clinical Process/ Effective-ness	**Hypertension: Annual Serum Creatinine Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months	ABIM					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 299		Clinical Process/ Effective-ness	**Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months	ABIM					X	
N/A/ 300		Clinical Process/ Effective-ness	**Hypertension: Blood Pressure Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (at goal)	ABIM					X	
N/A/ 301		Clinical Process/ Effective-ness	**Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal)	ABIM					X	
N/A/ 302		Clinical Process/ Effective-ness	**Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received dietary and	ABIM					X	

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			physical activity counseling at least once within 12 months							
N/A/ 303		Clinical Process/ Effective-ness	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	AAO		X			X	
N/A/ 304		Patient and Family Engagement	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	AAO		X			X	
0004/ 305		Clinical Process/	**Initiation and Engagement of Alcohol**	NCQA			X			HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
		Effective-ness	**and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement:** Percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis and who initiated treatment AND who had two or more additional services with an AOD diagnosis within 30 days of the initial visit							
0012/ 306		Population/ Public Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit	AMA-PCPI			X			
0014/ 307		Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age,	AMA-PCPI			X			

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation							
0027/ 308		Population/ Public Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies	NCQA			X			
0032/ 309		Clinical Process/ Effective-ness	**Cervical Cancer Screening:** Percentage of women aged 21 through 63 years who received one or more Pap tests to screen for cervical cancer	NCQA			X			HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0033/ 310		Population/ Public Health	**Chlamydia Screening for Women:** Percentage of women aged 15 through 24 years who were identified as sexually active and who had at least one test for chlamydia during the measurement year	NCQA			X			HITECH
0036/ 311		Clinical Process/ Effective-ness	**Use of Appropriate Medications for Asthma:** Percentage of patients aged 5 through 50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year	NCQA			X			HITECH
0052/ 312		Efficient Use of Healthcare Resources	**Low Back Pain: Use of Imaging Studies:** Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of diagnosis	NCQA			X			HITECH
0575/ 313		Clinical Process/ Effective-ness	**Diabetes Mellitus: Hemoglobin A1c Control (<8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8%	NCQA			X			

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
N/A/ 316		Clinical Process/ Effective-ness	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent 2. Moderate Level of Risk: Multiple (2+) Risk Factors 3. Lowest Level of Risk: 0 or 1 Risk Factor	CMS/ QIP			X			HITECH Million Hearts
N/A/ 317		Population/ Public Health	**Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 and older who are screened for high blood pressure	CMS/ QIP	X	X	X	X	X	HITECH ACO Million Hearts
0101/ 318		Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients aged 65 years and older who were screened for	AMA-PCPI/ NCQA				X		HITECH ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			future fall risk at least once within 12 months							
TBD/ TBD	X	Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure):** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke who arrive at the hospital within 4.5 hours of time last known well who were considered for t-PA administration	AMA-PCPI	X	X				
TBD/ TBD	X	Clinical Process/ Effective-ness	**Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure):** Percentage of all patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA, for whom t-PA was initiated within three hours of time last known well	AMA-PCPI	X	X				
0729/ TBD	X	Clinical Process/ Effective-ness	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of	MNCM				X		ACO

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			diabetes, who meet all the numerator targets of this composite measure: A1c < 8.0%, LDL < 100 mg/dL, blood pressure < 140/90 mmHg, tobacco non-user and for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated							
0658/ TBD	X	Care Coordina-tion	**Endoscopy and Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report	AMA-PCPI	X	X				
0493/ TBD	X	Care Coordina-tion	**Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified	CMS/ QIP	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry b. Data elements are applicable to consensus endorsed quality measures c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure. f. Registry may provide feedback directly to the provider's local registry if								

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			one exists							
0670/ TBD	X	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), or cardiovascular magnetic resonance (CMR) performed in low risk surgery patients for preoperative evaluation	ACC		X				
0671/ TBD	X	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and stress echo performed routinely after percutaneous cardiology intervention (PCI), with	ACC		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			reference to timing of test after PCI and symptom status							
0672/ TBD	X	Efficient Use of Healthcare Resources	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients for intial detection and risk assessment	ACC		X				
TBD/ TBD	X	Clinical Process/ Effective-ness	**Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up:** Percentage of medical records of patients aged 18 years and older with a diagnosis of MDD and a diagnosed co-morbid condition being treated by	AMA-PCPI		X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			another physician with communication to the other physician treating the co-morbid condition							
TBD/ TBD	X	Care Coordina-tion	**Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up (Paired Measure):** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a diagnosed co-morbid condition with communication to another physician treating the co-morbid condition who have a response from the other physician within 45 days of original communication OR who have a follow-up attempt within 60 days of original communication by the physician treating MDD to elicit a response from the other physician	AMA-PCPI		X				
1525/ TBD	X	Patient Safety	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 and older with nonvalvular AF or atrial flutter at high risk for thromboembolism,	AMA	X	X				HITECH

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			according to CHADS2 risk stratification, who were presecribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period							
TBD/ TBD	X	Clinical Process/ Effective-ness	**Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of end-stage renal disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist	AMA/ASPN	X	X				
1667/ TBD	X	Clinical Process/ Effective-ness	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL:** Percentage of calendar months within a 12-month period during	AMA	X	X				

NQF/ PQRS	New Measure	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
					PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
			which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL							

*Measures that can be reported using the GPRO web interface.

†These measures can only be reported by participants using the GPRO. They are not available for reporting for individual Eligible Professionals using this reporting method.

¥ Titles and descriptions in this table are aligned with proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

Beginning with reporting periods occurring in 2014, we are proposing the following 45 individual quality measures specified in Table 33 available for reporting under the PQRS:

TABLE 33: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR and/or the GPRO Web-Interface for 2014 and Beyond That Were NOT Available for Reporting under the 2012 PQRS

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
N/A/ TBD	Clinical Process/ Effective-ness	**Preventive Cardiology Composite:** • **Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal • **Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors • **Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with ≤ 1 risk factor for CHD) • **Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes	ABIM		X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		• **Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented • **Counseling for Diet and Physical Activity:** Percentage of patients in the sample who received dietary and physical activity counseling • **Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10% • **Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period							
N/A/ TBD	Care Coordina-tion	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits	AAHKS/ AMA-PCPI					X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
N/A/ TBD	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	AAHKS/ AMA-PCPI					X	
N/A/ TBD	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS/ AMA-PCPI)					X	
N/A/ TBD	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	AAHKS/ AMA-PCPI					X	
TBD/ TBD	Care Coordina-tion	**Radiation Dose Optimization: Utilization of a Standardized Nomenclature for CT Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems	AMA-PCPI					X	
TBD/ TBD	Patient Safety	**Radiation Dose Optimization: Cumulative Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) Scans and Cardiac Nuclear Medicine Scans:** Percentage of CT and cardiac nuclear medicine (myocardial perfusion) imaging reports for all patients, regardless of age, that	AMA-PCPI					X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies that the patient has received in the 12-month period prior to the current study							
TBD/ TBD	Patient Safety	**Radiation Dose Optimization: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	AMA-PCPI					X	
TBD/ TBD	Care Coordination	**Radiation Dose Optimization: Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for imaging studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available reciprocally to non-affiliated external entities on a secure, media free, searchable basis with patient authorization for at least a 12-month period after the study	AMA-PCPI					X	
TBD/ TBD	Care Coordination	**Radiation Dose Optimization: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of imaging studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	AMA-PCPI					X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis Composite:** • **Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise • **Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months • **Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months • **Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis,	ABIM		X				

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented • **Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months • **Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months • **Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration							
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise	ABIM					X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months	ABIM					X	
N/A/ TBD	Patient Safety	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months	ABIM					X	
N/A/ TBD	Care Coordina-tion	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented	ABIM					X	
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months	ABIM					X	
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65	ABIM					X	

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months							
N/A/ TBD	Clinical Process/ Effective-ness	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration	ABIM					X	
0060/ TBD	Clinical Process/ Effective-ness	**Hemoglobin A1c Test for Pediatric Patients:** Percentage of pediatric patients with diabetes with a HbA1c test during the measurement period	NCQA			X			HITECH
0108/ TBD	Clinical Process/ Effective-ness	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/ Hyperactivity Disorder (ADHD) Medication:** The percentage of children 6 to 12 years of age and newly prescribed attention-deficit/hyperactivity disorder (ADHA) medication who had at least three follow-up care visits within a 10-month period, one of which was within 30 days of when the first ADHD medication was dispensed. Two rates are reported. A. Percentage of children with a prescription dispensed for ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase B. Percentage of children with a prescription dispensed for ADHD medication who remained on the medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended	NCQA			X			HITECH
0110/ TBD	Clinical Process/ Effective-ness	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that	CQAIMH			X			HITECH

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		includes an appraisal for alcohol or chemical substance use							
0403/ TBD	Efficient Use of Healthcare Resources	**HIV/AIDS: Medical Visits:** Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 60 days between each visit	AMA/ NCQA			X			HITECH
0608/ TBD	Clinical Process/ Effective-ness	**Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy	Ingenix			X			HITECH
0710/ TBD	Clinical Process/ Effective-ness	**Depression Remission at Twelve Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment	MNCM			X			HITECH
0712/ TBD	Clinical Process/ Effective-ness	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit	MNCM			X			HITECH
1401/ TBD	Population/ Public Health	**Maternal depression screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life	NCQA			X			HITECH
Not yet endorsed/ TBD	Clinical Process/ Effective-ness	**Hypertension: Improvement in blood pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period	CMS			X			HITECH
Not yet endorsed/ TBD	Care Coordina-tion	**Closing the referral loop: receipt of specialist report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from	CMS			X			HITECH

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO* (web interface)*	Measures Groups	
		the provider to whom the patient was referred							
Not yet endorsed/ TBD	Patient and Family Engagement	**Functional status assessment for knee replacement:** Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments	CMS			X			HITECH
Not yet endorsed/ TBD	Patient and Family Engagement	**Functional status assessment for hip replacement:** Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments	CMS			X			HITECH
Not yet endorsed/ TBD	Patient and Family Engagement	**Functional status assessment for complex chronic conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments	CMS			X			HITECH
TBD/TBD	Clinical Process/ Effective-ness	**Children who have dental decay or cavities:** Percentage of children ages 1-17, who have had tooth decay or cavities during the measurement period	MCHB, HRSA			X			HITECH
TBD/TBD	Clinical Process/ Effective-ness	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period	University of Minnesota			X			HITECH
TBD/TBD	Patient Safety	**ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period	CMS			X			HITECH

*Measures that can be reported using the GPRO web interface.

¥ Titles and descriptions in this table are aligned with proposed 2014 Health Information Technology for Economic and Clinical Health (HITECH) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

We also note that we are not proposing to include the following 9 measures specified in Table 34 for 2014.

TABLE 34: Measures that are Not Proposed to be Included in the PQRS Measure Set for 2014 and Beyond

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0388/ 105	Patient Safety	**Prostate Cancer: Three Dimensional (3D) Radiotherapy:** Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT)	AMA-PCPI	X	X				
AQA adopted/ 173	Population/ Public Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	AMA-PCPI	X	X	X		X	
0084/ 200	Clinical Process/ Effective-ness	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy	AMA-PCPI/ ACCF/ AHA			X			
0013/ 237	Clinical Process/ Effective-ness	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded	AMA-PCPI			X			
0012/ 306	Population/ Public Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit	AMA-PCPI			X			
0014/ 307	Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation	AMA-PCPI			X			

NQF/ PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Reporting Mechanism					Other Quality Reporting Programs
				PQRS Claims	PQRS Qualified Registry	PQRS Qualified EHR	CMS-Selected GPRO (web interface)*	Measures Groups	
0027/ 308	Population/ Public Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies	NCQA			X			
0326/47	Care Coordination	**Advanced Care Plan:** Percentage of patients aged 65 years and older who have an advanced care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advanced care plan	AMA-PCPI/ NCQA			X			
0575/ 313	Clinical Process/ Effectiveness	**Diabetes Mellitus: Hemoglobin A1c Control (<8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8%	NCQA			X			

*Measures that can be reported using the GPRO web interface.

¥ Titles and descriptions in this table are aligned with the proposed 2013 EHR Pilot measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

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For the 2012 PQRS, the PQRS aligned the measures the program had available for EHR-based reporting with the EHR measures available for reporting under the EHR Incentive Program (76 FR 73364) and CMS proposes to retain those measures for 2013 and beyond. In fact, we are proposing to add or remove measures available for EHR-based reporting that align with what has been proposed for reporting under the EHR Incentive Program for CY 2014 (77 FR 13746). We also intend to align the PQRS measure set with other CMS programs such as the Value-based Modifier and Medicare Shared Savings Program.

As indicated in Tables 29 through 34, we are proposing a total of 264 measures in 2013. Of these proposed measures, we note that 250 of these measures were measures previously established for reporting under the 2012 PQRS. 14 of these proposed measures are newly proposed in 2013. In 2013, we are also proposing to retire 14 measures that were previously established for reporting under the 2012 PQRS. In 2014, we are proposing 34 additional new measures that were not previously established for reporting under the 2012 PQRS and proposing to retire 8 measures that were previously

established for reporting under the 2012 PQRS.

For Table 31, which specifies the tables we are not proposing to retain in the PQRS measure set for 2013 and beyond, we are not proposing the following measures for the following reasons:

(1) *Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports:* We are not proposing that this measure be because the measure is no longer endorsed by NQF and therefore does not satisfy the requirement for PQRS to provide consensus-based quality measures under section 1848(k)(2)(C)(i) of the Act. Although section 1848(k)(2)(C)(ii) of the Act provides an exception to proposing PQRS measures endorsed by the NQF, we are not exercising our authority to use this exception. The measure was not recommended for reporting by the Measure Application Partnership and we agree with the Measure Applications Partnership's (MAP) assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.(2) *Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(3) *Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Mental Status; Acute Otitis Externa (AOE): Pain Assessment:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(4) *Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectom:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(5) *Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(6) *Referral for Otologic Evaluation for Patients with History of Active Drainage from the Ear Within the Previous 90 Days:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(7) *Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*..

(8) *Heart Failure: Patient Education; Functional Communication Measure—Motor Speech*

(9) *Coronary Artery Disease (CAD): Symptom and Activity Assessment:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(10) *Pregnancy Test for Female Abdominal Pain Patients:* The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the *''MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking''* available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

(11) We also decline to propose the measure titled ''Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR)'' again for the 2013 PQRS because of our desire to align with the EHR Incentive Program. In addition, we believe that, since we anticipate that most eligible professionals reporting via EHR will also participate in the EHR Incentive Program, we believe it is redundant to have an eligible professional report on whether or not s/he has adopted an EHR.

(12) We are not proposing the measure titled ''Hypertension (HTN): Plan of Care'' again for 2013 because this measure is being retired by its measure owner.

For the measures we are not proposing to include in PQRS beginning in 2014 in Table 34, we did not propose the Prostate Cancer: Three Dimensional (3D) Radiotherapy; Hypertension (HTN): Blood Pressure Measurement; and Prenatal Care: Anti-D Immune Globulin measures (which are described in detail above in Table 34) for 2014 and beyond because the measures will be retired by its measure owners. We are proposing to retire the measure titled ''Preventive Care and Screening: Unhealthy Alcohol Use—Screening'' because this measure was recommended for removal from reporting by the Measure Applications Partnership. We are proposing to retire the measure titled ''Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation'' because evidence suggests that treatments other than Warfarin have proven more effective to treat Heart Failure. Lastly, we did not propose to retain the measures titled ''Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies'' and ''Advanced Care Plan'' for reporting via the EHR-based reporting mechanisms beginning in 2014 to align with the EHR Incentive Program.

As indicated in Tables 30 and 32, we are proposing a total of 212 measures for available for reporting beginning in 2013. Beginning 2014, we are proposing that 210 measures be available for reporting under PQRS. As indicated previously, these proposed measures are classified under 6 domains.

(1) *Patient safety.* We are proposing 21 measures under the patient safety domain available for reporting in PQRS beginning in 2013 or 2014. Of these measures, the following 18 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.
- Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac).
- Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Perioperative Care.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol.
- Prostate Cancer: Three Dimensional (3D) Radiotherapy.
- Documentation of Current Medications in the Medical Record.
- Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol.
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).
- Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics.
- Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac).
- Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures.
- Perioperative Temperature Management.
- Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy).

The following 3 measures that are classified under the patient safety domain are not NQF-endorsed. For these measures, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting under PQRS for the following reasons:

- Falls: Risk Assessment. We are proposing to include this measure under our authority under section 1848(k)(2)(C)(ii) to adopt a measure endorsed by the AQA alliance.
- Elder Maltreatment Screen and Follow-Up Plan. We are proposing to include this measure under our authority under section 1848(k)(2)(C)(ii) to adopt a measure endorsed by the AQA alliance.
- Image Confirmation of Successful Excision of Image–Localized Breast Lesion.

(2) *Patient and Family Engagement.* We are proposing 5 measures available for reporting in PQRS under the patient and family engagement domain beginning in 2013 or 2014. Of these measures, the following 4 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Oncology: Medical and Radiation—Plan of Care for Pain.
- Oncology: Medical and Radiation—Pain Intensity Quantified.
- Osteoarthritis (OA): Function and Pain Assessment.
- Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older.

The following measure that is classified under the patient and family engagement domain is not NQF-endorsed: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because this measure fills a measure satisfaction gap in the proposed PQRS measure set.

(3) *Care Coordination.* We are proposing 38 measures available for reporting in PQRS under the care coordination domain beginning in 2013 or 2014. Of these measures, the following 26 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Advanced Care Plan.
- Adult Kidney Disease: Hemodialysis Adequacy: Solute.
- Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute.
- Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy—Avoidance of.
- Melanoma: Coordination of Care.
- Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15 percent OR Documentation of a Plan of Care.
- Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy.
- Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
- Functional Communication Measure—Spoken Language Comprehension.
- Functional Communication Measure—Attention.
- Functional Communication Measure—Memory.
- Functional Communication Measure—Reading.
- Functional Communication Measure—Spoken Language Expression.
- Functional Communication Measure—Writing.
- Functional Communication Measure—Swallowing.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments.
- Radiology: Reminder System for Mammograms.
- Biopsy Follow-Up.
- Endoscopy and Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
- Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality.

Although the following 3 measures classified under the care coordination domain are not NQF-endorsed, we are

exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting in PQRS because these measures have been reviewed by the AQA:

- Functional Outcome Assessment.
- Rheumatoid Arthritis (RA): Glucocorticoid Management.
- Falls: Plan of Care.

The following 8 measures that are classified under the care coordination domain are also not NQF-endorsed. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because these measures fills gaps in assessing care coordination in the proposed PQRS measure set.

- Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear.
- Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR).
- Rate of Open Elective Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7)
- Rate of Elective Endovascular Aortic Repair (EVAR) of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2).
- Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home Post-Operative Day #2).
- Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness.
- CG–CAHPS Clinician/Group Survey.
- Coordination of Care of Patients with Co-Morbid Conditions—Timely Follow-Up (Paired Measure).

(4) *Clinical Process/Effectiveness.* We are proposing 127 measures available for reporting under the clinical process/effectiveness domain in PQRS beginning in 2013 or 2014. Of these measures, the following 97 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
- Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus.
- Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.
- Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Coronary Artery Disease (CAD): Antiplatelet Therapy.
- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).
- Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment.
- Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.
- Age-Related Macular Degeneration (AMD): Dilated Macular Examination.
- Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy
- Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.
- Aspirin at Arrival for Acute Myocardial Infarction (AMI).
- Stroke and Stroke Rehabilitation: Deep Vein Thrombosis (DVT) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage.
- Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy.
- Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge.
- Stroke and Stroke Rehabilitation: Screening for Dysphagia.
- Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered.
- Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older.
- Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery.
- Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery.
- Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.
- Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older.
- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
- Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
- Asthma: Pharmacologic Therapy for Persistent Asthma.
- Emergency Medicine: 12–Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain.
- Emergency Medicine: 12–Lead Electrocardiogram (ECG) Performed for Syncope.
- Emergency Medicine: Community-Acquired Pneumonia (CAP): Vital Signs.
- Emergency Medicine: Community-Acquired Pneumonia (CAP): Empiric Antibiotic.
- Asthma: Assessment of Asthma Control.
- Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline.
- Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy.
- Hematology: Multiple Myeloma: Treatment with Bisphosphonates.
- Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow CytometryBreast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
- Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.
- Hepatitis C: Testing for Chronic Hepatitis C—Confirmation of Hepatitis C Viremia.
- Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment.
- Hepatitis C: HCV Genotype Testing Prior to Treatment.
- Hepatitis C: Antiviral Treatment Prescribed.
- Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment.
- Hepatitis C: Counseling Regarding Risk of Alcohol Consumption.
- Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy.
- Acute Otitis Externa (AOE): Topical Therapy.
- Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.
- Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.
- Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients.
- Major Depressive Disorder (MDD): Diagnostic Evaluation.
- Major Depressive Disorder (MDD): Suicide Risk Assessment.
- Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy.

- Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.
- Preventive Care and Screening: Screening Mammography .
- Preventive Care and Screening: Colorectal Cancer Screening.
- Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD.
- Diabetes: Urine Screening.
- Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy .
- Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear.
- Melanoma: Continuity of Care—Recall System:.
- Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement.
- Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications.
- HIV/AIDS: CD4+ Cell Count or CD4+ Percentage.
- HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis.
- HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy.
- HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy.
- Diabetes Mellitus: Foot Exam.
- Coronary Artery Bypass Graft (CABG): Prolonged Intubation.
- Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate.
- Coronary Artery Bypass Graft (CABG): Stroke.
- Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure.
- Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration.
- Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge.
- Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge.
- Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge.
- Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula.
- Stroke and Stroke Rehabilitation: Thrombolytic Therapy.
- Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery.
- Oncology: Cancer Stage Documented.
- Radiology: Stenosis Measurement in Carotid Imaging Reports.
- Coronary Artery Disease (CAD): Lipid Control.
- Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment.
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea.
- HIV/AIDS: Screening for High Risk Sexual Behaviors.
- HIV/AIDS: Screening for Injection Drug Use.
- HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis.
- Heart Failure (HF): Left Ventricular Function (LVF) Testing.
- Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL–C) Control.
- Cardiac Rehabilitation Patient Referral from an Outpatient Setting.
- Anticoagulation for Acute Pulmonary Embolus Patients.
- Ultrasound Determination of Pregnancy Location for Pregnant Patients withRh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure.
- Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL.

We are proposing 29 measures for inclusion in the PQRS measure set under the clinical process domain in 2013/2014 that are not NQF-endorsed. Although the following 11 measures classified under the clinical domain are not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting in PQRS because these measures have been reviewed by the AQA:

- Adult Kidney: Disease Laboratory Testing (Lipid Profile).
- Adult Kidney Disease: Blood Pressure Management.
- Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA)—Hemoglobin Level > 12.0 g/dL.
- Rheumatoid Arthritis (RA): Tuberculosis Screening.
- Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity.
- Rheumatoid Arthritis (RA): Functional Status Assessment.
- Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis.
- Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers.
- Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers.
- Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence.
- Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence.

The following 18 measures that are classified under the care coordination domain are also not NQF-endorsed. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because these measures fill gaps in measuring clinical process in the proposed PQRS measure set.

- Asthma: Tobacco Use: Screening—Ambulatory Care Setting.
- Asthma: Tobacco Use: Intervention—Ambulatory Care Setting.
- Coronary Artery Disease (CAD): Symptom Management.
- Hypertension: Blood Pressure Management.
- Barrett's Esophagus.
- Radical Prostatectomy Pathology Reporting.
- Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients.
- Statin Therapy at Discharge after Lower Extremity Bypass (LEB).
- Preoperative Diagnosis of Breast Cancer.
- Sentinel Lymph Node Biopsy for Invasive Breast Cancer.
- Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies).
- Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome.
- Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy.
- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.
- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure).
- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure).
- Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions—Timely Follow-Up.
- Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric Kidney Disease: Adequacy of Volume Management.

(5) *Population/Public Health.* We are proposing 9 measures classified under

the population/public health available for reporting in PQRS beginning in 2013 or 2014. Of these measures, the following 7 measures are NQF-endorsed, and therefore, satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Preventive Care and Screening: Influenza Immunization.
- Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
- Pain Assessment and Follow-Up.
- Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan.
- Hepatitis C: Hepatitis A Vaccination in Patients with HCV.
- Hepatitis C: Hepatitis B Vaccination in Patients with HCV.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Two proposed PQRS measures in the population/public health domain are not NQF-endorsed. Although the measure ''Preventive Care and Screening: Unhealthy Alcohol Use—Screening'' classified under the population/public health domain is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure for reporting in PQRS because the measure have been reviewed by the AQA. The measure ''Preventive Care and Screening: Screening for High Blood Pressure'' classified under the population/public health domain is also not NQF-endorsed. However, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure for reporting under PQRS because the measures fill gaps in assessing population/public health safety in the proposed PQRS measure set.

(6) *Efficiency.* We are proposing 9 measures available for reporting in PQRS beginning in 2013 or 2014. Of these measures, all measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use.
- Appropriate Testing for Children with Pharyngitis.
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients.
- Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use.
- Radiology: Inappropriate Use of ''Probably Benign'' Assessment Category in Mammography Screening.
- Melanoma: Overutilization of Imaging Studies in Melanoma.
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients.
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI).
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients.

Please note that the titles of the measures may change slightly from CMS program and/or CMS program year based on specifications updates. We intend to continue to work toward complete alignment of measure specifications across programs whenever possible.

(3) Proposed PQRS quality measures Available for Reporting for Group Practices Using the GPRO Web-Interface

We have previously discussed our measure proposals for group practices using the GPRO web-interface. However, in order to emphasize the measures we are proposing for group practices using the GPRO web-interface, we have provided a summary of these proposed measures in the following Table 32. As indicated in Table 35, we are proposing 18 measures for reporting under the PQRS using the GPRO web-interface for 2013 and beyond to align with the quality measures available for reporting under the Medicare Shared Savings Program (76 FR 67890). Please note that the Medicare Shared Savings Program indicates that it established 22 measures. There is a discrepancy because the Medicare Shared Savings Program lists the Diabetes Composite measure as separate measures, whereas we are referring to the Diabetes Composite measure as one measure in Table 35.

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TABLE 35: Measures Proposed to be Included in the Group Practice Reporting Option (GPRO) Web-Based Interface for 2013 and Beyond¥

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure and Title Description	Measure Steward	Other Quality Reporting Programs
0059/ 1	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes: Hemoglobin A1c Poor Control:** Percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c > 9.0%	NCQA	HITECH ACO
0083/ 8	Heart Failure	Clinical Process/ Effective-ness	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	AMA-PCPI/ ACCF/ AHA	HITECH ACO
0097/ 46	Care Coordina-tion/ Patient Safety	Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented	AMA-PCPI/ NCQA	HITECH ACO
0041/ 110	Preventive Care	Population/ Public Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI	HITECH ACO
0043/ 111	Preventive Care	Clinical Process/ Effective-ness	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA	HITECH ACO
0031/ 112	Preventive Care	Clinical Process/ Effective-ness	**Breast Cancer Screening:** Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer	NCQA	HITECH ACO
0034/ 113	Preventive Care	Clinical Process/ Effective-ness	**Colorectal Cancer Screening:** Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer	NCQA	HITECH ACO
0066/ 118	Coronary Artery Disease	Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ ACCF/ AHA	HITECH ACO

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure and Title Description	Measure Steward	Other Quality Reporting Programs
0421/ 128	Preventive Care	Population/ Public Health	**Adult Weight Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated body mass index (BMI) in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 Age 18-64 years BMI ≥ 18.5 and < 25	CMS/ QIP	HITECH ACO
0418/ 134	Preventive Care	Population/ Public Health	**Screening for Clinical Depression:** Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented	CMS/ QIP	HITECH ACO
0074/ 197	Coronary Artery Disease	Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result <100 mg/dL OR patients who have a LDL-C result ≥100 mg/dL and have a documented plan of care to achieve LDL-C <100mg/dL, including at a minimum the prescription of a statin	AMA-PCPI/ ACCF/ AHA	HITECH ACO
0068/ 204	Ischemic Vascular Disease	Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year	NCQA	HITECH ACO Million Hearts
0028/ 226	Preventive Care	Population/ Public Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	HITECH ACO Million Hearts
0018/ 236	Hyperten-sion	Clinical Process/ Effective-ness	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled during the measurement year	NCQA	HITECH ACO Million Hearts
0075/ 241	Ischemic Vascular Disease	Clinical Process/ Effective-ness	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal	NCQA	HITECH ACO Million Hearts

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure and Title Description	Measure Steward	Other Quality Reporting Programs
			angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had a complete lipid profile performed during the measurement year and whose LDL-C<100 mg/dL		
N/A/ 317	Preventive Care	Population/ Public Health	**Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 years and older who are screened for high blood pressure	CMS/ QIP	HITECH ACO Million Hearts
0101/ 318	Care Coordina-tion/ Patient Safety	Patient Safety	**Falls: Screening for Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk (patients are considered at risk for future falls if they have had 2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months	AMA-PCPI/ NCQA	HITECH ACO
0729/ TBD	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0% • LDL < 100 mg/dL • blood pressure < 140/90 mmHg • tobacco non-user • (for patients with a diagnosis of ischemic vascular disease) daily aspirin use unless contraindicated	MNCM	ACO

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

We note that, due to our desire to align with the measures available for reporting under the Medicare Shared Savings Program, we are proposing not to retain the 13 measures specified in Table 36 for purposes of reporting via the GPRO-web interface beginning in 2013.

TABLE 36: Measures Included in the 2012 PQRS Group Practice Reporting Option Web-Based Interface that are Not Proposed for Inclusion in the Web-Based Interface Beginning in 2013¥

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Other Quality Reporting Programs
0064/ 2	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA	Million Hearts
0061/ 3	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA	
0081/ 5	Heart Failure	Clinical Process/ Effective-ness	**Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ ACCF/ AHA	
0067/ 6	Coronary Artery Disease	Clinical Process/ Effective-ness	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel	AMA-PCPI/ ACCF/ AHA	
0102/ 52	Chronic Obstruc-tive Pul-monary Disease	Clinical Process/ Effective-ness	**Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator	AMA-PCPI	
0055/ 117	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam	NCQA	
0056/ 163	Diabetes Mellitus	Clinical Process/ Effective-ness	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	NCQA	HITECH
0079/ 198	Heart Failure	Clinical Process/ Effective-ness	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period	AMA-PCPI/ ACCF/ AHA	
0082/ 199	Heart Failure	Clinical Process/ Effective-ness	**Heart Failure: Patient Education:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior changes during one or more visit(s) within 12 months	CMS/ QIP	

NQF/ PQRS	GPRO Disease Module	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Other Quality Reporting Programs
0079/ 228	Heart Failure	Clinical Process/ Effectiveness	**Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with LVF testing performed during the measurement period for patients hospitalized with a principal diagnosis of HF during the reporting period	CMS/ QIP	
0575/ 313	Diabetes Mellitus	Clinical Process/ Effectiveness	**Diabetes Mellitus: Hemoglobin A1c Control (<8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8%	NCQA	HITECH
0729/ 314	Diabetes Mellitus	Clinical Process/ Effectiveness	**Diabetes Mellitus: Daily Aspirin Use for Patients with Diabetes and Ischemic Vascular Disease** Percentage of patients aged 18 to 75 years of age with diabetes mellitus and ischemic vascular disease with documented daily aspirin use during the measurement year unless contraindicated	MNCM	
0729/ 315	Diabetes Mellitus	Clinical Process/ Effectiveness	**Diabetes Mellitus: Tobacco Non Use** Percentage of patients with a diagnosis of diabetes who indicated they were tobacco non- users	MNCM	

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification

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In addition to the measures we are proposing in Table 36, we are also proposing to have the following measure available for reporting occurring in 2013 and beyond: CG–CAHPS Clinician/Group Survey: Getting timely care, appointments and information; How well your doctors communicate; Patients rating of doctor; Access to specialists; Health promotion and education; Shared decision making; Courteous and helpful office staff; Care coordination; Between visit communication; Educating patients about medication adherences; and Stewardship of patient resources. We note that this survey measure requires a different form of data collection and analysis than the other proposed measures in the PQRS. Therefore, for this measure only, CMS intends to administer the survey on behalf of the group practices participating in the 2013 PQRS GPRO. In other words, CMS intends to collect the data for this measure on group practices' behalf for CY 2013 reporting periods.

(4) Proposed PQRS measures groups Available for Reporting for 2013 and Beyond

We propose the following 20 measures groups for reporting in the PQRS beginning with reporting periods occurring in 2013: Diabetes Mellitus; Chronic Kidney Disease (CKD); Preventive Care; Coronary Artery Bypass Graft (CABG); Rheumatoid Arthritis (RA); Perioperative Care; Back Pain; Hepatitis C; Heart Failure (HF); Coronary Artery Disease (CAD); Ischemic Vascular Disease (IVD); HIV/AIDS; Asthma; Chronic Obstructive Pulmonary Disease (COPD); Inflammatory Bowel Disease (IBD); Sleep Apnea; Dementia; Parkinson's Disease; Hypertension; Cardiovascular Prevention; and Cataracts. These 20 proposed measures groups were available for reporting under the PQRS in 2012.

Beginning in 2013, we are proposing the oncology measures groups for reporting under the PQRS that provides measures available for reporting related to breast cancer and colon cancer. We believe it is important to measure cancer care.

We propose the following 4 measures groups for inclusion in the PQRS beginning with reporting periods occurring in 2014: Osteoporosis; Total Knee Replacement; Radiation Dose; and Preventive Cardiology. These measures groups address conditions that the measures groups established in 2012 do not address.

In 2012, the PQRS included a community-acquired pneumonia (CAP) measures group among others. We are not proposing to include this measures group again in the PQRS measure set for the 2013 PQRS or subsequent years because measures contained within this measures group were not recommended for retention by the Measure Applications Partnership. We are also proposing, as identified in Table 47, to change the composition of the Coronary Artery Disease (CAD) measures group from what was finalized for 2012. Specifically, we are proposing to remove PQRS measure #196: Coronary Artery Disease (CAD): Symptom and Activity Assessment and replace this measure with PQRS measure #242: Coronary Artery Disease (CAD): Symptom Management in the CAD

measures group, because the measure #196 was not recommended for retention by the measure applications partnership. On the hand, measure #242 was recommended for retention by the Measure Applications Partnership.

Descriptions of the measures we are proposing within each proposed measures group are provided in Tables 37 through 62. Please note that some of the proposed measures included within a proposed PQRS quality measures group may also be available for reporting as an individual measure.

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TABLE 37: 2013 and Beyond Proposed Measures – Diabetes Mellitus Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0059/ 1	**Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0 percent	NCQA
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0061/ 3	**Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA
0055/ 117	**Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dialated eye exam	NCQA
0062/ 119	**Diabetes Mellitus: Urine Screening:** Percentage of patients aged 18 through 75 years with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy	NCQA
0056/ 163	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	NCQA

*This measures group is reportable through both claims and registry-based reporting.

TABLE 38: 2013 and Beyond Proposed Measures – Chronic Kidney Disease (CKD) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31)	AMA-PCPI
AQA adopted/ 121	**Adult Kidney Disease: Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	AMA-PCPI
AQA adopted/ 122	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care	AMA-PCPI
AQA adopted/ 123	**Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL:** Percentage of calendar months within a 12-month period during which a Hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy AND have a Hemoglobin level > 12.0 g/dL	AMA-PCPI

*This measures group is reportable through both claims and registry-based reporting

TABLE 39: 2013 and Beyond Proposed Measures – Preventive Care Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/ 39	**Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA-PCPI/ NCQA
0098/ 48	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months	AMA-PCPI/ NCQA
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31)	AMA-PCPI
0043/ 111	**Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA
0031/ 112	**Preventive Care and Screening: Screening Mammography:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer	NCQA
0034/ 113	**Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening	NCQA
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented. Normal Parameters: Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25.	CMS/ QIP
AQA adopted/173	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	AMA-PCPI
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

*This measures group is reportable through both claims and registry-based reporting

TABLE 40: 2013 and Beyond Proposed Measures – Coronary Artery Bypass Graft (CABG) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0134/ 43	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery** Percentage of patients aged 18 years and older undergoing isolated CABG surgery using an IMA graft	STS
0236/ 44	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received a beta-blocker within 24 hours prior to surgical incision	CMS/ QIP
0129/ 164	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require intubation > 24 hours	STS
0130/ 165	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection (involving muscle, bone, and/or mediastinum requiring operative intervention)	STS
0131/ 166	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any	STS

NQF/ PQRS	Measure Title and Description	Measure Developer
	confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	
0114/ 167	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	STS
0115/ 168	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	STS
0116/ 169	**Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication	STS
0117/ 170	**Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers	STS
0118/ 171	**Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen	STS

*This measures group is reportable through registry-based reporting only

TABLE 41: 2013 and Beyond Proposed Measures – Rheumatoid Arthritis (RA) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0054/ 108	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD	NCQA
AQA adopted/ 176	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti- rheumatic drug (DMARD)	AMA-PCPI/ NCQA
AQA adopted/ 177	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months	AMA-PCPI/ NCQA
AQA adopted /178	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	AMA-PCPI/ NCQA
AQA adopted/ 179	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	AMA-PCPI/ NCQA
AQA adopted/ 180	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	AMA-PCPI/ NCQA

*This measures group is reportable through both claims and registry-based reporting

TABLE 42: 2013 and Beyond Proposed Measures – Perioperative Care Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0270/ 20	**Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA-PCPI/ NCQA
0268/ 21	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis	AMA-PCPI/ NCQA
0271/ 22	**Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time	AMA-PCPI/ NCQA
0239/ 23	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	AMA-PCPI/ NCQA

*This measures group is reportable through both claims and registry-based reporting

TABLE 43: 2013 and Beyond Proposed Measures – Back Pain Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0322/ 148	**Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain	NCQA
0319/ 149/	**Back Pain: Physical Exam:** Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain	NCQA
0314/ 150	**Back Pain: Advice for Normal Activities:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain	NCQA
0313/ 151	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain	NCQA

*This measures group is reportable through both claims and registry-based reporting

TABLE 44: 2013 and Beyond Proposed Measures – Hepatitis C Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0395/ 84	**Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	AMA-PCPI
0396/ 85	**Hepatitis C: HCV Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment	AMA-PCPI
0397/ 86	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period	AMA-PCPI
0398/ 87	**Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	AMA-PCPI
0401/ 89	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months	AMA-PCPI
0394/ 90	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment	AMA-PCPI
0399/ 183	**Hepatitis C: Hepatitis A Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	AMA-PCPI
0400/ 184	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	AMA-PCPI

*This measures group is reportable through both claims and registry-based reporting

TABLE 45: 2013 and Beyond Proposed Measures – Heart Failure (HF) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0081/ 5	**Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ ACCF/ AHA
0083/ 8	**Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy	AMA-PCPI/ ACCF/ AHA
0079/ 198	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period	AMA-PCPI/ ACCF/ AHA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

*This measures group is reportable through registry-based reporting only

TABLE 46: 2013 and Beyond Proposed Measures – Coronary Artery Disease (CAD) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0067/ 6	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel	AMA-PCPI/ ACCF/ AHA
0074/ 197	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin	AMA-PCPI/ ACCF/ AHA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 242	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period and with results of an evaluation of level of activity AND an assessment for the presence *or* absence of anginal symptoms, with a plan of care to manage anginal symptoms, if present	AMA-PCPI/ ACCF/ AHA

*This measures group is reportable through registry-based reporting only

TABLE 47: 2013 and Beyond Proposed Measures – Ischemic Vascular Disease (IVD) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0073/ 201	**Ischemic Vascular Disease (IVD): Blood Pressure Management Control:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA

*This measures group is reportable through both claims and registry-based reporting

TABLE 48: 2013 and Beyond Proposed Measures – HIV/AIDS Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0404/ 159	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage:** Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months	AMA-PCPI/ NCQA
0405/ 160	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count	AMA-PCPI/ NCQA
0406/ 161	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm3 or who have a history of an AIDS- defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy	AMA-PCPI/ NCQA
0407/ 162	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care	AMA-PCPI/ NCQA
0409/ 205	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection	AMA-PCPI/ NCQA
0413/ 206	**HIV/AIDS: Screening for High Risk Sexual Behaviors:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for high risk sexual behaviors at least once within 12 months	AMA-PCPI/ NCQA
0415/ 207	**HIV/AIDS: Screening for Injection Drug Use:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for injection drug use at least once within 12 months	AMA-PCPI/ NCQA
0410/ 208	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months	AMA-PCPI/ NCQA

*This measures group is reportable through registry-based reporting only

TABLE 49: 2013 and Beyond Proposed Measures – Asthma Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0047/ 53	**Asthma: Pharmacologic Therapy for Persistent Asthma:** Percentage of patients aged 5 through 50 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment	AMA-PCPI/ NCQA
0001/ 64	**Asthma: Assessment of Asthma Control:** Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms	AMA-PCPI/ NCQA
N/A/ 231	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period	AMA-PCPI/ NCQA
N/A/ 232	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period	AMA-PCPI/ NCQA

*This measures group is reportable through both claims and registry-based reporting

TABLE 50: 2013 and Beyond Proposed Measures – Chronic Obstructive Pulmonary Disease (COPD) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0091/ 51	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA-PCPI
0102/ 52	**Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70 percent and have symptoms who were prescribed an inhaled bronchodilator	AMA-PCPI
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31)	AMA-PCPI
0043/ 111	**Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

*This measures group is reportable through both claims and registry-based reporting

TABLE 51: 2013 and Beyond Proposed Measures – Inflammatory Bowel Disease (IBD) Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 269	**Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period	AGA
N/A/ 270	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year	AGA
N/A/ 271	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year	AGA
N/A/ 272	**Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year	AGA
N/A/ 273	**Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received	AGA
N/A/ 274	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A/ 275	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA

*This measures group is reportable through registry-based reporting only

TABLE 52: 2013 and Beyond Proposed Measures – Sleep Apnea Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A/ 276	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of symptoms, including presence or absence of snoring and daytime sleepiness	AMA-PCPI/ NCQA
N/A/ 277	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis	AMA-PCPI/ NCQA
N/A/ 278	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy	AMA-PCPI/ NCQA
N/A/ 279	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured	AMA-PCPI/ NCQA

*This measures group is reportable through registry-based reporting only

TABLE 53: 2013 and Beyond Proposed Measures – Dementia Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A / 280	**Dementia: Staging of Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period	AMA-PCPI
N/A / 281	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period	AMA-PCPI
N/A / 282	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period	AMA-PCPI
N/A / 283	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	AMA-PCPI
N/A / 284	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	AMA-PCPI
N/A / 285	**Dementia: Screening for Depressive Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period	AMA-PCPI
N/A / 286	**Dementia: Counseling Regarding Safety Concerns:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	AMA-PCPI

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A / 287	**Dementia: Counseling Regarding Risks of Driving:** Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and driving alternatives within a 12 month period	AMA-PCPI
N/A / 288	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	AMA-PCPI

*This measures group is reportable through claims and registry-based reporting

TABLE 54: 2013 and Beyond Proposed Measures – Parkinson's Disease Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A / 289	**Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review:** All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications than can produce Parkinson- like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually	AAN
N/A / 290	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	AAN
N/A / 291	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually	AAN
N/A / 292	**Parkinson's Disease: Querying about Sleep Disturbances:** All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually	AAN
N/A / 293	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	AAN
N/A / 294	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	AAN

*This measures group is reportable through registry-based reporting only

TABLE 55: 2013 and Beyond Proposed Measures – Hypertension Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A/ 295	**Hypertension: Appropriate Use of Aspirin or Other Antiplatelet or Anticoagulant Therapy:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who were prescribed aspirin or other anticoagulant/antiplatelet therapy	ABIM
N/A/ 296	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 24 months	ABIM
N/A/ 297	**Hypertension: Urine Protein Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months	ABIM
N/A/ 298	**Hypertension: Annual Serum Creatinine Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months	ABIM
N/A/ 299	**Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months	ABIM
N/A/ 300	**Hypertension: Blood Pressure Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (at goal)	ABIM
N/A/ 301	**Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal)	ABIM
N/A/ 302	**Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months	ABIM

*This measures group is reportable through registry-based reporting only

TABLE 56: 2013 and Beyond Proposed Measures – Cardiovascular Prevention Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
0018/ 236	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA
N/A/ 317	**Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 and older who are screened for high blood pressure	CMS/ QIP

*This measures group is reportable through both claims and registry-based reporting

TABLE 57: 2013 and Beyond Proposed Measures – Cataracts Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0565/ 191	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	AMA-PCPI/ NCQA
0564/ 192	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	AMA-PCPI/ NCQA
N/A/ 303	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	AAO
N/A/ 304	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	AAO

*This measures group is reportable through registry-based reporting only

TABLE 58: 2013 and Beyond Proposed Measures – Oncology Measures Group*

NQF/ PQRS	Measure Title and Description	Measure Developer
0387/ 71	**Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN
0385/ 72	**Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients:** Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI/ ASCO/ NCCN
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31)	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route	CMS/ QIP

NQF/ PQRS	Measure Title and Description	Measure Developer
0384/ 143	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA-PCPI
0383/ 144	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain	AMA-PCPI
0386/ 194	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months	AMA-PCPI/ ASCO
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

*This measures group is reportable through registry-based reporting only

TABLE 59: 2014 and Beyond Proposed Measures – Osteoporosis Measures Group*

NQF/ PQRS	Measure Title	Measure Developer
0046/ 39	**Osteoporosis: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA
0049/ 41	**Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months	AMA
AQA Selected / 154	**Falls: Risk Assessment for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months	NCQA
AQA Selected / 155	**Falls: Plan of Care for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	NCQA
N/A / TBD	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise	ABIM
N/A / TBD	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months	ABIM
N/A / TBD	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men	ABIM

NQF/ PQRS	Measure Title	Measure Developer
	age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months	
N/A / TBD	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented	ABIM
N/A / TBD	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months	ABIM
N/A / TBD	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months	ABIM
N/A / TBD	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration	ABIM

*This measures group is reportable through claims and registry-based reporting

TABLE 60: 2014 and Beyond Proposed Measures – Total Knee Replacement Measures Group*

NQF/ PQRS	Measure Title	Measure Developer
N/A / TBD	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits	AAHKS/ AMA-PCPI
N/A / TBD	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	AAHKS/ AMA-PCPI
N/A / TBD	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS/ AMA-PCPI
N/A / TBD	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	AAHKS/ AMA-PCPI

*This measures group is reportable through and registry-based only

TABLE 61: 2014 and Beyond Proposed Measures – Radiation Dose Optimization Measures Group*

NQF/ PQRS	Measure Title	Measure Developer
TBD/ TBD	**Radiation Dose Optimization: Utilization of a Standardized Nomenclature for CT Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems	AMA-PCPI
TBD/ TBD	**Radiation Dose Optimization: Cumulative Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) Scans and Cardiac Nuclear Medicine Scans:** Percentage of CT and cardiac nuclear medicine (myocardial perfusion) imaging reports for all patients, regardless of age, that document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies that the patient has received in the 12-month period prior to the current study	AMA-PCPI
TBD/ TBD	**Radiation Dose Optimization: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	AMA-PCPI
TBD/ TBD	**Radiation Dose Optimization: Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for imaging studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available reciprocally to non-affiliated external entities on a secure, media free, searchable basis with patient authorization for at least a 12-month period after the study	AMA-PCPI
TBD/ TBD	**Radiation Dose Optimization: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of imaging studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	AMA-PCPI

*This measures group is reportable through both claims and registry-based reporting

TABLE 62: 2014 and Beyond Proposed Measures – Preventive Cardiology Measures Group*

NQF/ PQRS	Measure Title	Measure Developer
N/A/ TBD	**Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with ≤ 1 risk factor for CHD)	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes	ABIM

NQF/ PQRS	Measure Title	Measure Developer
N/A/ TBD	**Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients in the sample who received dietary and physical activity counseling	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10%	ABIM
N/A/ TBD	**Preventive Cardiology Composite: Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period	ABIM

*This measures group is reportable through both claims and registry-based reporting

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We invite public comment on the proposed Physician Quality Reporting System measures groups.

(5) Proposed Physician Quality Reporting System Measures for Eligible Professionals and Group Practices That Report Using Administrative Claims for the 2015 and 2016 Payment Adjustments

We are proposing the following measures in Table 63 for eligible professionals and group practices that report using administrative claims for the 2015 and 2016 payment adjustments. Our proposals on how to attribute beneficiaries to groups of physicians that elect the administrative claims option are discussed in the value-based payment modifier in section K below. We considered all of the measures included in the program year 2010 individual Physician Feedback reports that can be calculated using administrative claims but are proposing only a subset of the measures that were included in the program year 2010 individual Physician Feedback reports. We are proposing this subset of measures for both the PQRS payment adjustment and the value-based modifier because we believe these measures are clinically meaningful, focus on highly prevalent conditions among beneficiaries, have the potential to differentiate physicians, and be statistically reliable. To the extent that the value-based payment modifier finalizes other measures from the 2010 individual Physician Feedback reports that are listed in Table 65, it would be our intent to finalize those additional measures as well for purposes of the 2015 and 2016 PQRS payment adjustments so that the two programs can be aligned.

As specified in Table 63, we are proposing 19 measures. Of these 19 proposed measures, 17 of these measures are NQF-endorsed and therefore satisfying section 1848(k)(2)(C)(i) of the Act. With respect to the 2 measures that are not NQF-endorsed, ''Potentially Harmful Drug-Disease Interactions in the Elderly'' and ''Diabetes: LDL–C Screening, '' we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for inclusion in the PQRS administrative claims measure set. Both of these measures are relevant as they address care coordination by measuring the amount of time a patient has been readmitted and/or where their status is in the healthcare continuum following hospitalization. The utilization of the administrative claims measures will allow PQRS to implement different reporting options which capture a wider venue of participants without using the traditional methods of reporting and eliminate the potential payment adjustment for non-participators.

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TABLE 63: Proposed Measures for Eligible Professionals and Group Practices Who Report Using Administrative Claims for the 2015 and 2016 PQRS Payment Adjustment

NQF Number	Measure Title	Measure Steward	Domain of Care
0279	**Bacterial Pneumonia** The number of admissions for bacterial pneumonia per 100,000 population.	AHRQ	Care Coordination
0281	**UTI** The number of discharges for urinary tract infection per 100,000 population Age 18 Years and Older in a one year time period	AHRQ	Care Coordination
0280	**Dehydration** The number of admissions for dehydration per 100,000 population.	AHRQ	Care Coordination
	Composite of Chronic Prevention Quality Indicators	N/A	
	Diabetes Composite		
0638	**Uncontrolled diabetes** The number of discharges for uncontrolled diabetes per 100,000 population Age 18 Years and Older in a one year time period.	AHRQ	Care Coordination
0272	**Short Term Diabetes complications** The number of discharges for diabetes short-term complications per 100,000 Age 18 Years and Older population in a one year period.	AHRQ	Care Coordination
0274	**Long term diabetes complications** The number of discharges for long-term diabetes complications per 100,000 population Age 18 Years and in a one year time period.	AHRQ	Care Coordination
0285	**Lower extremity amputation for diabetes** The number of discharges for lower-extremity amputation among patients with diabetes per 100,000 population Age 18 Years in a one year time period.	AHRQ	Care Coordination
0275	**COPD** The number of admissions for chronic obstructive pulmonary disease (COPD) per 100,000 population.	AHRQ	Care Coordination
0277	**Heart Failure** Percent of the population with admissions for CHF.	AHRQ	Care Coordination
N/A	**All Cause Readmission** The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned.	CMS	Care Coordination
N/A	**30 Day Post Discharge Visit** The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned.	CMS	Care Coordination
0576	**Follow-Up After Hospitalization for Mental Illness** Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner	NCQA	Care Coordination
0021	**Annual Monitoring for Beneficiaries on Persistent Medications** Percentage of patients 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year.	NCQA	Patient Safety
0555	**Lack of Monthly INR Monitoring for Beneficiaries on Warfarin** Average percentage of 40-day intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period.	CMS	Patient Safety
0577	**Use of Spirometry Testing to Diagnose COPD** Percentage of patients at least 40 years old who have a new diagnosis or newly active chronic obstructive pulmonary disease (COPD) who received appropriate spirometry testing to confirm the diagnosis.	NCQA	Clinical Care
0549	**Pharmacotherapy Management of COPD Exacerbation** Percentage of chronic obstructive pulmonary disease (COPD) exacerbations for patients 40 years of age and older who had an acute inpatient discharge or ED encounter between January 1–November 30 of the measurement year and were dispensed appropriate medications	NCQA	Clinical Care
0543	**Statin Therapy for Beneficiaries with Coronary Artery Disease** Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease.	CMS	Clinical Care
0583	**Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications**	Resolution Health	Clinical Care

NQF Number	Measure Title	Measure Steward	Domain of Care
	Percentage of patients age 18 or older starting lipid-lowering medication during the measurement year who had a lipid panel checked within 3 months after starting drug therapy		
0053	**Osteoporosis Management in Women ≥ 67 Who Had a Fracture** Percentage of women 67 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the date of fracture.	NCQA	Clinical Care
0055	**Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years who received a dilated eye exam by an ophthalmologist or optometrist during the measurement year, or had a negative retinal exam (no evidence of retinopathy) by an eye care professional in the year prior to themeasurement year.	NCQA	Clinical Care
0057	**HbA1c Testing for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year.	NCQA	Clinical Care
0062	**Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes** Percentage of adult diabetes patients aged 18-75 years with at least one test nephropathy screening test during the measurement year or who had evidence existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria).	NCQA	Clinical Care
0063	**Lipid Profile for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 who had an LDL-C test performed during the measurement year.	NCQA	Clinical Care
0075	**Lipid Profile for Beneficiaries with Ischemic Vascular Disease** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to measurement year, who had a complete lipid profile during the measurement year.	NCQA	Clinical Care
0105	**Antidepressant Treatment for Depression** Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner.	NCQA	Clinical Care
0031	**Breast Cancer Screening for Women ≤ 69** Percentage of eligible women 40-69 who receive a mammogram in during the measurement year or in the year prior to the measurement year.	NCQA	Clinical Care

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We invite public comment on the proposed measures for eligible professionals and group practices that report using administrative claims. We seek comment on whether these are these proposed measures.

7. Proposed Maintenance of Certification Program Incentive: Proposed Self-Nomination Process for Entities Wishing To Be Qualified for the 2013 and 2014 Maintenance of Certification Program Incentives

We propose that new and previously qualified entities wishing to become qualified to provide their members with an opportunity to earn the 2013 and/or 2014 Maintenance of Certification Program incentives undergo a self-nomination and qualification process. Once qualified, the entity would be able to submit data on behalf of its eligible professionals.

For the self-nomination process, we propose that an entity wishing to be qualified for the 2013 and/or 2014 Maintenance of Certification Program incentive would be required to submit a self-nomination statement containing all of the following information via the web:

- Provide detailed information regarding the Maintenance of Certification Program with reference to the statutory requirements for such program.
- Indicate the organization sponsoring the Maintenance of Certification Program, and whether the Maintenance of Certification Program is sponsored by an American Board of Medical Specialties (ABMS) board. If not an ABMS board, indicate whether and how the program is substantially equivalent to the ABMS Maintenance of Certification Program process.
- Indicate that the program is in existence as of January 1 the year prior to the year in which the entity seeks to be qualified for the Maintenance of Certification Program incentive. For example, to be qualified for the 2013 Maintenance of Certification Program incentive, the entity would be required to be in existence by January 1, 2012.
- Indicate that the program has at least one (1) active participant.
- The frequency of a cycle of Maintenance of Certification for the specific Maintenance of Certification Program of the sponsoring organization, including what constitutes ''more frequently'' for both the Maintenance of Certification Program itself and the practice assessment for the specific Maintenance of Certification Program of the sponsoring organization.
- Confirmation from the board that the practice assessment will occur and be completed in the year the physician is participating in the Maintenance of Certification Program Incentive.
- What was, is, or will be the first year of availability of the Maintenance of Certification Program practice assessment for completion by an eligible professional.
- What data is collected under the patient experience of care survey and how this information would be provided to CMS.
- Describe how the Maintenance of Certification program monitors that an

eligible professional has implemented a quality improvement process for their practice.

• Describe the methods, and data used under the Maintenance of Certification Program, and provide a list of all measures used in the Maintenance of Certification Program for the year prior to which the entity seeks to be qualified for the Maintenance of Certification Program incentive (for example, measures used in 2012 for the 2013 Maintenance of Certification Program incentive), including the title and descriptions of each measure, the owner of the measure, whether the measure is NQF endorsed, and a link to a Web site containing the detailed specifications of the measures, or an electronic file containing the detailed specifications of the measures.

For the qualification process, we propose that an entity must meet all of the following requirements to be considered for qualification for purposes of the 2013 and 2014 Maintenance of Certification Program incentives:

• The name, NPI and applicable TINs of eligible professionals who would like to participate for the 2013 and/or 2014 Maintenance of Certification Program incentives.

• Attestation from the board that the information provided to CMS is accurate and complete.

• The board has signed documentation from eligible professional(s) that the eligible professional wishes to have the information released to us.

• Information from the patient experience of care survey.

• Information certifying the eligible professional has participated in a Maintenance of Certification Program for a year, ''more frequently'' than is required to qualify for or maintain board certification status, including the year the physician met the board certification requirements for the Maintenance of Certification Program, and the year the eligible professional participated in the Maintenance of Certification Program ''more frequently'' than is required to maintain or qualify for board certification.

• Information certifying the eligible professional has completed the Maintenance of Certification Program practice assessment at least one time each year the eligible professional participates in the Maintenance of Certification Program Incentive.

We are proposing this self-nomination and qualification process because the process is identical to the self-nomination and qualification process finalized for the 2011 and 2012 Maintenance of Certification Program incentives and we believe such requirements remain appropriate. As the incentives only run through 2014, we believe it is important to keep the requirements consistent with what has been required for the 2011 and 2012 Maintenance of Certification Program incentives. We invite public comment on our proposed self-nomination and qualification process for entities who wish to be qualified for the 2013 and 2014 Maintenance of Certification Program incentive.

8. Informal Review

We established an informal review process for 2012 and beyond in the CY 2012 Medicare PFS final rule (76 FR 73390). In this proposed rule, we address the additional parameters of eligible professionals and group practices subject to a PQRS payment adjustment requesting an informal review. For eligible professionals and group practices that are subject to the payment adjustments that wish to request an informal review, in addition to the requirements we previously established, we propose the following:

• For eligible professionals and group practices wishing to submit an informal review related to the payment adjustment, we propose that an eligible professional electing to utilize the informal review process must request an informal review by February 28 of the year in which the payment adjustment is being applied. For example, if an eligible professional requests an informal review related to the 2015 payment adjustment, the eligible professional would be required to submit his/her request for an informal review by February 28, 2015. We believe this deadline provides ample time for eligible professionals and group practices to discover that their respective claims are being adjusted due to the payment adjustment.

• Where we find that the eligible professional or group practice did satisfactorily report for the payment adjustment, we propose to cease application of the payment adjustment and reprocess all claims that have been erroneously adjusted to date.

We invite public comment on our proposals for the PQRS informal review process.

H. The Electronic Prescribing (eRx) Incentive Program

We established the requirements for the 2013 and 2014 eRx Incentive Program in the CY 2012 Medicare PFS final rule (76 FR 73393). This section contains additional proposals for the 2013 and 2014 eRx Incentive Program.

1. Proposed Alternative Self-Nomination Process for Certain Group Practices Under the eRx GPRO

In the CY 2012 Medicare PFS final rule (76 FR 73394), we established that a group practice wishing to participate in the eRx Incentive Program under the eRx GPRO must self-nominate via the web. However, we propose an alternative submission mechanism for self-nomination by groups participating in the MSSP, Pioneer ACO, or PGP Demonstration. Specifically, we propose that the participating TINs within these groups that wish to participate in the eRx Incentive Program using the eRx GPRO must submit a self-nomination statement by sending a letter indicating its intent to participate in the eRx Incentive Program under the eRx GPRO. We also propose that the group practice must submit an XML file describing the eligible professionals included in the group practice. We are proposing this alternative submission mechanism for group practices that are participating as groups in the MSSP, Pioneer ACO, or PGP Demonstration because it is not technically feasible for CMS to receive this information from these group practices via the web. We invite public comment on this proposed alternative mechanism for submitting self-nomination statements and the XML file for the types of group practices identified above that want to participate in the eRx Incentive Program using the eRx GPRO.

2. The 2013 Incentive: Proposed Criterion for Being a Successful Electronic Prescriber for Groups Comprised of 2–24 Eligible Professionals Selected To Participate Under the eRx GPRO

As stated in section III.G, we are proposing to modify § 414.90(b) to define a group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN.'' Under § 414.92(b), we define a group practice as a practice that indicates its desire to participate in the eRx group practice option and meets the definition of group practice according to the PQRS at § 414.90(b), or a group practice participating in certain other Medicare programs (for example, PGP demonstration, Shared Savings Program). Therefore, since we are proposing to change the minimum group practice size from 25 to 2, we are proposing to add another criterion for being a successful electronic reporter under the program for the 2013

Incentive (for the other criteria we previously adopted for the ERx GPRO Reporting Option, please see 76 FR 73407). Specifically, we are proposing the following criterion for being a successful electronic prescriber for group practices participating in the eRx GPRO comprised of 2–24 eligible professionals for purposes of the 2013 eRx incentive: report the electronic prescribing measure's numerator code during a denominator-eligible encounter for at least 225 times during the 12-month 2013 incentive reporting period (January 1, 2013–December 31, 2013). We are proposing lower criterion for group practices participating under the eRx GPRO with 2–24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. We chose this reporting threshold because this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11–25 eligible professionals that participated in the GPRO II in 2010 (75 FR 73509). We invite public comment on our proposed criterion for being a successful electronic prescriber for the 2013 incentive for groups comprised of 2–24 eligible professionals.

3. The 2014 Payment Adjustment: Proposed Criterion for Being a Successful Electronic Prescriber for Groups Comprised of 2–24 Eligible Professionals Selected To Participate Under the eRx GPRO

As stated in section III.G, we are proposing to modify § 414.90(b) to define a group practice as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN.'' Under § 414.92(b), we define a group practice for the purposes of being able to participate under the eRx GPRO as a practice that indicates its desire to participate in the eRx group practice option and either meets the definition of group practice according to the PQRS at § 414.90(b) or is a group practice participating in certain other Medicare programs (for example, PGP demonstration, Shared Savings Program). Therefore, since we are proposing to change the minimum group practice size from 25 to 2, we are proposing to add another criterion for being a successful electronic reporter under the program for the 2014 payment adjustment (for the other criteria we previously adopted for the ERx GPRO Reporting Option, please see 76 FR 73412–73414). Specifically, we are proposing the following criterion for being a successful electronic prescriber for purposes of the 2014 payment adjustment for group practices comprised of 2–24 eligible professionals participating under the eRx GPRO: Report the electronic prescribing measure's numerator code at least 225 times for the 6-month 2014 payment adjustment reporting period (January 1, 2013–June 30, 2013). We are proposing this lower criterion for group practices participating under the eRx GPRO with 2–24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. In addition, we note that this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11–25 eligible professionals that participated in the GPRO II in 2010 (75 FR 73509). We invite public comment on the proposed criterion for being a successful electronic prescriber for the 2014 eRx payment adjustment for the 6-month payment adjustment reporting period for group practices composed of 2–24 eligible professionals.

4. Proposed Analysis for the Claims-Based Reporting Mechanism

We understand that, in certain instances, it is permissible for an eligible professional to have their Medicare Part B claims reprocessed. Please note that, if a Medicare Part B claim is reopened for reprocessing, the reprocessing of claim does not allow an eligible professional to attach a G-code on a claim for purposes of reporting quality measures, such as the electronic prescribing measure. Therefore, we are proposing to modify § 414.92 to indicate that claims may not be reprocessed for the sole purpose of attaching a reporting G-code on a claim.

5. Proposed Significant Hardship Exemptions

Section 1848(a)(5)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment, if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. In the CY 2012 final rule with comment period, we finalized, as set forth at § 414.92(c)(2)(ii)(B), four circumstances under which an eligible professional or eRx GPRO can request consideration for a significant hardship exemption for the 2013 and 2014 eRx payment adjustments (76 FR 73413):

- The eligible professional or group practice practices in a rural area with limited high speed internet access.
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.
- The eligible professional or group practice is unable to electronically prescribe due to local, state, or Federal law or regulation.
- The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

We have received feedback from stakeholders requesting significant hardship exemptions from application of the eRx payment adjustment based on participation in the EHR Incentive Program, a program which requires a certain level of electronic prescribing activity. Under the EHR Incentive Program, eligible professionals [4] may receive incentive payments beginning in CY 2011 for successfully demonstrating ''meaningful use'' of Certified EHR Technology (CEHRT) and will be subject to payment adjustments beginning in CY 2015 for failure to demonstrate meaningful use. For further explanation of the statutory authority and regulations for the EHR Incentive Program, we refer readers to the July 28, 2010 final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule,'' (75 FR 44314). As a result of such feedback, we believe that in certain circumstances it may be a significant hardship for eligible professionals and group practices who are participants of the EHR Incentive Program to comply with the successful electronic prescriber requirements of the eRx Incentive Program. Therefore, we are proposing to revise the regulation at § 414.92(c)(2)(ii)(B) to add the following two additional significant hardship exemption categories for the 2013 and 2014 eRx payment adjustments:

- Eligible professionals or group practices who achieve meaningful use during certain eRx payment adjustment reporting periods.
- Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.

[4] ''Eligible professional'' is defined for the EHR Incentive Program at 42 CFR 495.4, 495.100, and 495.304.

A. Eligible Professionals or Group Practices Who Achieve Meaningful Use During Certain 2013 and 2014 eRx Payment Adjustment Reporting Periods

Under Stage 1 of meaningful use for the EHR Incentive Program, an eligible professional is required to meet certain objectives and associated measures in order to achieve meaningful use. One of these objectives is for the eligible professional to generate and transmit permissible prescriptions electronically, and the measure of whether the eligible professional has met this objective is more than 40 percent of all permissible prescriptions written by the eligible professional are transmitted electronically using Certified EHR Technology (§ 495.6(d)(4)). We note that the EHR Incentive Program and the eRx Incentive Program share a common goal of encouraging electronic prescribing and the adoption of technology that enables eligible professionals to electronically prescribe. This goal is advanced under each program via the respective program requirements—the electronic prescribing objective under the EHR Incentive Program and the requirement that an EP be a ''successful electronic prescriber'' under the eRx Incentive Program. Indeed, both programs require that the eligible professionals indicate their electronic prescribing activity. Under the EHR Incentive Program, an eligible professional must attest to the percentage of his or her permissible prescriptions that were generated and transmitted electronically using Certified EHR Technology during the applicable EHR reporting period, which must exceed 40 percent. Under the eRx Incentive Program, to avoid the payment adjustment, eligible professional must be a successful electronic prescriber, which is achieved by the reporting of the eRx quality measure a certain number of instances during the applicable reporting period (each instance of reporting of the eRx quality, which includes reporting of specific quality data codes, signifies that the professional generated an electronic prescription for a specified service or encounter). In most cases, we believe the electronic prescribing objective of meaningful use would be a more rigorous standard for eligible professionals to meet than the standard adopted under the eRx Incentive Program (as demonstrated via the reporting of the eRx quality measure). In addition, there seems to be no added benefit with regard to reporting (presumably lower) electronic prescribing activity under the eRx Incentive Program given that the identical goals (encouraging electronic prescribing) of both programs would have been fulfilled through the eligible professional's achievement of meaningful use. For those reasons, we believe it may pose a significant hardship for eligible professionals who are meaningful EHR users to additionally comply with the requirements of being a successful electronic prescriber under the eRx Incentive program.

For the reasons stated, under this proposed significant hardship category, we propose that individual eligible professionals (and every eligible professional member of a group practice group practice practices for the 2014 payment adjustment only) would need to achieve meaningful use of Certified EHR Technology for a continuous 90-day EHR reporting period (as defined for the EHR Incentive Program) that falls within the 6-month reporting period (January 1–June 30, 2012) for the 2013 eRx payment adjustment or the 12- or 6-month reporting periods (January 1–December 31, 2012 or January1–June 30, 2013, respectively) for the 2014 eRx payment adjustment to be eligible to request a significant hardship exemption. We also propose that for purposes of the 2013 and 2014 eRx payment adjustments this hardship exemption category would apply to individual EPs and group practices (that is, every member of the group) who instead achieve meaningful use of Certified EHR Technology for an EHR reporting period that is the full CY 2012. In section III.H.5.b. below, we discuss the proposed deadlines and procedures for requesting consideration of an exemption under this proposed significant hardship exemption category.

B. Eligible Professionals or Group Practices Who Demonstrate Intent To Participate in the EHR Incentive Program and Adoption of Certified EHR Technology

We note that we finalized at § 414.92(c)(2)(ii)(A)(3) a significant hardship exemption category for the 2012 eRx payment adjustment, under which eligible professionals and group practices seeking consideration for an exemption were required to register to participate in the EHR Incentive Program and adopt CEHRT (76 FR 54958). That significant hardship category addressed significant hardships relating to the selection, purchase and adoption of eRx technology (for example, potential significant financial hardship of purchasing two sets of eRx equipment for both programs) that may have occurred as a result of the timing of the release of the standards and requirements for CEHRT and the Certified Health IT Product List, the establishment of the respective program requirements for the eRx and EHR Incentive Programs, and the 2012 eRx payment adjustment reporting periods. Given that eligible professionals have had adequate time to identify EHR products that have been certified and that the requirements for these programs have been implemented and, various stages of reporting are underway, we do not believe this significant hardship exemption category would continue to be applicable for the 2013 and 2014 eRx payment adjustments. We understand, however, that although an eligible professional may now have the requisite information about requirements for CEHRT and each respective program, there may nevertheless exist a significant hardship with regard to compliance with the requirements for being a successful electronic prescriber under the eRx Incentive Program, given the nature of CEHRT and how it is used/implemented in one's practice.

When an eligible professional or eligible professional in a group practice first adopts CEHRT, we understand significant changes may be required with regard to how the eligible professional's practice operates. Further, necessary steps are involved in fully implementing CEHRT once it has been adopted, including: installation, configuration, customization, training, workflow redesign and the establishment of connectivity with entities that facilitate electronic health information exchange (such as for electronic prescriptions). Thus, we believe it would be difficult for an eligible professional or eligible professional in a group practice who has adopted CEHRT to be able to begin electronically prescribing on day one. Rather, we expect a natural lag time would likely occur between an eligible professional's adoption of CEHRT and the point at which CEHRT has been fully implemented such that an eligible professional could begin electronically prescribing. We believe this implementation timeline may pose a significant hardship for an eligible professional or group practice who seeks to comply with the requirements for being a successful electronic prescriber under the eRx Incentive Program and also participate for the first time in the EHR Incentive Program. Under the EHR Incentive Program, an eligible professional who is demonstrating meaningful use of CEHRT for the first time must do so for any continuous 90-day period within

the calendar year (the ''EHR reporting period''). In the absence of this significant hardship exemption category, eligible professionals or group practices who choose a 90-day EHR reporting period that falls later in the year may potentially have to adopt two systems (for example, a stand-alone electronic prescribing system for purposes of participating in the eRx Incentive Program, and CEHRT for purposes of participating in the EHR Incentive Program), which could be financially burdensome. Alternatively, such eligible professionals who wish to use CEHRT for purposes of participating in both programs may potentially have to adopt and implement CEHRT well in advance of their 90-day EHR reporting period in order to meet an earlier reporting period for the eRx Incentive Program.

Therefore, for the 2013 and 2014 eRx payment adjustments, we are proposing a significant hardship exemption category to address this situation. We believe, however, that for this category it is necessary for eligible professionals and group practices to show they intend to participate in the EHR Incentive Program for the first time and have adopted CEHRT. Therefore, to be eligible for consideration for an exemption under this proposed significant hardship exemption category for the 2013 and 2014 eRx payment adjustments, we propose that eligible professionals or group practices must register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt CEHRT by a date specified by CMS. We further note that, given the nature of the significant hardship at issue under this category, this proposal would be limited to eligible professionals and group practices (that is, every individual EP member of the group practice): (1) Who have not previously adopted CEHRT or received an incentive payment under the Medicare or Medicaid EHR Incentive Programs; and (2) who attempt to participate in the Medicare or Medicaid EHR Incentive Programs from January 2, 2012 through October 15, 2012, or the effective date of the final rule (which includes the 6-month 2013 eRx payment adjustment reporting period of January 1, 2012–June 30, 2012) for the 2013 eRx payment adjustment, or during the 6 month payment adjustment reporting period for the 2014 eRx payment adjustment (January 1, 2013 through June 30, 2013).

With respect to eligible professionals or group practices who intend to adopt EHR technology in the future or have not yet taken the steps required in order to apply for this significant hardship exemption, we believe that mere intent to adopt CEHRT or attest at a later date does not sufficiently demonstrate that an eligible professional will adopt CEHRT to participate in the Medicare or Medicaid EHR Incentive Programs. Unlike those eligible professionals who would have registered for the Medicare or Medicaid EHR Incentive Programs and have adopted CEHRT available for immediate use, we would have to monitor and provide oversight over those eligible professionals who have not yet taken these steps to participate in the Medicare or Medicaid EHR Incentive Programs. We also do not believe that such eligible professionals or group practices would necessarily be facing a significant hardship as contemplated in this proposed exemption category. Accordingly, all of the proposed requirements to qualify for an exemption under this significant hardship exemption category would need to be met by the time the eligible professional requests an exemption. In section III.H.5.b. below, we discuss the proposed deadlines and procedures for requesting consideration of an exemption under this proposed significant hardship exemption category. We invite public comment on these two proposed significant hardship exemption categories for the 2013 and 2014 payment adjustments.

C. Proposed Deadlines and Procedures for Requesting Significant Hardship Exemptions

In the CY 2012 final rule with comment period, we established a process whereby eligible professionals would submit significant hardship exemptions for the existing significant hardship exemption categories for the eRx payment adjustments (76 FR 54963). Unfortunately, with respect to submitting these proposed significant hardship exemptions for the 2013 eRx payment adjustment, it would not be operationally feasible to accept significant hardship exemption requests in the manner we previously established. Therefore, we propose that, in order to request a significant hardship under the two proposed significant hardship exemption categories for the 2013 eRx payment adjustment, CMS would analyze the information provided to us in the Registration and Attestation System under the EHR Incentive Program to determine whether the eligible professional or group practice (that is, every EP member of the group practice) has either (1) achieved meaningful use under the EHR Incentive Program during the applicable reporting periods we noted previously, or (2) registered to participate in the EHR Incentive Program via the Registration and Attestation system for the EHR Incentive Program (located at *https://ehrincentives.cms.gov/hitech/login.action*) and adopted CEHRT, or both, if applicable. We understand that providing an eligible professionals CEHRT product number is an optional field in the Registration Page. Please note that if requesting a significant hardship exemption under proposed category 2, the eligible professional must provide its CEHRT product number when registering for the EHR Incentive Program. In the event that it is not operationally feasible to accept this information via the Registration and Attestation system for the EHR Incentive Program, we propose that we would accept requests for significant hardship exemptions under these two proposed categories via a mailed letter to CMS to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

Regardless of which method is finalized for the 2013 eRx payment adjustment, we propose that eligible professionals would be required to submit this significant hardship requests by October 15, 2012 or the effective date of the final rule for this provision, whichever is later. For those eligible professionals who request a significant hardship exemption based on achieving meaningful use under the EHR Incentive Program during the 12- or 6-month reporting periods for the 2013 payment adjustment, we also propose that the eligible professional would be required to have attested under the EHR Incentive Program by October 15th of 2012 (or if later, the effective date of the final rule), in order to qualify for a significant hardship exemption for the 2013 payment adjustment. For those eligible professionals requesting a significant hardship exemption for the 2013 eRx payment adjustment under the second proposed significant hardship exemption category (that is, intent to participate in the EHR Incentive Program and adoption of CEHRT), we propose that these eligible professionals who intend to participate in the EHR Incentive Program from January 1, 2011 through October 15, 2012 or the effective date of the final rule would be required to register for the EHR Incentive Program and adopt CEHRT by the same deadline noted above, in order to qualify for a significant hardship

exemption for the 2013 eRx payment adjustment.

We note that we are proposing a later deadline of October 15, 2012 (or the effective date of the final rule, if later) for the submission of these requests because the deadline for submitting requests under other previously established significant hardship exemption categories to the 2013 eRx payment adjustment (June 30, 2012) has passed and other similar dates we might choose would likely have passed by the time the final rule is effective. We note that this October 15, 2012 deadline is consistent with our intent to finalize our proposals related to these two additional significant hardship exemptions in early Fall 2012, prior to the publication of the CY 2013 Medicare PFS final rule. However, to the extent we are not able to finalize these proposals in the Fall 2012, please note that we may finalize the provisions related to the two proposed significant hardship exemption categories in the CY 2013 Medicare PFS final rule. If such is the case, we propose to extend the October 15, 2012 deadline to the effective date of the CY 2013 Medicare PFS final rule.

In addition, we would like to be able to process all such requests before we begin making the claims processing systems changes later this year to adjust eligible professionals' or group practices' payments starting on January 1, 2013. However, we anticipate that, in some cases, particularly in instances where eligible professionals submit significant hardship exemption requests closer towards the deadline, we may not be able to complete our review of the requests before the claims processing systems updates are made to begin reducing eligible professionals' and group practices' PFS amounts in 2013. In such cases, if we ultimately approve the eligible professional or group practice's request for a significant hardship exemption after January 1, 2013, we would need to reprocess all claims for services furnished up to that point in 2013 that were paid at the reduced PFS amount, which we anticipate may take several months. In order to avoid the reprocessing of claims, we encourage eligible professionals who would be submitting a significant hardship exemption request under these two categories to do so as soon as possible, rather than waiting until the deadline to submit such a request.

We note that we are only proposing submission of requests for significant hardship exemptions under these 2 categories under an individual eligible professional level only because it is not technically feasible for us to operationally analyze information on the EHR Incentive Program's Registration and Attestation page using the TIN, as the information stored in this system is stored by NPI. However, we seek not to preclude eligible professionals currently in an eRx GPRO for 2012 from submitting requests for significant hardship exemptions under these 2 proposed categories. Therefore, to allow the submission of significant hardship requests for the 2013 eRx payment adjustment under these 2 proposed categories, we propose that eligible professionals within an eRx GPRO may, as individuals, request a significant hardship exemption under these 2 proposed categories. Please note, however, that if an entire eRx GPRO wishes to request a significant hardship exemption under these 2 proposed categories, then each eligible professional in the group practice must submit a request.

With respect to submitting exemption requests for the 2 proposed significant hardship exemption categories for the 2014 eRx payment adjustment, we propose the following method for submitting a request for a significant hardship exemption: Via the Communication Support Page (which is the method established for submitting the established significant hardship exemption categories).

In addition, we considered accepting significant hardship exemption requests for the 2 proposed significant hardship exemption categories for the 2014 eRx payment adjustment by CMS receiving eligible professional's information through the Registration and Attestation System for the EHR Incentive Program (similar to our proposed submission process for the 2013 eRx payment adjustment) and via a mailed letter to CMS using the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850. We invite public comment on these considered submission options.

We propose that the deadline for submitting these significant hardship exemption requests for the 2014 eRx payment adjustment would be June 30, 2013, which is the same deadline established for submitting a significant hardship exemption request for the existing significant hardship exemption categories. Additionally, and consistent with our proposal for the 2013 eRx payment adjustment, we propose that an eligible professional or group practice (that is, all members of the practice) that achieves meaningful use under the EHR Incentive Program during the 6- or 12-month reporting periods for the 2014 eRx payment adjustment would be required to attest by June 30, 2013. Similarly, for eligible professionals requesting a significant hardship exemption for the 2014 eRx payment adjustment under the second proposed significant hardship exemption category (i.e., intent to participate in the EHR Incentive Program and adoption of CEHRT), we propose that these eligible professionals who intend to participate in the EHR Incentive Program during the last six months of 2013 would be required to register for the EHR Incentive Program and adopt CEHRT by June 30, 2013, in order to qualify for a significant hardship exemption for the 2014 eRx payment adjustment. We understand that these deadlines may exclude some eligible professionals who attest or register for the EHR Incentive Program at later dates, but these deadlines are necessary in order to avoid the reprocessing of claims. We note, however, that these proposed deadlines would not extend any deadlines applicable under the EHR Incentive Program. That is, for purposes of the EHR Incentive Program, an eligible professional must still attest to being a meaningful user by the deadline established under the EHR Incentive Program, even if such deadline falls prior to the proposed eRx Incentive program significant hardship exemption deadline. We invite public comment on this proposed process for submitting requests significant hardship exemptions under these two proposed categories.

6. Informal Review

To better facilitate issues surrounding the issuance of incentives and payment adjustments, we propose to establish an informal review process for the eRx Incentive Program. We are proposing an informal review process similar to the informal review process established for the PQRS (76 FR 73390), because eligible professionals and group practices are already familiar with this process. The proposed informal review process, which is described below, would only be available for the 2013 eRx incentive payments and the 2014 eRx payment adjustment.

For an informal review regarding the 2013 incentive, we propose that an eligible professional or group practice must request an informal review within 90 days of the release of his or her feedback report, irrespective of when an eligible professional or group practice actually accesses his/her feedback report.

For an informal review regarding the 2014 payment adjustment, we propose that an eligible professional or group practice must request an informal review by January 31, 2013. We believe this deadline provides ample time for eligible professionals and group practices to discover that their respective claims are being adjusted due to the 2014 payment adjustment and seek informal review.

We propose that the request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review. In its request for an informal review, eligible professional may also submit other information to assist in the review. We propose that an eligible professional may request an informal review through the web. We believe use of the web would provide a more efficient way for CMS to record informal review requests, as the web would guide the eligible professional through the creation of an informal review requests. For example, the web-based tool would prompt an eligible professional of any necessary information he or she must provide. Should it be technically not feasible to receive requests for informal reviews via the web, we propose that as eligible professional would be able to request an informal review via email.

We further propose that we would make our determination and provide the eligible professional or group practice with a written response to his or her request for an informal review within 90 days of receiving the request.

Based on our informal review and once we have made a determination, we propose that we would provide the eligible professional or group practice a written response. Where we find that the eligible professional or group practice did successfully report for the 2013 incentive, we would provide the eligible professional or group practice with the applicable incentive payment. Where we find that the eligible professional or group practice did successfully report (that is, meet criteria for being a successful electronic prescriber) for purposes of the 2014 payment adjustment, we would cease application of the 2014 payment adjustment and reprocess all claims that have been adjusted. We further propose that decisions based on the informal review would be final, and there would be no further review or appeal.

We invite public comment on our proposals for the eRx Incentive Program informal review process for the 2013 incentive and the 2014 payment adjustment.

a. Proposed Criteria for the PQRS-Medicare EHR Incentive Pilot

The Medicare EHR Incentive Program provides incentive payments to eligible professionals (EPs) who demonstrate meaningful use of certified EHR technology (CEHRT). EPs who fail to demonstrate meaningful use will be subject to payment adjustments beginning in 2015. We established a phased approach to meaningful use, which we expect will include three stages (75 FR 44321), and all EPs are currently in Stage 1. In the CY 2012 Medicare PFS final rule, we established the PQRS-Medicare EHR Incentive Pilot in an effort to pilot the electronic submission of CQMs for the Medicare EHR Incentive Program and move towards the alignment of quality reporting requirements between Stage 1 of the Medicare EHR Incentive Program and the PQRS (76 FR 73422). We refer readers to the final rule for further explanation of the requirements of the Pilot (76 FR 73422–73425). Specifically, we established that an EP participating in the PQRS-Medicare EHR Incentive Pilot would be able to report clinical quality measures (CQMs) data extracted from Certified EHR Technology via use of a PQRS qualified direct EHR product or PQRS qualified EHR data submission vendor product (76 FR 73422). We propose to modify § 495.8 to extend this Pilot for the 2013 payment year as it was finalized for the 2012 payment year. We are also proposing to remove from § 495.8(a)(2)(v) the cross-reference to § 495.6(d)(10) in order to conform with the proposed changes to § 495.6(d) that were included in the EHR Incentive Program—Stage 2 NPRM (77 FR 13698, 13702). This proposal includes the following:

- For the 2013 payment year only, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified EHR data submission vendor product that would submit CQM data extracted from the EP's CEHRT to CMS. Under this option, identical to the submission process used for the Pilot in 2012 for the 2012 payment year, the PQRS qualified EHR data submission vendor would calculate the CQMs from the EP's CEHRT and then submit the calculated results to CMS on the EP's behalf via a secure portal for purposes of this Pilot.
- For the 2013 payment year only, identical to the submission process used for the Pilot in 2012 for the 2012 payment year, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified direct EHR product to submit CQM data directly from his or her CEHRT to CMS via a secure portal using the infrastructure of the PQRS EHR-based reporting mechanism.

In addition, for the 2013 payment year, we are proposing to extend the use of attestation as a reporting method for the CQM component of meaningful use for the EHR Incentive Program. For 2013, EPs would be able to continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. We refer readers to the EHR Incentive Program—Stage 1 final rule for further explanation of the CQM reporting criteria for EPs and attestation (75 FR 44386–44411, 44430–44434).

We invite public comment on our proposal to extend the PQRS-Medicare EHR Incentive Pilot and attestation as it was established for the 2012 payment year to the 2013 payment year. Please note that we are only proposing the extension of the PQRS-Medicare EHR Incentive Pilot to the 2013 payment year, because Stage 2 of the EHR Incentive Program is expected to begin in 2014. The proposals for Stage 2 of the EHR Incentive Program were provided in a standalone proposed rule published on March 7, 2012 (77 FR 13698).

I. Medicare Shared Savings Program

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

Under section 1899 of the Act, CMS has established a Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the **Federal Register** on November 2, 2011 (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

Section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use

alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program (76 FR 67902). In the Shared Savings Program final rule, we finalized the following requirements with regard to PQRS incentive payments under the Shared Savings Program: (1) The 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889–67890); (2) reporting via the GPRO web interface (76 FR 67893); (3) criteria for satisfactory reporting (76 FR 67900); and (4) January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements under the Shared Savings Program is set forth at § 425.504.

Under § 425.504(a)(1), ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf of their eligible professionals for the PQRS incentive under the Shared Savings Program. ACO providers/suppliers that are eligible professionals constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Under § 425.504(a)(2)(ii), an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under the Shared Savings Program during the reporting period according to the method of submission established by CMS in order to receive a PQRS incentive under the Shared Savings Program. For the years in which a PQRS incentive is available, if eligible professionals that participate in an ACO as ACO providers/suppliers qualify for a PQRS incentive payment under the Medicare Shared Savings Program, the ACO participant TIN(s) under which those ACO providers/suppliers bill, will receive an incentive payment based on the allowed charges of those ACO providers/suppliers. Under § 425.504(a)(4), ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a PQRS incentive outside of the Medicare Shared Savings Program. The PQRS incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B PFS allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

As discussed in section III.G of this proposed rule, as required by section 1848(a)(8) of the Act, a payment adjustment will apply under the PQRS beginning in 2015. For eligible professionals who are not satisfactory reporters, the PFS amount for covered professional services furnished by the eligible professional during 2015 shall be equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. Therefore, consistent with our authority under section 1899(b)(3)(D) of the Act, we propose to amend § 425.504 to incorporate reporting requirements for the PQRS payment adjustment under the Shared Savings Program for eligible professionals that are ACO providers/suppliers.

We are proposing to incorporate requirements for the PQRS payment adjustment that are consistent with requirements for PQRS incentives that we previously adopted in the Shared Savings Program final rule. Specifically, for purposes of the PQRS payment adjustment, we propose to incorporate the same PQRS GPRO under the Shared Savings Program that is currently used for purposes of the PQRS incentive under the Shared Savings Program. Under this proposal, eligible professionals that are ACO providers/suppliers would constitute a group practice that would report quality measures via the GPRO data collection tool for purposes of both the PQRS incentive under the Shared Savings Program and the PQRS payment adjustment under the Shared Savings Program.

For purposes of the payment adjustment, we propose to use the final GPRO quality measures adopted under the Shared Shavings Program that appear in Table 1 of the Shared Savings Program final rule (76 FR 67899–67890). We further propose to incorporate the same criteria for satisfactory reporting that were finalized for the PQRS incentive under the Shared Savings Program, which are described in the Shared Savings Program final rule (76 FR 67900). Specifically:

- An ACO on behalf of its eligible professionals must report on all measures included in the GPRO data collection tool under the Shared Savings Program final rule.
- Beneficiaries would be assigned to the ACO using the methodology described in § 425.400. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs must to complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO must report on 100 percent of assigned beneficiaries for the domain, measures set, or individual measure.
- The GPRO data collection tool must be completed for all domains, measure sets and measures described in Table 1 of the of the Shared Savings Program final rule (76 FR 67889–67890).

Consistent with the reporting requirements for the PQRS incentive under the Shared Savings Program, ACOs would only need to satisfactorily report the 22 GPRO quality measures identified in Table 1 of the Shared Savings Program final rule (76 FR 67889–67890), and would not need to report the other 11 Shared Savings Program quality performance measures for purposes of satisfactory reporting for the PQRS payment adjustment. However, the ACO would still be required to satisfy the ACO quality performance standards for purposes of determining eligibility for shared savings, as described in § 425.502.

We believe that using the same quality measures and the same criteria for satisfactory reporting, including the same assignment and sampling methodology, under the Shared Savings program for both the PQRS incentive and payment adjustment is appropriate. Aligning the satisfactory reporting requirements for the PQRS payment adjustment under the Shared Savings Program with the reporting requirements for purposes of the PQRS incentive under the Shared Savings Program would enable eligible professionals that participate in ACOs as ACO providers/suppliers to comply with these reporting requirements, without imposing any additional reporting burden. In addition, as noted above, the 22 GPRO measures that are reported for purposes of the PQRS incentive under the Shared Savings Program must also be reported for purposes of assessing ACOs' quality performance under the Shared Savings Program and determining the percentage of shared savings that ACOs are eligible to receive. Under the Shared Savings Program regulations at § 425.500(e)(3), ACOs are required to report on all of the

quality measures established by CMS, and the failure to report on those quality measures accurately, completely, and timely may subject the ACO to termination or other sanctions. Thus, ACOs already have significant incentives to report the 22 GPRO measures completely and accurately. Furthermore, aligning the reporting requirements could help to encourage greater participation in the Shared Savings Program, by minimizing the reporting burden imposed upon ACOs and their participants.

Although we propose to use the same timeframe of January 1 through December 31 that we adopted for the PQRS incentive under the Shared Savings Program as the reporting period for the PQRS payment adjustment, we propose that the *timing* of the reporting period would differ for purposes of the PQRS payment adjustment. Specifically, we propose that the reporting period for the payment adjustment would fall 2 years prior to when the payment adjustment would be assessed. For example, under the Shared Savings Program, the reporting period for the 2015 payment adjustment would be from January 1, 2013 through December 31, 2013. It is necessary for us to use a reporting period that precedes the year in which the payment adjustment is applicable to avoid retroactive payments and the reprocessing of claims. In addition, it is not operationally feasible for us to use a full calendar year reporting period that falls closer to the year in which the payment adjustment is applicable because we need sufficient time to determine if the requirements for satisfactory reporting have been met and to adjust our claims systems prior to the start of the applicable year. We note that the length and timing of the reporting period that we are proposing for the PQRS payment adjustment under the Shared Savings Program is consistent with the one used for the traditional PQRS (76 FR 73392).

We also note that this proposal results in overlapping reporting periods for both the PQRS incentive and payment adjustment. For example, the measure data collected for the 2013 calendar year reporting period (January 1, 2013–December 31, 2013) would be used for purposes of both the Physician Quality Reporting System 2013 incentive and 2015 payment adjustment under the Shared Savings Program. We believe using the same reporting period for purposes of both the incentive and payment adjustment would result in less reporting burden, since one set of measures from one reporting period would be used for purposes of both the PQRS incentive and payment adjustment. We believe ACOs will perceive this as more efficient than requiring one set of measures reported during one timeframe for purposes of the PQRS incentive and another set during another timeframe for purposes of the payment adjustment.

Therefore, we propose that, if an ACO satisfactorily reports the ACO GPRO web interface measures during the applicable reporting period, its participant TINs with ACO providers/suppliers who are eligible professionals, would not be subject to the PQRS payment adjustment. If an ACO does not satisfactorily report the ACO GPRO web interface measures during the applicable reporting period, its participant TINs with ACO providers/suppliers who are eligible professionals, would be subject to the PQRS payment adjustment starting in 2015.

Since the publication of the Shared Savings Program final rule, we have received a number of inquiries regarding whether ACO participant TINs need to self-nominate or register to participate in PQRS GPRO under the Shared Savings Program, since there are such registration and self-nomination requirements under the traditional PQRS GPRO. We wish to clarify that no registration or self-nomination is required for ACO providers/suppliers that are eligible professionals to participate in PQRS under the Shared Savings Program.

Finally, just as ACO providers/suppliers that are eligible professionals with an ACO may only participate under their ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of receiving an incentive as both a group and as an individual under the same TIN (76 FR 67903), we propose that ACO providers/suppliers that are eligible professionals within an ACO must participate under the ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of the PQRS payment adjustment. Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as an individual under the traditional PQRS or under the traditional PQRS GPRO.

We recognize that some eligible professionals may move across programs and reporting options from year to year. For instance, an eligible professional that is an ACO provider/supplier and participates in the PQRS under the Shared Savings Program in 2013 may later exit the Shared Savings Program and participate in PQRS individual reporting in 2014. Alternatively, a group practice participating in the traditional PQRS GPRO in 2013 may be an ACO participant in 2014. In instances in which eligible professionals change their PQRS reporting option from year to year, we believe that as long as the eligible professional satisfactorily reported for purposes of the payment adjustment during the applicable reporting period, then the eligible professional should not be subject to the payment adjustment even if the eligible professional was reporting under a different reporting method than at the time the payment adjustment would be assessed. Using the earlier example, if an eligible professional is an ACO provider/supplier and satisfactorily reports under the PQRS under the Shared Savings Program in 2013 but subsequently exits the Shared Savings Program and participates in PQRS individual reporting in 2014, the eligible professional would not be subject to the payment adjustment in 2015. Similarly, a group practice that satisfactorily reports under the traditional PQRS GPRO in 2013 and becomes an ACO participant in 2014 would not be subject to the payment adjustment in 2015. We recognize that group practices and ACOs may reorganize and that individual providers and groups of providers may move in and out of ACOs from year to year, so we believe this approach offers maximum flexibility for eligible professionals and groups of providers to make appropriate decisions regarding their participation in an ACO and allows ACOs to recruit new participants, by eliminating any risk that eligible professionals will be assessed with the payment adjustment as a result of such changes. We believe it would be unfair to assess the payment adjustment on an eligible professional on the basis of switching reporting options, if the eligible professional had satisfactorily reported during the applicable reporting period. We invite public comment on our proposals for Shared Savings Program ACOs and the PQRS payment adjustment and on the alternative considered.

Please note that, in this proposed rule, we also discuss a proposal amending requirements for ACO data to be publicly reported on Physician Compare in section III.G. of this proposed rule.

J. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under

Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the State or jurisdiction where performed. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.'' The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2012 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 29.4 percent reduction to physician payments scheduled to take effect that year. As noted above, the statute was subsequently amended to impose a zero percent update for CY 2012 instead of the 29.4 percent reduction. OACT now estimates CY 2012 chiropractic expenditures to be approximately $630 million. We are currently recouping $10 million through adjustments to the chiropractic CPT codes in CY 2012, and the percent of this reduction is approximately 1.5 percent.

We are continuing the implementation of the required BN adjustment by recouping $10 million in CY 2013. Our Office of the Actuary estimates chiropractic expenditures in CY 2013 will be approximately $470 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 30.9 percent reduction to physician payments scheduled to take effect under current law. To recoup $10 million in CY 2013, the payment amount under the PFS for the chiropractic CPT codes (CPT codes 98940, 98941, and 98942) will be reduced by approximately 2 percent. We are reflecting this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the relative value units (RVUs). Avoiding an adjustment to the RVUs would preserve the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011–2012 PFS regulations, we are implementing this methodology and recouping from the chiropractor fee schedule codes set forth above. Our methodology meets the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration.

K. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

1. Value-Based Payment Modifier and Physician Feedback Reporting Program Overview of Proposals

Section 1848(p) of the Act requires the Secretary to ''establish a payment modifier that provides for differential payment to a physician or a group of physicians'' under the PFS ''based upon the quality of care furnished compared to cost * * * during a performance period.'' In addition, section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the payment modifier beginning January 1, 2015 to specific

physicians and groups of physicians the Secretary determines appropriate. This section also requires the Secretary to apply the value-based payment modifier for all physicians and groups of physicians (and allows the Secretary to apply the value-based payment modifier for eligible professionals as defined in section 1848(k)(3)(B) of the Act as the Secretary determines appropriate) beginning not later than January 1, 2017. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be implemented in a budget neutral (BN) manner.

Section 1848(n) of the Act requires the Secretary to provide confidential Physician Feedback reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians in those reports.

In developing our proposals for the value-based payment modifier, we have reviewed our experience over the past 3 years in providing Physician Feedback reports to certain physicians and groups of physicians. The Physician Feedback reports allow us to test different methodologies and to obtain stakeholder feedback that can be used to further refine the reports and inform our policy proposals and recommendations. We have also linked the Physician Feedback reports with the Physician Quality Reporting System (PQRS), by including the quality measures physicians and groups of physicians reported in the PQRS program in the 2010 Physician Feedback reports that we produced and disseminated in 2011 (to groups of physicians) and early 2012 (to individual physicians).

In this proposed rule, we discuss our proposals to implement the value-based payment modifier (which will affect payments starting in 2015). These proposals focus on creating value for Medicare fee-for-service (FFS) beneficiaries by focusing on prevention and effective chronic disease care and by encouraging high quality care for the most difficult cases. The proposals recognize that physician quality measurement is still evolving and that our methodologies are still developing. We designed our proposals to (1) provide groups of physicians with 25 or more eligible professionals an option that their value-based payment modifier be calculated using a quality-tiering approach; (2) focus our payment adjustment (both upward and downward) on those groups of physicians that are outliers, that is on those that are significantly different from the mean; and (3) align the value-based payment modifier with the PQRS and utilize Medicare claims data in order to reduce administrative burden on groups of physicians. We believe that our proposals are adaptable to smaller groups of physicians and physicians in solo practices that will be subject to the value-based payment modifier starting in 2017 and we seek comment on the potential for our current proposals to be applied to all physicians and groups of physicians. We also encourage physicians and other stakeholders to work with us to include additional quality measures (including additional outcome measures) that meaningfully measure the care they provide to Medicare beneficiaries.

Our proposed scoring methodology for the value-based payment modifier would assess quality of care furnished compared to cost during the performance period (which is 2013 for the first year) to calculate an adjustment to payments under the PFS during the payment adjustment period (which is 2015 for the first year). In light of our desire to align CMS quality improvement programs, this methodology relies, in part, on the data submitted on quality measures by groups of physicians through the PQRS. Quality measurement is necessary, but not sufficient, for quality improvement and a focus on value.[5] To balance our goals of beginning the implementation of the value-based payment modifier consistent with the legislative requirements and to give us and the physician community experience in its operation, we propose to separate all groups of physicians with 25 or more eligible professionals into two categories based on how they have chosen to participate in the PQRS.

The first category includes those groups of physicians that have met the criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentives or the criteria for satisfactory reporting using the administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment. These groups of physicians will have fulfilled a key condition for quality improvement and a focus on value, that is, to measure quality by reporting data on quality measures that can be used to assess quality of care furnished. Thus, we propose initially to set the value-based payment modifier at 0.0 percent for these groups of physicians, meaning that the value-based payment modifier would not affect their payments under the PFS.

Within this category of satisfactory PQRS reporters, we propose to offer an option that their value-based payment modifier be calculated using a quality-tiering approach. This option would allow these groups of physicians to earn an upward payment adjustment for high performance (high-quality tier and low-cost tier) performance, and to be at risk for a downward payment adjustment for poor performance (low-quality tier and high-cost tier). Because of the BN requirement and proposed limit on the downward adjustment noted below, we cannot specify the exact amount of the upward payment adjustment for groups of physicians achieving high performance. We propose, however, that the maximum downward payment adjustment for these groups would be −1.0 percent for poor performance because we recognize that 2015 is the initial year for the value-based modifier and we wish to provide for a very modest adjustment for the initial years. We believe this methodology would encourage future improvement in terms of better value for Medicare beneficiaries without being overly burdensome to groups of physicians that requested to have their value-based payment modifier be calculated using the quality-tiering approach.

The second category includes those groups of physicians with 25 or more eligible professionals that have not met the PQRS satisfactory reporting criteria identified above, including those groups of physicians that have decided not to participate in any PQRS reporting mechanism. Because we would not have quality measure performance rates on which to assess the quality of care furnished by these groups of physicians, we propose to set their value-based payment modifier at −1.0 percent as described in more detail in our proposal below. We note that this downward payment adjustment for the 2015 value-based payment modifier would be in addition to the −1.5 percent payment adjustment that is assessed under section 1848(a)(8) of the Act for failing to meet the satisfactory reporting criteria under PQRS. Therefore, groups of physicians with 25 or more eligible professionals that fail to meet the PQRS satisfactory reporting criteria would be subject to a downward adjustments during 2015 of 1.5 percent for eligible professionals who fail to be satisfactory reporters under the PQRS and 1.0 percent for the value-based payment modifier. Because the value-based payment modifier provides upward

[5] Mark R. Chassin, et al. ''Accountability Measures—Using Measurement to Promote Quality Improvement,'' N Eng. J. of Med. 2010; 363:683–688 (Aug. 2010), available at *http://www.nejm.org/doi/full/10.1056/NEJMsb1002320*.

payment adjustments for groups of physicians on the high-quality and lost-cost tiers, we encourage groups of physicians with 25 or more eligible professionals to elect that their value-based payment modifier be calculated using the quality-tiering approach.

In this proposed rule, we (1) expand upon our vision of how we see the value-based payment modifier helping transform Medicare from a passive payer to an active purchaser of higher quality, more efficient healthcare; (2) propose to whom the value-based payment modifier would apply starting in CY 2015 in ways that emphasize the value-based payment modifier's focus on increasing quality measurement such that all physicians and groups of physicians would be subject to value-based payment modifier starting in CY 2017; (3) propose ways to align the value-based payment modifier with the quality measures and reporting requirements established under the PQRS; (4) propose how we would score the value-based payment modifier and apply the BN requirement in ways that encourage quality reporting through the PQRS; and (5) describe how we have used and plan to continue to use the Physician Feedback reports to further inform physicians and groups of physicians about their quality of care and resource use.

2. Value-Based Payment Modifier Overview

The value-based payment modifier is an important component in revamping how care and services are paid for under the PFS that has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and effective healthcare. We recognize that although the quality of care furnished is high in many regards, this fact ignores ''[h]ealth care today harms too frequently and routinely fails to deliver its potential benefits'' to patients.[6] Indeed, the Institute of Medicine has stated that the ''health care system as currently structured does not, as a whole, make the best use of its resources.'' [7] Findings from the 2010 Physician Feedback reports confirm this statement: high value (high quality and low cost) can be achieved and there is substantial room for quality improvement and better value.[8] We believe that the value-based payment modifier can be used to incentivize and reward high quality, efficiently furnished care by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians).

We recognize, however, that physicians are the forefront of care delivery and that changes in payment policy can directly affect medical care that physicians furnish to Medicare beneficiaries. Consistent with the National Quality Strategy, our aim is to promote preventive care and improve rather than impede the care that beneficiaries currently receive, especially for the chronically ill and those with the most complicated cases. Thus, we seek to implement payment policies that complement and support ''the courage, hard work, and commitment of doctors, nurses, and others in health care'' to improve the health care systems in which they work.[9]

We explained in the CY 2012 PFS proposed rule that Medicare is beginning to implement value-based payment adjustments for other types of services, including inpatient hospital services (76 FR 42908). We have also developed plans to implement value-based purchasing for skilled nursing facilities, home health services and ambulatory surgical center services. In implementing value-based purchasing initiatives generally, we seek to meet the following goals:

- Recognize and reward high quality care and quality improvements.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, we believe these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

++ To the extent possible, and recognizing differences in payment system readiness and statutory requirements and authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve a focused core set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

++ The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

++ To the extent practicable, the measures we use should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

- Promote more efficient and effective care through the use of evidence based measures, less rework and duplication, and less fragmented care.

++ Providers should be accountable for the costs of care, being both rewarded for reducing unnecessary expenditures and responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve and maintain the quality of care they deliver.

++ To the extent possible, and recognizing differences in payers' value based purchasing initiatives, providers should redesign care processes to deliver higher quality and more efficient care to their entire patient population.

Because of the centrality of physicians to high-quality, efficient, patient-centered care furnished in multiple settings, we believe that in the long run the value-based payment modifier should rely on measuring physician performance (both quality of care and cost) at four levels (to the extent practicable)—the individual physician level, the group practice level, the facility level (for example, hospital), and the community level. Physicians make decisions on a patient-by-patient basis as to what services are indicated and furnished. These decisions are made independently by physicians within multiple settings (that is, individual office practice, group practice, hospital) and are dependent, in part, on how care is organized in a community. Consequently, physicians have the potential to drive both quality of care and costs at all levels of the health system and these decisions have an impact on patient outcomes and costs for populations of patients. We envision

[6] Institute of Medicine, ''Crossing the Quality Chasm,'' (2001) at 1; Elizabeth A. McGlynn, ''The Case for Keeping Quality on the Health Reform Agenda,'' prepared testimony before the Senate Committee on Finance (June 3, 2008), available at *http://www.rand.org/content/dam/rand/pubs/testimonies/2008/RAND_CT306.pdf*

[7] ''Crossing the Quality Chasm'' at 3.

[8] CMS, ''Analysis of 2010 Quality and Resource Use Reports for Medical Practice Groups'' (2012), available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/QRURs_for_Medical_Practice_Groups.pdf.*

[9] ''Crossing the Quality Chasm'' at 4.

a physician value-based payment modifier in the future that blends performance at each of these levels (as applicable) and reinforces our objectives to encourage and reward physicians for furnishing high-quality, efficient, patient-centered clinical care.

To start to implement this long-term vision of the value-based payment modifier, we have undertaken numerous activities in the past year to inform our proposals in this rule. We have obtained stakeholder input about the content (including the completeness of the quality measures) and methodologies we have used in the Physician Feedback reports, as well as input on how the private sector has used physician pay-for-performance programs. In particular, we conducted five national provider calls about methodologies we have used in the Physician Feedback reports and similar private sector initiatives.[10] We also held (and continue to hold) numerous sessions with Physician Feedback report recipients (both at the individual and group practice level) to obtain additional feedback to improve the methodologies used in the reports.

These recent activities complement the work we have undertaken to implement the statutory objectives to improve quality of care furnished by physicians and groups of physicians to Medicare beneficiaries. For example, the Congress required the Physician Group Practice (PGP) Demonstration, which we implemented in 2005. The PGP Demonstration was the first pay-for-performance initiative under the Medicare program that involved a shared savings model. The demonstration created incentives for physician groups to coordinate the overall care furnished to Medicare beneficiaries and rewarded them for improving the quality and cost efficiency of health care services. By the fifth year of the demonstration, all 10 of the participating physician groups achieved quality benchmark performance on at least 30 of the 32 measures, and seven of the groups achieved benchmark performance on all 32 performance measures. The PGP quality reporting tool and its methodology also became the basis for the Group Practice Reporting Option (GPRO) under the PQRS.

In 2003, we implemented the Medicare Care Management Performance (MCMP) demonstration project. The demonstration showed that small and solo physician practices are willing to participate in quality measurement and reporting. Almost 700 physician practices of various sizes used a GPRO-like reporting tool to report data on 23 quality measures.

In 2006, Congress established what is now known as the Physician Quality Reporting System (PQRS), which is a voluntary quality reporting program that, as subsequently amended, provides a combination of incentive payments and payment adjustments to eligible professionals (including group practices) based on whether they satisfactorily report data on quality measures for covered professional services furnished to Medicare Part B FFS beneficiaries. In 2010, 268,968 eligible professionals[11] participated in PQRS in addition to those physicians participating in quality reporting through the PQRS GPRO option.

Recently, we provided physicians and groups of physicians with confidential Physician Feedback reports that provide them with comparative performance data on quality of care they furnish compared to costs. Results from the most recent group practice reports show little correlation between quality of care furnished and cost for the 35 participating group practices to whom we provided reports—high quality can be associated with high or low cost (and vice versa) (see Physician Feedback Program discussion below). Moreover, overall results from the individual Physician Feedback reports based on 2010 data show that clinical care is highly fragmented and there is substantial room for improvement in the quality of care furnished to Medicare fee for service beneficiaries.

Based on what we have learned from the aforementioned demonstration projects, the results from the PQRS and the confidential Physician Feedback reports, and our outreach on the national provider calls on private sector programs, we believe the value-based payment modifier and the Physician Feedback reports can be used to incentivize and reward high quality, efficiently furnished care by providing upward payment adjustments under the PFS to high performing physicians and downward adjustments for low performing physicians. To do so, we believe the following specific principles should govern the implementation of the value-based payment modifier.

- *A focus on measurement and alignment.* It is difficult to maintain high quality care and improve quality and performance without measurement. Therefore, the value-based payment modifier should incorporate performance on more quality measures than those that we finalized in the CY 2012 PFS final rule (76 FR 73429 through 73432). These additional measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups and reflect the diversity of services furnished. These measures should be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program. In the proposals described later in this section, we propose to expand the quality measures for the value-based payment modifier. We also encourage physicians to work with us to include additional quality measures (including outcome measures) that meaningfully measure the care they furnish to Medicare beneficiaries.
- *A focus on physician choice.* Physicians should be able to choose the level at which their performance will be assessed reflecting physicians' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs, such as the PQRS and the Medicare EHR Incentive program to reduce administrative burden and encourage greater program participation. In the proposals described later in this section, we propose to rely on the quality measure data collected through the PQRS Group Practice Reporting Option (GPRO) and Medicare EHR Incentive Program to obtain most of the performance data for the value-based payment modifier.
- *A focus on shared accountability.* CMS has a role in fostering high value care for individual patients, but also focusing on how that patient interacts with the health care system generally. We believe that the value-based payment modifier can facilitate shared accountability by assessing performance at the practice group level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician. In the proposals described later in this section, we propose to use performance on several outcome measures that we will calculate for physicians reporting measures at the group level that encourage them to seek innovative ways to furnish high-quality, patient-centered, and efficient care to the Medicare FFS patients they treat. We also seek to start a discussion on how best to incorporate individual, hospital-based, and community-based quality and cost measures as a

[10] See CMS, Physician Feedback Program Teleconferences and Events, available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/CMS-Teleconferences-and-Events.html.*

[11] Eligible professionals include physicians and non-physicians such as physician assistants and nurse practitioners.

component of the value-based payment modifier so that we align quality measurement strategies across providers and settings of care.

• *A focus on actionable information.* In conjunction with adjusting payment based on performance, CMS should provide meaningful and actionable information to help physicians identify clinical areas where they are doing well as well as areas in which performance could be improved. The Physician Feedback reports can serve this purpose. In the proposals described later in this section, we propose ways to provide additional feedback to physicians and groups of physicians through the Physician Feedback reports.

• *A focus on a gradual implementation.* We believe that the value-based payment modifier should focus initially on outliers (that is, those groups of physicians that are demonstrably high or low performers as compared to their peers that treat like beneficiaries). We also believe that groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in 2015 as we phase in the value-based payment modifier. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed to organize them around medical condition, refine physician peer groups to focus on how like beneficiaries are treated, create finer payment distinctions that focus on increasing value, and provide greater payment incentives for high performance. In the proposals described later in this section, we propose to allow groups of physicians with 25 or more eligible professionals to elect how the value-based payment modifier would be applied to them under the PFS starting in 2015. We also propose a scoring methodology that can identify outliers (both high and low performers) and is flexible to accommodate these future goals.

We seek comment on these principles as guides to our implementation of the value-based payment modifier.

3. Proposals for the Value-Based Payment Modifier

In the following sections, we describe our proposals for each component of the value-based payment modifier. These components include: The quality measure reporting methods; the quality and cost measures; the attribution methodology; the payment adjustment amount; the scoring methodology; and the review and inquiry process. Following the discussion of these components, we summarize how the components would work together for a group of physicians with 25 or more eligible professionals that submits data on quality measures using the PQRS GPRO web-interface and requests that their value-based payment modifier be calculated using the quality-tiering approach.

a. Proposed Application of the Value-Based Payment Modifier

Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the value-based payment modifier to items and services furnished beginning on January 1, 2015, for specific physicians and groups of physicians the Secretary determines appropriate, and beginning not later than January 1, 2017 for all physicians and groups of physicians. For purposes of this proposed rule, physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

We propose to initially include all groups of physicians with 25 or more eligible professionals in the value-based payment modifier. For purposes of establishing group size, we propose to use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act. This section defines an eligible professional as any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a quality speech-language pathologist; or (4) a qualified audiologist. In addition, we propose to define a group of physicians as ''a single Tax Identification Number (TIN) with 25 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.'' We chose these groups of physicians in order to align with the reporting requirements for group practices and the definitions used in the PQRS. We also propose to assess whether a group of physicians has 25 or more eligible professionals at the time the group of physicians is selected to participate under the PQRS GPRO.

We propose to apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing or coinsurance would not be affected. We also propose to apply the value-based payment modifier to the items and services billed by eligible professionals who are physicians under the TIN, not to other eligible professionals that also may bill under the TIN.

In addition, application of the value-based payment modifier at the TIN level means that we would not ''track'' or ''carry'' a physician's performance from one TIN to another TIN. In other words, if a physician changes groups from TIN A in the performance period (2013) to TIN B in the payment adjustment period (2015), we would apply TIN B's value-based payment modifier to the physician's payments for items and services billed under TIN B during 2015. We are making this proposal for two reasons. First, payment at the group practice (TIN level) reflects the view that the group in which a physician practices matters. Second, we believe it will be more straightforward for groups of physicians to understand how the value-based payment modifier affects their TIN's payment in the payment adjustment period if all physician billing under the TIN receive the same value-based payment modifier. We seek comment on these proposals.

It is critical to note that our proposals would allow groups of physicians with 25 or more eligible professionals to decide how the value-based payment modifier would be applied to their PFS payments. In light of our desire to align CMS quality improvement programs, this methodology relies, in part, on the data submitted on quality measures by groups of physicians through the PQRS. Quality measurement is necessary, but not sufficient, for quality improvement and a focus on value. We propose to separate all groups of physicians with 25 or more eligible professionals into two categories based on how they have chosen to participate in the PQRS.

The first category includes those groups of physicians with 25 or more eligible professionals that have met the proposed criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentive or the proposed criteria for satisfactory reporting using the administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment. These groups of physicians will have fulfilled a key condition for quality improvement and a focus on value, that is, to measure quality by submitting and/or having data on quality measures that can then be used to assess quality of care furnished. We propose initially to set the value-based payment modifier at 0.0 percent for these groups of physicians, meaning that the value-based payment modifier would not affect their payments under the PFS. We point out that in order for a group of physicians to meet the

satisfactory reporting criteria, the group of physicians must first self-nominate as a group as described above in Section III.G.1.b.2 of this proposed rule regarding the PQRS.

Within this category of satisfactory PQRS reporters, we propose to offer an option that their value-based payment modifier be calculated using the quality-tiering approach described below in subsection (h) Proposed Value-Based Payment Modifier Scoring Methodology. Under these proposals, groups of physicians could earn an upward payment adjustment for high performance (high-quality tier compared to low-cost tier) performance, and be at risk for a downward payment adjustment for poor performance (low-quality tier compared to high-cost tier). We seek comment, however, on whether to calculate the value-based payment modifier for all groups of physicians that are satisfactory PQRS reporters using the quality-tiering approach described in subsection (h) below, rather than providing an option for such groups of physicians to request that we do so.

The second category includes those groups of physicians with 25 or more eligible professionals that have not met the PQRS satisfactory reporting criteria identified above. Under our proposal, a group of physicians could fail to meet the PQRS satisfactory reporting criteria because the group of physician decided not to participate in any PQRS reporting mechanism or because the group attempted to submit data, but failed to meet the criteria to become a satisfactory reporter (e.g., did not report data appropriately on the requisite number of beneficiaries or measures). Because we would not have quality measure performance rates on which to assess the quality of care furnished by these groups, we propose to set their value-based payment modifier at -1.0 percent, meaning they would receive 99.0 percent of the paid amounts for the items and services billed under the PFS.

We believe this approach is a reasonable way to phase in the value-based payment modifier because groups of physicians have demonstrated their ability to submit data on quality measures at the group level using the PQRS GPRO since 2011. And for 2012, we revised the eligibility criteria for the PQRS GPRO to include groups with at least 25 eligible professionals. Thus, we believe that these groups of physicians have had sufficient opportunity to make an informed decision about submitting data on quality measures that also could be used in the value-based payment modifier starting in 2015.

Moreover, section 1848(p)(5) of the Act requires us to, as appropriate, apply the value-based payment modifier ''in a manner that promotes systems-based care.'' In this context, systems-based care is the processes and workflows that (1) make effective use of information technologies, (2) develop effective teams, (3) coordinate care across patient conditions, services, and settings over time, and (4) incorporate performance and outcome measurements for improvement and accountability.[12] We believe that groups of physicians have the ability and the resources to redesign such processes and workflows to achieve these objectives and furnish high-quality and cost-effective clinical care.

Starting in 2017, we would apply the value-based payment modifier to all physicians and groups of physicians as required by the statute. We seek comment on whether we should offer individual physicians and groups of physicians with fewer than 25 eligible professionals an option that their value-based payment modifier be calculated using a quality-tiering approach starting in 2015. If we did so, we could calculate a value-based payment modifier for groups of physicians with as few as two eligible professionals and apply the value-based payment modifier at the TIN level in the manner described in these proposals for groups of 25 or more eligible professionals. Likewise, we seek comment on how to adapt our proposals to calculate a value-based payment modifier at the TIN level for physicians in solo practices (TINs comprised of one NPI).

We also seek comment on whether we should develop a value-based payment modifier option for hospital-based physicians to elect to be assessed based on the performance of the hospital at which they are based. In particular, hospital performance could be assessed using the measure rates the hospitals report on the quality measures in the Inpatient Quality Reporting (IQR) and the Outpatient Quality Reporting (OQR) programs. If so, we seek comment on which IQR and OQR measures (and the applicable reporting period) would be appropriate to include in such an option and a way to identify and verify whether physicians are hospital-based. The IQR measures can be found at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1141662756099* and the OQR measures can be found at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.*

In addition, we seek comment on how best to ascertain whether a group of physicians with 25 or more eligible professionals requests the option that their value-based payment modifier be calculated using a quality-tiering approach. We seek to establish a system that reduces administrative burden on physicians, enables these groups of physicians to indicate how they plan to submit data on quality measures through the PQRS, and is easy to administer. We could, for example, build off of the self-nomination process that we have proposed for groups of physicians to participate in the PQRS GPRO. As discussed in Section III.G.1.b.2 of this proposed rule regarding the PQRS, we anticipate that we will have the ability to collect self-nomination statements via the web in 2013. As proposed above, these self-nomination statements would be submitted by January 31, 2013 for the 2013 performance period. In the event that the web-based functionality is unable to accept self-nomination statements for 2013, we have proposed that groups of physicians submit a self-nomination statement via a letter (in a prescribed format) to CMS in a timely manner.

We also could establish a separate web-based registration system that permits groups of physicians to, throughout calendar year 2013, request that their value-based payment modifier be calculated using the quality-tiering approach (rather than submit a self-nomination statement by January 31, 2013 as proposed in the PQRS self-nomination process). Another approach would be to require that groups of physicians submit a letter (in a prescribed format) to CMS in a timely manner. We seek comment on these approaches.

We propose not to offer groups of physicians with 25 or more eligible professionals that are participating in the Medicare Shared Savings Program or are associated with the Pioneer ACO program, assuming they meet the PQRS satisfactory reporting criteria, the option that their value-based payment modifier be calculated using the quality-tiering approach. As of April 2012, 27 ACOs are participating in the Shared Savings Program, and 32 ACOs are participating in the Pioneer ACO program. We anticipate more ACOs will enter the

[12] Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches, Vol 2: Culture and Redesign. AHRQ Publication No. 08–0034–2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321–330.

Medicare Shared Savings Program beginning July 1, 2012, and on January 1st annually thereafter. Shared Savings Program ACOs will be in a ''pay for reporting'' mode in 2013, while Pioneer ACOs will be in a ''pay for performance'' mode in 2013.

We make this proposal because we are mindful that the physicians and groups of physicians that are, or will be, participating in the Shared Savings Program and the Pioneer ACO program have made sizable investments to redesign care processes based on the incentives created by these programs. Indeed, these organizations have committed to reporting on a broader set of quality measures than we are proposing for the value-based payment modifier to demonstrate the quality of care their beneficiaries are receiving. We do not wish to unintentionally disturb these investments. Therefore, we seek comment on ways to structure the value-based payment modifier starting in 2017 so it does not create incentives that conflict with the goals of the Shared Savings Program and the Pioneer ACO program. Alternatively, we seek comment on whether we should permit groups of physicians that are participating in these two programs the option that their value-based payment modifier be calculated using a quality-tiering approach and applied to their payments under the PFS starting in 2015.

We note that the value-based payment modifier is applicable only to payment for physicians' services under the PFS. The value-based payment modifier does not apply to services that physicians furnish in Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and Critical Access Hospitals (CAHs) billing under method II (but not method I or the standard method), because they are not considered as being paid under the PFS.

b. Proposed Performance Period

We previously finalized CY 2013 as the initial performance period for the value-based payment modifier that will be applied in CY 2015 (76 FR 73436). This means that we will use performance on quality and cost measures during CY 2013 to calculate the value-based payment modifier that we would apply to items and services for which payment is made under the PFS during CY 2015. Likewise, we propose that performance in CY 2014 be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016.

As we explained previously in the CY 2012 PFS final rule with comment period (76 FR 73435), we explored different options to close the gap between the performance period (that is, 2013) and the payment adjustment period (that is, 2015), but that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate a value-based payment modifier and notify physicians and groups of physicians of their quality and cost performance and value-based payment modifier prior to the payment adjustment period. We also explained that a system that adjusted payments to take into account the value-based payment modifier after claims have been paid would be onerous on physicians and beneficiaries. We continue to explore ways to provide more timely feedback to physicians and to narrow the gap between the performance period and the payment adjustment period and seek comment on practical alternatives that we could implement to do so. We seek comment on our proposal to use CY 2014 as the performance period for the 2016 value-based payment modifier.

c. Proposed Quality Measures

In this section we discuss our proposals to align quality measure reporting for the value-based payment modifier with PQRS reporting methods, to expand the range of quality measures that we will use for the value-based payment methodology, and to start a discussion on how to assess community based quality of care.

(1) Alignment of Quality Reporting Options With PQRS Satisfactory Reporting Criteria

As discussed above, we propose to categorize groups of physicians with 25 or more eligible professionals into two categories depending upon whether they have met the PQRS satisfactory reporting criteria established above for the value-based payment modifier. We note that under those proposed criteria for satisfactory reporting, groups of 25 or more eligible professionals would be able to submit data on quality measures using one of following proposed PQRS reporting mechanisms: PQRS GPRO using the web-interface, claims, registries, or EHRs; or PQRS administrative claims-based option. These reporting mechanisms are discussed above in Section III.G of this proposed rule (Physician Payment, Efficiency, and Quality Improvement—Physician Quality Reporting System). The satisfactory reporting criteria for the PQRS GPRO reporting mechanisms are described in Tables 27 and 28. The satisfactory reporting criteria for the PQRS administrative claims-based reporting option is described in Section III.G. (''Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Administrative Claims-based Reporting Mechanism.'') We propose to rely on these proposed criteria for satisfactory reporting in order to categorize groups of physicians for purposes of the value-based payment modifier.

For those groups of physicians that have met the PQRS satisfactory reporting criteria and request that their value-based payment modifier be calculated using a quality-tiering approach, we propose to use the performance rates on the quality measures reported through any of these reporting mechanisms. We seek comment on this proposal. We are concerned, however, that some groups of physicians may attempt to submit data on PQRS quality measures using one of the GPRO reporting mechanisms (web-interface, claims, registries, or EHRs) and fail to meet the criteria for satisfactory reporting and thus be categorized as non-PQRS reporters (and be subject to the −1.0 percent downward adjustment). To address this issue, we seek comment on whether to assess performance on the measures included in the PQRS administrative claims-based reporting option as a default if a group of physicians attempts to participate in one of the PQRS GPRO reporting mechanisms and does not meet the PQRS criteria for satisfactory reporting.

In addition, we seek comment on which PQRS reporting mechanisms we should offer to individual physicians if we were to apply the value-based payment modifier applied to their payments under the PFS starting in 2015 or 2016. Tables 25 and 26 describe the proposed PQRS reporting options available to individual physicians for the 2013 and 2014 PQRS incentives.

(2) Quality Measure Alignment With the Physician Quality Reporting System

In the CY 2012 PFS final rule with comment period (76 FR 73432), we finalized, for physicians practicing in groups, all measures in the GPRO of PQRS for 2012. We also stated that we expected to update these measures for the initial performance year (CY 2013) of the value-based payment modifier based on the measures finalized in subsequent rulemaking under PQRS. (76 FR 73427 through 73432). We propose to include all individual measures in

the PQRS GPRO web-interface, claims, registries, and EHR reporting mechanisms for 2013 and beyond for the value-based payment modifier. These quality measures are included in Tables 30 and 32. We seek comment on this proposal.

We also seek comment on the quality measures that we should propose for individual physicians if we were to provide individual physicians the ability to elect to have the value-based payment modifier apply to their payments under the PFS starting in 2015 or 2016. In the CY 2012 PFS final rule with comment period, we finalized for individual physicians, the PQRS core set of measures for CY 2012 and the core set of measures, alternate core, and additional measures in the Medicare EHR Incentive Program for 2012. We seek comment on which PQRS measures for 2013 and beyond to include in calculating the value-based payment modifier at the individual level. Table 32 lists the PQRS measures we are proposing for reporting through PQRS for 2013 and beyond. We believe incorporating all the PQRS measures provides a broad set of quality measures from which physicians can choose how best to assess their performance. We seek comment on these issues and the above proposals.

(3) Administrative Claims Option Under PQRS

Under the PQRS, we propose to provide an option for physicians and groups of physicians to select an administrative claims-based reporting option for purposes of the PQRS payment adjustment for 2015 and 2016 only. We discuss two issues surrounding this proposed administrative claims-based reporting option as it relates to the value-based payment modifier: (1) the level at which to assess the administrative claims-based measures (individual or group), and (2) the scope of quality measures that will be assessed using administrative claims.

(a.) Level of Performance Assessment

We can either assess performance at the individual physician level, as we did in the 2010 individual Physician Feedback reports, or at the group practice level and apply the performance rate to the physicians that are part of that group. Measurement and assessment at the individual level (as identified by a National Provider Identification number (NPI)) provides actionable information for improvement for physicians and can incentivize physician accountability for quality of care and cost. Despite these benefits, assessments of individual physicians using administrative claims-based measures may result in insufficient numbers of cases at the individual level to develop statistically reliable performance rates for each measure. Moreover, because physician performance would affect payment, we believe performance rates should be statistically reliable.

Assessment of physician performance at the group practice level (as identified by a single Taxpayer Identification Number (TIN)) reflects the view that the group in which a physician practices matters.[13] Group practice assessments will allow for a larger number of cases to assess performance scores and a larger number of outcome measures than assessments solely at the individual level. The larger number of cases also means the performance scores will be more statistically reliable on which to modify payment. It also allows us to calculate more quality measures in more domains of the National Quality Strategy. For these reasons, for purposes of the value-based payment modifier, we propose to assess performance rates for the measures in the PQRS administrative claims-based reporting option at the TIN level and apply the calculated performance score and the resulting value-based payment modifier to all physicians that bill under that TIN during the payment adjustment period. We seek comment on this proposal.

(b.) Quality Measures

In the CY 2010 individual Physician Feedback reports, which we distributed to over 23,000 physicians in Iowa, Kansas, Missouri, and Nebraska in March 2012, we provided performance rates on 28 administrative claims-based measures. These measures focused on clinical care of prevalent and chronic diseases among Medicare beneficiaries and medication management measures and were assessed at the individual physician level (that is, NPI). Twenty-seven of the 28 measures were endorsed by the National Quality Forum and the remaining measure was developed and is maintained by the National Committee for Quality Assurance (NCQA). Specifications for all 28 administrative claims-based measures can be found at *https://www.cms.gov/physicianfeedbackprogram*.

We propose to include, for purposes of assessing performance for the PQRS administrative claims-based reporting option, 15 of these measures, which are indicated in Table 64. We have selected these 15 measures because they are clinically meaningful, focus on highly prevalent conditions among beneficiaries, have the potential to differentiate physicians, and are reliable. Most of the proposed measures do not rely on the use of Part D drug data that we do not have for all Medicare FFS beneficiaries. We also note that these proposed measures are similar to the measures adopted in several private sector programs.[14] We also seek comment, however, on whether to include any of the remaining 13 measures that we have not proposed, but included in the Physician Feedback Reports. These measures are listed in Table 65.

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[13] See e.g., Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches, Vol 2: Culture and Redesign. AHRQ Publication No. 08–0034–2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321–330.

[14] Zirui Song, *et al,* ''Health Care Spending and Quality in Year 1 of the Alternative Quality Contract,'' New England Journal of Medicine, 365:10 (Sept. 2011).

TABLE 64: Proposed Measures for the Administrative Claims Option for 2015 and 2016

NQF Number	Measure Title	Measure Steward	Domain of Care
0576	**Follow-Up After Hospitalization for Mental Illness** Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner	NCQA	Care Coordination
0021	**Annual Monitoring for Beneficiaries on Persistent Medications** Percentage of patients 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year.	NCQA	Patient Safety
0555	**Lack of Monthly INR Monitoring for Beneficiaries on Warfarin** Average percentage of 40-day intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period.	CMS	Patient Safety
0577	**Use of Spirometry Testing to Diagnose COPD** Percentage of patients at least 40 years old who have a new diagnosis or newly active chronic obstructive pulmonary disease (COPD) who received appropriate spirometry testing to confirm the diagnosis.	NCQA	Clinical Care
0549	**Pharmacotherapy Management of COPD Exacerbation** Percentage of chronic obstructive pulmonary disease (COPD) exacerbations for patients 40 years of age and older who had an acute inpatient discharge or ED encounter between January 1–November 30 of the measurement year and were dispensed appropriate medications	NCQA	Clinical Care
0543	**Statin Therapy for Beneficiaries with Coronary Artery Disease** Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease.	CMS	Clinical Care
0583	**Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications** Percentage of patients age 18 or older starting lipid-lowering medication during the measurement year who had a lipid panel checked within 3 months after starting drug therapy	Resolution Health	Clinical Care
0053	**Osteoporosis Management in Women ≥ 67 Who Had a Fracture** Percentage of women 67 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the date of fracture.	NCQA	Clinical Care
0055	**Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years who received a dilated eye exam by an ophthalmologist or optometrist during the measurement year, or had a negative retinal exam (no evidence of retinopathy) by an eye care professional in the year prior to themeasurement year.	NCQA	Clinical Care
0057	**HbA1c Testing for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year.	NCQA	Clinical Care
0062	**Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes** Percentage of adult diabetes patients aged 18-75 years with at least one test nephropathy screening test during the measurement year or who had evidence existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria).	NCQA	Clinical Care
0063	**Lipid Profile for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 who had an LDL-C test performed during the measurement year.	NCQA	Clinical Care
0075	**Lipid Profile for Beneficiaries with Ischemic Vascular Disease** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to measurement year, who had a complete lipid profile during the measurement year.	NCQA	Clinical Care
0105	**Antidepressant Treatment for Depression** Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner.	NCQA	Clinical Care
0031	**Breast Cancer Screening for Women ≤ 69** Percentage of eligible women 40-69 who receive a mammogram in during the measurement year or in the year prior to the measurement year.	NCQA	Clinical Care

TABLE 65: Remaining Measures Not Proposed for the Administrative Claims Option

NQF Number	Measure Title	Measure Steward	Domain of Care
Not NQF Endorsed	**Potentially Harmful Drug-Disease Interactions in the Elderly** The percentage of Medicare members 65 years of age and older who have evidence of an underlying disease, condition or health concern and who were dispensed an ambulatory prescription for a contraindicated medication, concurrent with or after the diagnosis.	NCQA	Patient Safety
0071	**Acute Myocardial Infarction (AMI): Persistence of Beta-Blocker Treatment After a Heart Attack** Percentage of patients age 18 years and older during the measurement year who were hospitalized and discharged alive with a diagnosis of acute myocardial infarction (AMI) and who received persistent beta-blocker treatment for six months after discharge	NCQA	Clinical Care
0022	**Use of High-Risk Medications in the Elderly: (a) Patients Who Receive At Least One Drug To Be Avoided** Percentage of patients ages 65 years and older who received at least one high-risk medication in the measurement year **(b) Patients Who Receive At Least Two Different Drugs To Be Avoided** Percentage of patients 65 years of age and older who received at least two different high-risk medications in the measurement year	NCQA	Patient Safety
0556	**INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications** Percentage of episodes with an INR test performed 3 to 7 days after a newly-started interacting anti-infective medication for Part D beneficiaries receiving warfarin	CMS	Patient Safety
0568	**Appropriate Follow-Up for Patients with HIV** Percentage of patients diagnosed with HIV who received a CD4 count and an HIV RNA level laboratory test in the 6 months following diagnosis	Health Benchmarks	Clinical Care
0623	**Breast Cancer – Cancer Surveillance** Percentage of female patients 18 and older with breast cancer who had breast cancer surveillance in the past 12 months	Active Health Management	Clinical Care
0625	**Prostate Cancer – Cancer Surveillance** Percentage of males with prostate cancer that have had their PSA monitored in the past 12 months	Active Health Management	Clinical Care
0054	**Arthritis: Disease Modifying Antirheumatic Drug (DMARD) Therapy in Rheumatoid Arthritis** Percentage of patients 18 years and older, diagnosed with rheumatoid arthritis who have had at least one ambulatory prescription dispensed for a DMARD	NCQA	Clinical Care
0581	**Deep Vein Thrombosis Anticoagulation At Least 3 Months** Percentage of patients diagnosed with a lower extremity DVT more than 3 months prior to the end of the measurement year (who do not have contraindications to warfarin therapy and who do not have an IVC filter in the 90 days after the onset of PE) who had at least 3 months of anticoagulation after the event or patients showing compliance with anticoagulation therapy as indicated by a Home PT Monitoring device or multiple instances of prothrombin time testing over the 3-month period	Resolution Health	Clinical Care
0593	**Pulmonary Embolism Anticoagulation At Least 3 Months** Percentage of patients diagnosed with a PE more than 3 months prior to the end of the measurement year (who do not have contraindications to warfarin therapy and who do not have an IVC filter in the 90 days after the onset of PE) who had at least 3 months of anticoagulation after the event or patients showing compliance with anticoagulation therapy as indicated by a Home PT Monitoring device or multiple instances of prothrombin time testing over the 3-month period	Resolution Health	Clinical Care
0614	**Steroid Use – Osteoporosis Screening** Percentage of patients, 18 and older, who have been on chronic steroids for at least 180 days in the past 9 months and who had a bone density evaluation or osteoporosis treatment	Active Health Management	Clinical Care
0567	**Appropriate Work-Up Prior To Endometrial Ablation Procedure** Percentage of women who had an endometrial ablation procedure during the measurement year who received endometrial sampling or hysteroscopy with biopsy during the previous year	Active Health Management	Clinical Care
0584	**Hepatitis C: Viral Load Test** Percentage of patients 18 years or older with Hepatitis C (HCV) who began HCV antiviral therapy during the measurement year and had HCV Viral Load testing prior to initiation of antiviral therapy	Resolution Health	Clinical Care

(4) Outcome Measures for Groups of Physicians

We finalized in the CY 2012 PFS final rule (76 FR 73432) for physicians practicing in groups to include the rates of potentially preventable hospital admissions for two ambulatory care sensitive conditions (ACSCs) at the group practice level: heart failure; and chronic obstructive pulmonary disease. We also noted that several commenters to the CY 2012 proposed PFS rule expressed support for using outcome measures that assess the rate of potentially preventable hospital admissions including the Consumer-Purchaser Disclosure Project, a group of large purchasers of health care services. We believe it is appropriate to focus on potentially preventable hospital admissions because, as our 2010 Physician Feedback reports have shown, hospital inpatient, outpatient, and emergency department costs account for over 50 percent of total per capita costs. Thus, we propose to include four outcome measures in the value-based payment modifier for all groups of physicians with 25 or more eligible professionals. These outcome measures are discussed below. It is important to note that we propose to calculate these measures for groups of physicians with 25 or more eligible professionals regardless of which reporting mechanisms the groups of physicians choose to report quality data: PQRS GPRO using the web-interface, claims, registries, or EHRs; or the PQRS administrative claims-based reporting option.

Currently the Physician Feedback reports that we provide to group practices include potentially preventable hospital admission measures for three chronic conditions: heart disease, chronic pulmonary obstructive disease, and diabetes (a composite measure including uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes). In addition, the Physician Feedback reports provide potentially preventable hospital admission measures for three acute conditions: dehydration; urinary tract infection; and bacterial pneumonia. Specifications for all six of these measures can be found at *http://www.qualityindicators.ahrq.gov/Modules/PQI_TechSpec.aspx*.

However, given the potential that any group of physicians may have relatively few potentially preventable hospital admissions for a given condition, we propose to create for the value-based payment modifier two composites from these measures: an acute condition composite; and a chronic care composite. Compositing measures is a well-established technique in quality measurement to increase reliability when the number of cases is small because it combines individual measures into one composite measure. Additionally, presenters on the National Provider Calls CMS held on February 29 and March 14 entitled ''Physician Value-Based Payment Modifier Program: Experience from Private Sector Physician Pay-for-Performance Programs'' specifically recommended this approach for the value-based payment modifier. (Transcripts and slides from these presentations are available at *http://www.cms.gov/physicianfeedbackprogram*.)

We propose that the acute condition composite combine the rates of potentially preventable hospital admission for dehydration, urinary tract infection, and bacterial pneumonia. We propose that the chronic care composite combine the rates of potentially preventable hospital admissions for diabetes, heart failure, and chronic obstructive pulmonary disease. We believe group practices will be incentivized to prevent these types of hospital admissions, which will improve patient care and reduce per capita costs.

We also propose to use two other quality measures to assess care coordination at the group level that we currently use in other CMS physician quality programs: the all-cause hospital readmission measure used in the Medicare Shared Savings Program (described on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_QualityMeasures.pdf*) and the 30-day post-discharge visit measure used in the PGP Transition Demonstration (described at *https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//PGP_Transition_Quality_Specs_Report.pdf*). We believe that the all-cause hospital readmission measure provides a strong incentive for groups to focus on reducing hospital readmissions. In addition, the 30-day post-discharge visit measure helps incentivize physicians to engage in more effective care coordination. Recent literature cites a study in which there was no visit to a physician's office between the time of discharge and rehospitalization for 50 percent of patients who were rehospitalized within 30 days after a medical discharge to the community.[15] Based on input and comments from stakeholders, including other payers, we believe that such follow up visits can reduce unnecessary rehospitalizations. These four measures are summarized in Table 66.

[15] N Engl J Med 2009; 360:1418–1428

TABLE 66: Four Outcome Measures for the Value-Based Payment Modifier for Groups of Physicians

NQF Number	Measure Title	Measure Steward	Domain of Care
N/A	**1. Composite of Acute Prevention Quality Indicators**	N/A	Care Coordination
0279	**Bacterial Pneumonia** The number of admissions for bacterial pneumonia per 100,000 population.	AHRQ	
0281	**UTI** The number of discharges for urinary tract infection per 100,000 population Age 18 Years and Older in a one year time period	AHRQ	
0280	**Dehydration** The number of admissions for dehydration per 100,000 population.	AHRQ	
N/A	**2. Composite of Chronic Prevention Quality Indicators**	N/A	Care Coordination
	Diabetes Composite		
0638	**Uncontrolled diabetes** The number of discharges for uncontrolled diabetes per 100,000 population Age 18 Years and Older in a one year time period.	AHRQ	
0272	**Short Term Diabetes complications** The number of discharges for diabetes short-term complications per 100,000 Age 18 Years and Older population in a one year period.	AHRQ	
0274	**Long term diabetes complications** The number of discharges for long-term diabetes complications per 100,000 population Age 18 Years and in a one year time period.	AHRQ	
0285	**Lower extremity amputation for diabetes** The number of discharges for lower-extremity amputation among patients with diabetes per 100,000 population Age 18 Years in a one year time period.	AHRQ	
0275	**COPD** The number of admissions for chronic obstructive pulmonary disease (COPD) per 100,000 population.	AHRQ	
0277	**Heart Failure** Percent of the population with admissions for CHF.	AHRQ	
N/A	**3. All Cause Readmission** The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned.	CMS	Care Coordination
N/A	**4. 30 Day Post Discharge Visit** The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned.	CMS	Care Coordination

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We also note that we are making plans to seek National Quality Forum endorsement for these four measures as required by section 1848(p)(2)(B)(ii) of the Act. We seek comment on our proposals to use these four measures in the value-based payment modifier for all groups of physicians with 25 or more eligible professionals.

At this time we are not making proposals regarding how to assess community-level performance and how such assessments could be included in the value-based payment modifier for groups of physicians. We seek comment, however, on whether measurement and adjustment at the community level would further our objectives to encourage and reward physicians and groups of physicians for furnishing high-quality, efficient, patient-centered clinical care.

d. Proposed Cost Measures

Section 1848(p)(3) of the Act requires us to evaluate costs, to the extent practicable, based on a composite of appropriate measures of costs. In the CY 2012 PFS final rule with comment period (76 FR 73434), we finalized use of total per capita cost measures and per capita costs measures for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes) for the value-based payment modifier. Total per capita costs include payments under both Part A and Part B. Total per capita costs do not include Medicare payments under Part D for drug expenses. We propose to use at least a 60-day run out with a completion factor from our Office of the Actuary (for example, claims paid through March 1 of the year following December 31, the close of the performance period) to calculate the total per capita cost measures. We seek comment on this proposal.

We used these five measures in the 2010 Physician Feedback reports for individual physicians and physician groups; they also will be included in the 2011 Physician Feedback reports that we expect to disseminate later in 2012. We propose to continue to use these five measures to calculate the cost composite for the value-based payment modifier. We also are developing plans to submit these per capita cost measures for National Quality Forum endorsement.

Several recipients of the 2010 Physician Feedback reports objected to being ''held responsible'' for total per capita costs of the beneficiaries that they treated, because they could not affect the other costs incurred by the patient. In our view, the total per capita cost measure is just one metric used to assess the costs of care. It has no impact until we use it to make comparisons among

physicians and groups of physicians. In other words, it is not the measure itself (because it reflects the total cost of care beneficiaries received), but how we use it to assess performance that matters. As described more fully in the composite scoring methodology proposals below, we propose to make cost comparisons among groups of physicians using a similar beneficiary attribution methodology such that we make ''apples to apples'' comparisons. We believe that this would be an appropriate approach to using the total per capita cost measure in the value-based payment modifier. We seek comment on these proposals.

(1) Proposed Payment Standardization Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that ''* * * costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under section 1848(n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)) * * *'' In layman's terms, this directive requires us to standardize Medicare payments to ensure fair comparisons across geographic areas.

Payment standardization removes local or regional price differences that may cause cost variation a physician cannot influence through practicing efficient care. In Medicare, an effective payment standardization methodology would exclude Medicare geographic adjustment factors such as the geographic practice cost index (GPCI) and the hospital wage index so that, for example, per capita costs for beneficiaries in Boston, Massachusetts can be compared to those of beneficiaries in Lincoln, Nebraska. Payment standardization, therefore, allows fair comparisons of resource use costs for physicians to those of peers who may practice in locations or facilities where Medicare payments are higher or lower.

We have developed a detailed Medicare payment standardization methodology that excludes such geographic payment rate differences. We developed the methodology with substantial stakeholder input, and we update it annually to incorporate any payment system changes. More details of the CMS payment standardization methodology that we are proposing can be found at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

We have used this standardization approach, for example, in feedback reports we provide to hospitals related to the Medicare Spending per Beneficiary measure. The CMS payment standardization methodology includes a number of payment adjustments across the spectrum of fee-for-service Medicare. For example, the methodology eliminates adjustments made to national payment amounts that reflect PE and regional labor cost differences (measured by the GPCI and hospital wage index); substitutes a national amount when services are paid using a state fee schedule; eliminates supplemental payments to hospitals that treat a high share of poor and uninsured patients (that is, Medicare disproportionate share hospital (DSH) payments) or that receive indirect graduate medical education (IME) payments; removes incremental payments for community hospitals and Medicare-dependent hospitals above their base payments; and eliminates certain rural add-on payments for inpatient psychiatric hospitals and inpatient rehabilitation facilities. Outlier payments are treated as they would be if payments were not standardized, but they are adjusted to reflect wage differences.

The CMS payment standardization methodology also eliminates the effect of incentive payments under the PFS for physicians that furnish services in rural areas and other underserved communities such that they are not disadvantaged in the value-based payment modifier. For example, section 1833(m) of the Act provides incentive payments for physicians who furnish medical care services in geographic areas that are designated as primary medical care Health Professional Shortage Areas (HPSAs) under section 332 (a)(1)(A) of the Public Health Service (PHS) Act. The CMS standardization methodology does not include these incentive payments in standardized Part B costs so that physicians that furnish services in these areas are not disadvantaged in the value-based payment modifier. We believe that by doing so we are complying with the requirement in Section 1848(p)(6) to ''take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities when applying the value-based payment modifier.''

We standardized the cost measures in the 2010 Physician Feedback reports to allow fair comparisons of costs across physicians. However, we note that the methodology used in the 2010 Physician Feedback reports differs from the methodology that we are proposing for the value-based payment modifier. Although that methodology achieved the same goal of ensuring fair comparisons, the standardization techniques used for the 2010 reports were performed at the regional level (because the reports focused on providers in four states) and used an averaging approach. Thus many of the national adjustments that we have proposed in this rule were not applicable to the 2010 Physician Feedback reports. In the 2011 Physician Feedback reports that we expect to disseminate later in 2012, we will use the national payment standardization methodology currently used to standardize payments in hospital feedback reports for the Medicare Spending per Beneficiary measure. We propose to use that same methodology to standardize cost measures for purposes of the value-based payment modifier. We believe that this approach to payment standardization allows us to standardize payments nationally and to use a consistent approach across multiple programs and CMS initiatives. We seek comments on this proposal.

(2) Proposed Risk Adjustment Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that costs be adjusted to ''* * * take into account risk factors[,] such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary.''

Risk adjustment accounts for differences in patient characteristics not directly related to patient care, but that may increase or decrease the costs of care. In the Physician Feedback reports, after standardizing per capita costs for geographic factors, we also adjusted them based on the unique mix of patients attributed to the physician or group of physicians. Costs for beneficiaries with high risk factors (such as a history of chronic diseases, disability, or increased age) are adjusted downward, and costs for beneficiaries with low risk factors are adjusted upward. Thus, for individual physicians or physician groups who have a higher than average proportion of patients with serious medical conditions or other higher-cost risk factors, risk adjusted per capita costs are lower than the unadjusted costs, because costs of higher-risk patients are adjusted

downward. Similarly, for individual physicians or physician groups who treated comparatively lower-risk patients, risk adjusted per capita costs were higher than unadjusted costs, because costs for lower-risk patients were adjusted upwards.

In the Physician Feedback program, we applied a risk adjustment methodology to account for patient differences in per capita costs that were due to patient demographics such as age and gender, socioeconomic factors such as Medicaid dual eligible status, and prior health conditions that can affect a beneficiary's costs, regardless of the efficiency of the care provided. This risk adjustment methodology uses the CMS' Hierarchical Condition Categories (HCC) model, which incorporates beneficiary characteristics and prior year diagnoses to predict relative Medicare Part A and Part B payments. This model was originally developed under contract to CMS by researchers at Boston University and Research Triangle Institute (RTI) with clinical input from Harvard Medical School physicians based on an analysis of Medicare FFS beneficiaries diagnoses and expenditures. The model is updated every year to incorporate new diagnosis codes and is recalibrated regularly to reflect more recent diagnosis and expenditure data.

The HCC model assigns prior year ICD–9–CM diagnosis codes (each with similar disease characteristics and costs) to 70 generally high-cost clinical conditions to capture medical condition risk. The HCC risk scores also incorporate patient age, gender, reason for Medicare eligibility (age or disability), and Medicaid eligibility status, which is in part a proxy for socioeconomic status and reflects the greater resources typically used by beneficiaries eligible for both Medicare and Medicaid. The risk adjustment model also includes the beneficiary's end stage renal disease (ESRD) status. More information about the risk adjustment model is on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/122111_Slide_Presentation.pdf*.

We have examined the impacts of applying the above risk adjustment methodology for physicians included at the group and individual level in the 2010 Physician Feedback reports and believe the approach provides a reasonable method to adjust per capita costs based on beneficiary characteristics. The results show that the risk adjustment methodology, in the aggregate, compresses the range of per capita costs substantially and that a group of physicians' total per capita cost measures can experience substantial adjustment based upon the risk profile of the beneficiary population. For groups of physicians, the risk adjustment methodology had the effect of reducing the absolute difference between the groups with the lowest per capita cost and the highest total per capita cost by 55.7 percent. In particular, the lowest third of the groups were increased by an average of 6.2 percent and the most expensive third were lowered by 10.4 percent. The middle third, on average, were lowered by 0.1 percent. The range of adjustments was between −10.3 percent and +8.2 percent. We found similar results at the individual level.

We propose to use the same risk adjustment model for risk adjusting total per capita costs and the total per capita costs for beneficiaries with four chronic diseases (coronary artery disease, COPD, diabetes, and heart failure) as we have used for the group and individual 2010 Physician Feedback reports. We seek public comment on applying the same risk adjustment approach to the value-based payment modifier as with the Physician Feedback reports.

(3) Episode-Based Cost Measures

Section 1848(n)(9)(A)(ii) of the Act as added by section 3003 of the Affordable Care Act, required CMS to develop a Medicare episode grouper by January 1, 2012. Four contractors submitted prototype episode groupers to CMS in September 2011, and, after evaluating the prototypes, we selected one to develop its prototype episode grouper into a comprehensive Medicare episode grouper. This process will entail additional technical and analytical development, as well as testing of the more fully developed episode grouping product. Initially the episode grouper will focus on selected chronic conditions and acute events. As development of the selected episode grouper continues, we expect to see the number of conditions increase. We plan to use the episode grouper in future Physician Feedback reports in order to test and gain stakeholder input into the development of the episodes of care.

Although the statute does not require the use of the episode-based cost measures for the value-based payment modifier, it requires that we use such cost measures in the Physician Feedback reports. We plan to include episode-based cost measures for several conditions in the Physician Feedback reports beginning in 2013 (based on 2012 data). Interested parties that commented on the CY 2012 PFS final rule with comment period (76 FR 73434) recommended that we use episode-based cost measures in the value-based payment modifier, rather than total per capita costs, because episode-based costs are used in many private sector pay-for-performance programs and directly reflect care provided by physicians. We anticipate providing episode-based cost measures in the Physician Feedback reports before proposing them for the value-based payment modifier in future rulemaking.

e. Attribution of Quality and Cost Measures

Calculation of administrative claims-based quality and cost measure performance rates requires us to attribute Medicare beneficiaries to groups of physicians. For example, for the PQRS administrative claims-based reporting option, we must attribute beneficiaries to groups of physicians (as identified by a single TIN) so that we are able to calculate the relevant quality measure and cost measure performance rates. Likewise, we must attribute beneficiaries to groups of physicians that submit data on quality measures under the PQRS GPRO in order to calculate the cost measure performance rates. In the 2010 Physician Feedback reports, we used two different attribution methodologies: one method for individual physicians (''degree of involvement method'') and another method for groups of physicians (''plurality of care method''). This section discusses our proposals for using these attribution methods to calculate the quality and cost measures for the value-based payment modifier. We note that the attribution methods do not impact beneficiaries' choice of providers.

We used the plurality of care method to attribute beneficiaries in the 2010 Physician Feedback reports provided to the group practices using the PQRS GPRO web-interface. In this method, we attributed Medicare FFS beneficiaries to the group practice that billed a larger share of office and other outpatient Evaluation and Management (E/M) services (based on dollars) than any other group of physician practice (that is, the plurality). In addition, beneficiaries had to have at least two E/M services at the group of physicians. We used this attributed population to identify a sample of beneficiaries eligible for the quality measures reported via the PQRS GPRO web-interface. We also calculated the per capita cost measures based on this attributed population.

In the discussion above regarding beneficiary attribution for groups of physicians choosing to report quality

measures through the PQRS GPRO web-interface, we are seeking comment on the continued use of the ''plurality of care'' attribution methodology or to use the Medicare Shared Savings Program attribution methodology for 2013 and beyond. The Medicare Shared Savings Program attribution methodology is described at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes_Regulations_Guidance.html*. For purposes of program alignment, we propose to use the same attribution methodology that we finalize for the PQRS GPRO web-interface to attribute beneficiaries to groups of physicians for purposes of the value-based payment modifier. This proposal means that we would calculate the per capita cost measures based on the same attributed beneficiary population as we use for determining the quality measures for the group of physicians that report PQRS quality data through: PQRS GPRO using the web-interface, claims, registries, or EHRs; or PQRS administrative claims-based option.

We are concerned, however, that such an attribution methodology may be too restrictive because it relies solely on office (E/M) visit codes and it could fail to attribute beneficiaries whom the group practices would identify as their beneficiaries. This situation may occur, for example, with single specialty groups such as radiologists or anesthesiologists that do not submit claims that use E/M codes. For these reasons, we seek comment on whether to use an alternative approach (such as the ''degree of involvement'' method that is discussed next) for all groups of physicians except those reporting quality measures using the PQRS GPRO web-interface.

We used the ''degree of involvement'' method to attribute beneficiaries for cost purposes to individual physicians in the CY 2010 Physician Feedback reports, which we produced for physicians (23,730 physicians in total) in four states: Iowa; Kansas; Missouri; and Nebraska. Under this attribution method, we classified the patients for which a physician submitted at least one Medicare FFS Part B claim into three categories (directed, influenced, and contributed) based on the amount of physician involvement with the patient:[16]

- For *directed* patients, the physician billed for 35 percent or more of the patient's office or other outpatient evaluation and management (E&M) visits.
- For *influenced* patients, the physician billed for fewer than 35 percent of the patient's outpatient E&M visits but for 20 percent or more of the patient's total professional costs.
- For *contributed* patients, the physician billed for fewer than 35 percent of the patient's outpatient E&M visits and for less than 20 percent of the patient's total professional costs.

The result of this methodology is that all of the beneficiaries for which a physician submitted Medicare Part B claims are attributed to the physician, but the beneficiaries are classified according to the degree of physician involvement with the beneficiary. We then calculated per capita cost measures for the beneficiaries within each of these three classifications. In addition, a beneficiary can be attributed to more than one physician (and in different categories) if the beneficiary received services from more than one physician.

Based on the CY 2010 reports, physicians that ''directed'' care billed, on average, approximately three E/M visits with the patient, which represented over 64 percent of all E/M services furnished by the physicians treating the beneficiary. Although the directed attribution rule permits two physicians to be attributed to the same beneficiary (because only two physicians could each have greater than 35 percent of the beneficiaries E/M visits), in practice that rarely happened as a physician that directed care of a beneficiary had the substantial majority of E/M visits, that accounted for 31 percent of costs among all physicians treating the beneficiary. These observations indicate the physician had substantial control over the patient's care. In addition to primary care specialties, the other specialties with the greatest percentage of physicians directing care were rheumatology and oncology.

Physicians that ''influenced'' care had, on average, one E/M visit with the beneficiary, but also had slightly over one-third of the beneficiaries' total Part B costs. Although the average number of E/M visits was low, the physician, on average, billed for one procedure during the year and this procedure was the most expensive one for the patient. This share of Part B costs was greater than physicians that directed or contributed to a beneficiary's care. Although the influenced attribution rule permits up to five physicians to influence care (because five physicians could each bill 20 percent of total Part B costs), this rarely happened as a physician that influenced care of a beneficiary had, on average, approximately 84 percent of total Part B costs compared to other physicians that could have influenced care. Medical specialists and surgeons, including ophthalmology, orthopedic surgery, plastic and reconstructive surgery had the greatest percent of beneficiaries for which they influenced care.

Physicians that ''contributed'' to care had, on average, less than one E/M visit per year with the beneficiary and billed for less than, on average, 20 percent of average beneficiaries' total professional costs, thus indicating that the beneficiary received care from many providers. On average, at least five physicians contributed to a beneficiary's care (not including those that directed or influenced that care).

We calculated average total per capita cost measures for physicians by attribution rule and these costs are shown in Table 67. Not surprisingly, total per capita costs for directed and influenced beneficiaries were about 50 percent of the total per capita costs of physicians with contributed beneficiaries. The costs in Table 67 show that beneficiaries that receive care from multiple physicians, have substantially higher per capita costs. In addition, approximately 20 percent of Medicare beneficiaries covered by the 2010 Physician Feedback reports had contributed care in which physicians only contributed to it. In other words, the care furnished was neither ''directed'' nor ''influenced'' by a physician.

TABLE 67—AVERAGE PER CAPITA COSTS BY ATTRIBUTION RULE FOR PHYSICIANS IN IOWA, KANSAS, NEBRASKA, AND MISSOURI

Attribution rule	Average total per capita cost
All physicians	$18,831

[16] CMS, ''Detailed Methodology for Individual Physician Reports'' (2012), available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/QRURs_for_Individual_Physicians.pdf*.

TABLE 67—AVERAGE PER CAPITA COSTS BY ATTRIBUTION RULE FOR PHYSICIANS IN IOWA, KANSAS, NEBRASKA, AND MISSOURI—Continued

Attribution rule	Average total per capita cost
Physicians with Directed Beneficiaries	10,719
Physicians with Influenced Beneficiaries	9,407
Physicians with Contributed Beneficiaries	20,243

We believe the value-based payment modifier should address not only the care for beneficiaries that a physician may ''direct'' or ''influence,'' but also play a role in encouraging more efficient, not just more, care for beneficiaries. We believe that any attribution rule should consider the ''contributed'' beneficiaries, especially those beneficiaries that are neither directed nor influenced by other physicians, because the care of these beneficiaries is where the greatest potential for improved care and coordination reside.

As explained more below, we seek comment on whether to attribute two populations of beneficiaries to groups of physicians using (1) a combination of the directed and influenced rules and (2) the contributed rule. If we were to finalize this attribution methodology, we would calculate a separate per capita cost measures for each patient population. For example, we would calculate one total per capita cost measure for the groups of physicians' ''directed and influenced'' beneficiaries and a second total per capita cost measure for the groups' ''contributed'' beneficiaries. (In the value-based payment modifier scoring methodology section below, we explain our proposals for how to score and weight these measures to ensure fair comparisons among groups of physicians).

First, we would attribute beneficiaries to a group of physicians that billed for 35 percent or more of the patient's office or other outpatient (E/M) visits or at least 20 percent or more of the beneficiary's total professional costs. This proposal combines the ''directed'' and ''influenced'' methods discussed above. Combining ''directed'' and ''influenced'' beneficiaries into one attributed patient population is reasonable because groups of physicians that care for these beneficiaries treat them, on average, more than any other physician or are responsible for a large percentage of professional costs. Combining the ''directed'' and ''influenced'' rules attributes beneficiaries to the group of physicians over which they have substantial control of resource utilization.

Second, we would attribute a second and separate patient population to the group of physicians which would consist of the remaining beneficiaries to whom a group of physicians provided service but who were not attributed in the first patient population (for example, beneficiaries for which the group of physicians did not bill for 35 percent of more of E/M visits and for less than 20 percent of professional costs). This rule corresponds to the ''contributed'' category discussed above. We believe that attributing a second patient population to groups of physicians ensures accountability for all beneficiaries to whom a group of physicians furnishes services. We seek comment on whether to use the ''degree of involvement'' attribution method for all groups of physicians that submit data on PQRS quality measures through PQRS GPRO using claims, registries, and EHRs, and through the PQRS administrative claims-based option.

f. Proposed Composite Scores for the Value-Based Payment Modifier

Section 1848(p)(2) of the Act requires that quality of care be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished. Likewise, section 1848(p)(3) of the Act requires that cost measures used in the value-based payment modifier be evaluated, to the extent practicable, based on a composite of appropriate measures of costs. This section discusses our proposals for constructing the quality of care and cost composites.

(1) Proposed Quality of Care and Cost Domains

In many of our value-based purchasing programs such as Hospital Value-Based Purchasing and the Medicare Shared Savings Program, we selected and classified measures into quality domains that reflect important national objectives for quality assessment and improvement. We believe it is important to align the quality measures used in the value-based payment modifier with the national priorities established in the National Quality Strategy. The National Quality Strategy outlined six priorities including:

- Make care safer by reducing harm caused in the delivery of care (patient safety).
- Ensure that care engages each person and family as partners (patient experience).
- Promote effective communication and coordination of care (care coordination).
- Promote the most effective prevention and treatment practices for leading causes of mortality (clinical care).
- Work with communities to promote wide use of best practice to enable healthy living (population/community health).
- Make quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models (efficiency).[17]

We propose to classify each of the quality measures that we proposed for the value-based payment modifier into one of these six domains. We propose to weight each domain equally to form a quality of care composite. We believe this is a straightforward approach that recognizes the importance of each domain. Within each domain, we propose to weight each measure equally so that groups of physicians have equal incentives to improve care delivery on all measures. To the extent that a domain does not contain quality measures, the remaining domains would be equally weighted to form the quality of care composite. For example, if three domains contain quality information, each domain would be weighted at 33.3 percent to form the quality composite.

In terms of the cost composite, we finalized in the CY 2012 PFS final rule (76 FR 73434) total per capita costs (Parts A and B) and total per capita costs for beneficiaries with four chronic diseases (diabetes, CAD, COPD, heart failure). We propose to group these five per capita cost measures into two separate domains: total overall cost (one measure) and total costs for

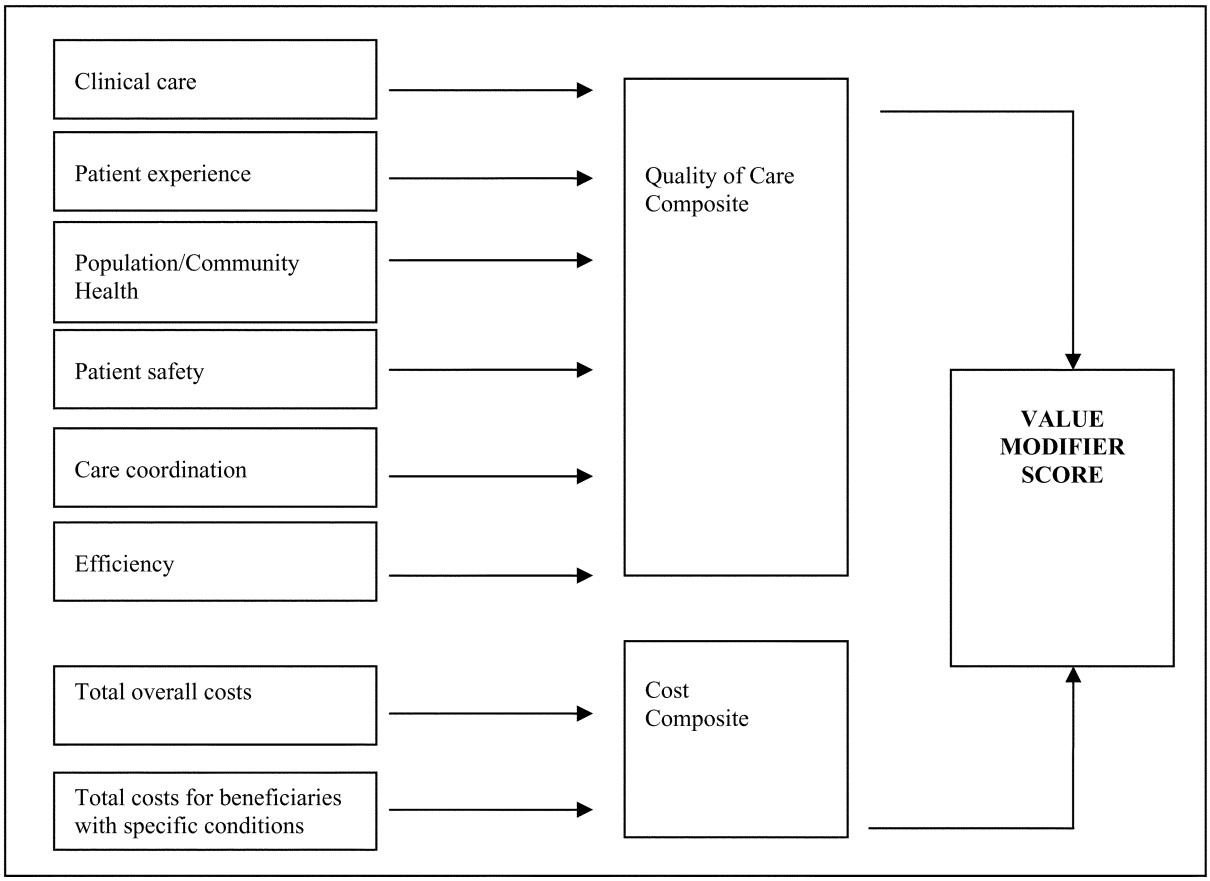
[17] National Quality Strategy, *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

beneficiaries with specific conditions (four measures). A separate domain for costs for beneficiaries with specific conditions highlights our desire to incentivize efficient care for beneficiaries with these conditions.

Similar to the quality of care composite, we propose to weight each cost domain equally to form the cost composite and within the cost domains we propose to weight each measure equally. In those instances in which we cannot calculate a particular cost measure, for example due to too few cases, we propose to weight the remaining cost measures in the domain equally.

If we were to attribute two patient populations to each group of physicians as discussed above regarding the ''degree of involvement'' attribution methodology, we propose to weight the measures in each population based on the group of physicians' allowed charges for beneficiaries attributed to each population so that the cost composite accurately reflects the cost of care furnished. We seek comment on these proposals. Table 68 graphically depicts these proposals for the quality of care and cost composites and how they relate to the value-based payment modifier.

TABLE 68: Relationship between Quality of Care and Cost Composites and the Value-Based Payment Modifier



(2) Proposed Value-Based Payment Modifier Scoring Methods

We adopted different methods to score quality and cost measures in our value-based purchasing programs with each scoring methodology tailored to further the program's purpose. For example, in the Medicare Shared Savings Program, we finalized a point system scoring methodology that assesses performance against established Medicare program benchmarks for each quality measure. In the hospital-value based purchasing program, we used a point system methodology that considered both a hospital's achievement and improvement from a baseline performance period. We then translated these points using a linear exchange function to develop a unique payment modifier for each hospital.

For the value-based payment modifier, we believe the composite scoring methodology should keep intact the underlying distribution of performance rates so that the composite scores distinguish clearly between high and low performance. Groups of physicians also should easily be able to understand how performance on a quality or cost measure can affect their composite score, and hence their payment. We also believe that the composite scoring methodology should be used at all performance assessment levels (individual physician, group of physicians, hospital). Thus, because we are proposing to provide flexibility to groups of physicians as to the quality measures they report, the scoring methodology needs to be able to compare ''apples to apples.''

Therefore, we propose a scoring approach that focuses on how the group of physicians' performance differs from the benchmark on a measure-by-measure basis. For each quality and cost measure, we propose to divide the difference between a group of physicians' performance rate and the benchmark by the measure's standard deviation. The benchmarks, as further

described below, are the national means of the quality or cost measure. This step produces a score for each measure that is expressed in standardized units. As discussed above, we propose to weight each measure's standardized score equally with other measures in the domain to obtain the domain standardized score. We propose to weight the domain scores equally to form the quality of care and cost composites. We seek comment on this proposal.

We believe that this proposal achieves our policy objective to distinguish clearly between high and low performance and to allow us to create composites of quality of care for groups of physicians that report different quality measures. We also note that this approach is used in several private sector physician profiling efforts.[18]

Table 69 illustrates how we would score three hypothetical quality measures in the same quality domain under our proposal. A standardized score of zero means that performance is at the national mean. Higher standardized scores (for example, 2.98) mean that performance is better than the national mean. Likewise, a large negative score means that performance is much lower than the national mean. In the example shown in Table 69, the quality domain score would be 0.79 (the average of the three quality measures' standardized units) meaning the group of physicians scored slightly better than average in this quality domain. We would use the same method for the quality measures in the other domains that a group of physicians reported.

TABLE 69—EXAMPLE OF STANDARDIZED SCORES IN ONE QUALITY DOMAIN

	Group of physicians' performance rate	Benchmark (national mean)	Standard deviation	Standardized unit
Quality Measures	.....	.....	.....	.....
Measure 1	95.0	93.5	3.3	0.47
Measure 2	71.4	86.3	13.9	−1.07
Measure 3	100.0	60.6	13.2	2.98
Quality Domain Score	.....	.....	.....	0.79

(3) Proposed Benchmarks and Peer Groups for Quality Measures

We propose that the benchmark for each quality measure be the national mean of each measure's performance rate during the performance period. We propose to unify the calculation of the benchmark by weighting the performance rate of each physician and group of physicians submitting data on the quality measure by the number of cases used to calculate the performance rate. Alternatively, we could weight each quality measure reported by groups of physicians by the number of physicians in the group. We seek not to bias how physicians choose to report quality measures (that is, at the group or individual level) by establishing different benchmarks for the same quality measures. Moreover, we believe beneficiaries are entitled to high quality care, regardless of whether a group of physicians or an individual physician furnishes it.

In addition, we propose that the benchmarks for quality measures in the PQRS administrative claims-based reporting option be the national mean of each quality measure's performance rate calculated at the TIN level. We propose to calculate the national mean by including the all TINs of groups of physicians with 25 or more eligible professionals. We propose to weight the TIN's performance rate by the number of cases used to calculate the quality measure.

To help groups of physicians understand how their quality measure performance affects their quality of care composite score, we propose to publish the previous years' performance rates (and standardized scores) on each quality measure. By doing so, groups of physicians will be better informed on how their performance may affect their payment in the coming year. We note, for example, that ''topped out'' quality measures are unlikely to have significantly higher or lower standardized scores for each measure because performance is clustered around the mean, and this scoring method seeks to differentiate performance from the mean. We seek comment on these proposals.

(4) Proposed Benchmarks and Peer Groups for Cost Measures

To ensure fair cost comparisons that identify groups of physicians that are outliers (both high and low), we believe the same methodology should be used to attribute beneficiaries to the groups of physicians and to the groups of physicians in the peer group. We seek to compare like groups of physicians that use the same cost attribution methodology to ensure we are making ''apples to apples'' comparisons among groups of physicians. As discussed above, there are two ways to attribute beneficiaries to groups of physicians (''plurality of care'' and ''degree of involvement''). We have proposed to use the ''plurality of care'' method for groups of physicians, regardless of whether they report data on PQRS quality measures using the GPRO web-interface, claims, registries, or EHRs; or the PQRS administrative claims-based option. Thus, we propose that the peer group for the cost measures include all other groups of physicians for which we use the ''plurality of care'' to attribute beneficiaries.

We seek comment on how the cost measure peer groups would change if we adopt the ''degree of involvement'' methodology for groups of physicians other than groups of physicians using the PQRS GPRO web-interface to submit data on quality measures.

Alternatively, we seek comment on establishing cost benchmarks on a quality measure-by-quality measure basis. Under this alternative approach, we would set the benchmark as the mean per capita cost of the physicians or groups of physicians that reported the quality measure—whether it was reported by a group of physicians or at the individual physician level. This approach encourages groups of physicians to select to report quality measures that reflect their practice patterns and patient populations more

[18] See e.g., Tufts Health Plan, ''How Does Tufts Health Plan Tier Its Doctors'' available at *http://www.tuftshealthplan.com/members/members.php?sec=how_your_plan_works&content=your_choice&rightnav=your_choice_nav&WT.mc_id=members_leftnav_hypw_yourchoice&WT.mc_ev=click.*

accurately. We seek comment on whether we should adopt this approach.

We also note that although we are not proposing in this rule to use episode-based costs, the scoring methodology that we have proposed can readily be used to identify high and low performers relative to a national benchmark for episodes of care. For example, we could develop an episode cost profile for a typical beneficiary with macular degeneration. We could then use the proposed scoring methodology to identify groups of physicians that have high and low episode costs relative to the benchmark. In addition, if we were to use such episode-based cost measures, we could use attribution methods that seek to stratify beneficiaries by relevant condition-specific characteristics to ensure fair and accurate peer group comparisons among physicians. We seek comment on our plans to use this approach in the future.

(5) Proposed Reliability Standard

We believe it is crucial that the value-based payment modifier be based on quality of care and cost composites that reliably measure performance. Statistical reliability depends on performance variation for a measure across physicians (''signal''), the random variation in performance for a measure within a physician's payment of attributed beneficiaries (''noise''), and the number of beneficiaries attributed to the physician. In other words, reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the quality (or cost) furnished by the physicians (or group of physicians) rather than random variation due to the sample of cases observed. Reliability is important so that we can confidently distinguish the performance of one physician (or group of physicians) from another.[19] Potential reliability values range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in differences in performance across physicians (or groups of physicians). Generally, reliabilities in the 0.40–0.70 range are often considered moderate and values greater than 0.70 high.

Therefore, we propose to establish a minimum number of cases in order for a quality or cost measure to be included in the quality of care or cost composite. To the extent that a group of physicians fails to meet the minimum number of cases for a particular measure, the measure would not be counted and the remaining measures in the domain would be given equal weight. To the extent that we cannot develop either a reliable quality of care composite or cost composite because we do not have reliable domain information, we would not calculate a value-based payment modifier and payment would not be affected. We recognize that a trade-off exists between developing a program that will eventually cover all physicians and groups of physicians and providing statistically reliable performance results. In this instance, as we increase the reliability threshold by requiring a higher minimum case size threshold, the number of physicians and groups of physicians for which we can develop a reliable quality of care or cost composite decreases. Based on an analysis of the individual CY 2010 Physician Feedback reports and on recent literature, we propose a minimum case size of 20 for both quality and cost measures to ensure high statistical reliability.[20] This proposal means that if a group of physicians does not have 20 or more beneficiaries eligible for a particular measure, that particular measure would not be included in the calculation of the value-based payment modifier.

Our reliability analysis of the quality and cost measures in the 2010 individual Physician Feedback reports informs our minimum case size proposal. The average reliability of the total per capita cost measure assessed at the individual level for physicians in all specialties was high (greater than .70) when the minimum case size was 20 or more. There was a slight increase in average reliability by increasing minimum case size to 30 cases. Increasing the minimum case size from 20 to 30, however, decreases the number of physicians for which we can calculate a reliable cost measure for physicians. The decrease in the number of physicians is small for some specialties (for example, internal medicine, family practice) but is much greater for other specialties (for example, thoracic surgery, allergy/immunology).

Reliability was high for nine of the 15 administrative claims-based quality measures that we are proposing for purposes of the value-based payment modifier for the PQRS administrative claims-based reporting option when the minimum case size was 20 or greater. Average reliability increases slightly by increasing case size to 30, but the number of physicians decreases, on average, by 30 percent of eligible physicians. We anticipate that statistical reliability of the quality and cost measures will increase when we assess physicians at the TIN level rather than NPI level, because, on average, a TIN will be attributed more beneficiaries than an NPI. We seek comment on these proposals.

g. Proposed Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of physician payment that should be subject to the adjustment for the value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians due to high performance and decrease for others due to low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In making proposals about the amount of Medicare payment made under the PFS at risk for the value-based payment modifier, we considered that there are two other payment adjustments affecting physicians' Medicare payment in 2015 that could further decrease physician payments in 2016. Specifically, under PQRS, a physician who does not satisfactorily submit data on quality measures during the applicable reporting period in 2013 have their fee schedule amount reduced by 1.5 percent for service furnished in 2015. This PQRS downward payment adjustment to the fee schedule will increase to 2 percent in 2016 (and thereafter) based on reporting periods that fall in CY 2014 (and thereafter, reporting period or periods that fall two years prior to the year in which the PQRS payment adjustment is assessed). However, as noted previously in this preamble, individual physicians and groups of physicians that satisfactorily submit data on PQRS quality measures via any of the reporting methods proposed for the 2015 and 2016 PQRS payment adjustment would avoid the PQRS downward payment adjustment. The second payment adjustment is for physicians that are not meaningful EHR users. Section 1848(a)(7) of the Act provides for a downward payment adjustment of 1 percent in 2015 (based on performance in 2013), 2 percent in 2016 (performance in 2014), and 3 percent in 2017 (performance in 2015). We note that the adjustment in 2015 for not being a meaningful EHR user is

[19] John L. Adams, ''The Reliability of Provider Profiling, A Tutorial,'' Rand Corporation (2009).

[20] Robert L. Houchens, ''The Reliability of Physician Cost Profiling in Medicare,'' (Aug. 2010) (Describing how for most physician specialties, Medicare physician cost profile scores are substantially more reliable than those derived from commercial settings).

increased by 1 percentage point (to −2 percent) if the physician was subject to the eRx Incentive Program payment adjustment for 2014.

To balance our goals of beginning the implementation of the value modifier consistent with the legislative requirements and to give us and the physician community experience in its operation, we propose to separate groups of physicians with 25 or more eligible professionals into two categories.

For those groups of physicians that have met the criteria for satisfactory reporting established for the value-based payment modifier and request that their value-based payment modifier be calculated using a quality-tiering approach, we propose that the maximum payment adjustment be −1.0 percent for poor performance (Table 70 displays the different downward payment adjustments depending upon a group of physicians' quality and cost tiers). We recognize that 2015 is the initial year for the value-based modifier and, thus, we are providing for a very modest adjustment for the program's initial years. A payment adjustment of −1.0 percent means that groups of physicians would receive 99.0 percent of the PFS payment amount for the service involved. Due to the BN requirement, we are not proposing the exact amount of the upward payment adjustments for high performance under the value-based payment modifier because the upward payment adjustments (in the aggregate) will have to balance the downward payment adjustments in order to achieve BN. Thus, we propose to determine the projected aggregate amount of downward payment adjustments and then calculate the upward payment adjustment factor based on the amount of the projected aggregate upward payment adjustments. Our proposals regarding the payment modifier scoring models in the next section explain how we proposed to calculate upward adjustments for high performance.

For groups of physicians with 25 or more eligible professionals that have not met the criteria for satisfactory reporting established for the value-based payment modifier (including those groups that have not participated in any of the PQRS reporting mechanisms), we propose to set their value-based payment modifier at −1.0 percent. We arrived at our proposal for a −1.0 percent downward adjustment using the following rationale. Section 1848(p) of the Act requires us to differentiate payment based on a comparison of quality of care furnished compared to cost. Because we do not have performance rates on which to assess the quality of care furnished by these groups, we can differentiate payment based on costs only. A cost-only comparison would set a lower downward adjustment for low-cost groups than for high-cost groups. Due to the fact that the value-based payment modifier is just starting in 2015, we do not wish to apply a greater downward payment adjustment for non-satisfactory reporters than we are proposing for the low quality/high cost groups that request that their value-based payment modifier be calculated using a quality-tiering approach. Thus, we propose to equalize the downward payment adjustment across these groups of physicians, despite the fact that they may have different costs. We seek comment on this approach.

h. Proposed Value-Based Payment Modifier Scoring Methodology

Section 1848(p)(1) of the Act requires the Secretary to establish a payment modifier that provides for differential payment to a physician or group of physicians under the fee schedule based upon the quality of care furnished compared to cost during a performance period. As noted previously, the statute requires that quality of care furnished and cost shall be evaluated, to the extent practicable, based on composites of quality of care furnished and cost. This section discusses our proposals for comparing the quality of care furnished to cost for those groups of physicians that request their value-based payment modifier be calculated using a quality-tiering approach.

In making our proposals, we developed two models that compare the quality of care furnished to costs: A quality tier model and a total performance score model. We propose the quality-tiering model for the value-based payment modifier, but we seek comment on the total performance score model. We also note that the literature on physician pay-for-performance includes other models, such as one based on an efficient frontier, that we are not proposing here.[21] We seek comment on these proposals.

(1) Quality-Tiering Model

The quality-tiering model compares the quality of care composite with the cost composite to determine the value-based payment modifier. To make this comparison, we propose to classify the quality of care composites scores into high, average, and low quality of care categories based on whether they are statistically above, not different from, or below the mean quality composite score. We seek to ensure that those groups of physicians classified as high or low performers have performance that is meaningfully different from average performance (to be sure that no group of physicians is disadvantaged for performance only slightly different from the benchmark) and is precisely measured (to ensure that no group of physicians is disadvantaged by an inaccurate performance assessment). We propose to assess meaningful differences as those performance scores that are at least one standard deviation from the mean. We propose to assess prevision by requiring a group of physicians' score to be statistically different from the mean at the 5.0 percent level of significance. We seek comment on these proposals and on whether we should only examine meaningful differences that are at least two or three standard deviations away from the mean. We also seek comment on whether to define the high and low categories of the quality composites as a fixed percentage (for example, 2.5 percent) of the number of groups of physicians or of the amount of payments under the PFS. Such an approach would minimize the number of group of physicians subject to payment adjustments.

Likewise, we propose to identify those groups of physicians that have cost composite scores that are statistically different from the mean cost composite score of all groups of physicians. We propose to classify these groups of physicians into high, average, and low cost categories based on whether they are significantly above, not different from, or below the mean cost composite score as described above with reference to quality composite. We propose to assess meaningful differences as those performance scores that are at least one standard deviation from the mean and we propose to assess precision at the 5.0 percent level of significance. We seek comment on these proposals and on whether we should only examine meaningful differences that are at least two or three standard deviations away from the mean. We also seek comment on whether to define the high and low categories of the cost composites as a fixed percentage (for example, 2.5 percent) of the number of groups of physicians or of the amount of payments under the PFS.

We propose to compare quality of care composite classification with the cost

[21] David Knutson, *et al.,* ''Alternative Approaches to Measuring Physician Resource Use,'' Second Interim Report (Dec. 2010), available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Knutson_MN_2nd_Interim Report_AltApproaches_2010.pdf.*

composite classification to determine the value-based payment modifier adjustment according to the amounts in Table 70.

TABLE 70—VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	+2.0x*	+1.0x*	+0.0%
Average quality	+1.0x*	+0.0%	−0.5%
Low quality	+0.0%	−0.5%	−1.0%

*Groups of physicians eligible for an additional +1.0x if reporting measures and average beneficiary risk score in the top 25 percent of all risk scores.

We propose to establish the upward payment adjustment factor (''x'') after the performance period has ended based on the aggregate amount of downward payment adjustments. We also propose to aggregate the downward payment adjustments in Table 70 with the downward adjustment for groups of physicians with 25 or more eligible professionals first and then to solve for the upward payment adjustment factor (''x''). For example, after determining the aggregate projected amount of the downward payment adjustments, CMS could calculate that the payment adjustment factor (''x'') would be 0.75 percent such that high quality/low cost groups of physicians would receive a 1.5 percent (2 x 0.75) upward payment adjustment during the payment adjustment period.

We also propose an additional incentive for groups of physicians to furnish care to high-risk Medicare beneficiaries. We seek to ensure that the value-based payment modifier does not cause unintended consequences in which groups of physicians decline to treat the most difficult cases. In particular, we propose that the scoring methodology provide a greater upward payment adjustment (+1.0x) for groups of physicians that care for high-risk patients (as evidenced by the average HCC risk score of the attributed beneficiary population) and submit data on PQRS quality measures through PQRS via the GPRO using the web-interface, claims, registries, or EHRs. We propose to increase the upward payment adjustment to +3x (rather than +2x) for groups of physicians classified as high quality/low cost and to +2x (rather than +1x) for groups of physicians that are either high quality/average cost or average quality/low cost if the group of physicians' attributed patient population has an average risk score that is in the top 25 percent of all beneficiary risk scores. In other words, we are not proposing this additional upward payment adjustment (+1.0x) for groups of physicians that select the PQRS administrative claims-based reporting option.

We propose this quality-tiering scoring methodology because it compares the quality of care furnished to cost as required by the statute. It also allows physicians to understand clearly how their payment is affected by their scores on the quality of care and cost composites. We also believe it is a reasonable way to start to modify physician payment because it clearly distinguishes the outliers (for example, high quality/low cost compared to low quality/high cost) from mean performance. The framework also allows us to fine tune payment adjustments as we gain greater experience with the proposed methodologies.

We seek comment on this proposal and on the proposed scoring methodologies. We seek comment in particular on whether it is appropriate to apply the same upward payment adjustment in Table 70 to groups of physicians classified as high quality/medium cost and medium quality/low cost. In addition, we seek comment on whether we should not provide as great an upward payment adjustment for those groups of physicians that select to report under the PQRS via the administrative claims-based reporting option, so that we encourage greater PQRS participation.

(2) Total Performance Score

A second approach to scoring the value-based payment modifier is a total performance score approach. This approach allows us to develop a unique value-based payment modifier for each group of physicians. This approach results in a range of continuous payment adjustments rather than the thresholds proposed in the quality tier approach. Under this approach, we could calculate a total performance score (TPS) by equally weighting the quality of care and cost composites. A negative score for the quality composite (Physician Group 2 in Table 71) means the group of physicians performed below the national average on the relevant quality measures. Likewise, a negative score for the cost composite means the group of physicians had higher costs than the national average. A score of zero means that the group of physicians performed at the national average. The example in Table 71 illustrates how we could calculate the TPS for three groups of physicians. In this example, Physician Groups 1 and 3 are above average and Physician Group 2 is below average.

TABLE 71—EXAMPLE OF TOTAL PERFORMANCE SCORE

	Quality composite (50%)	Cost composite (50%)	TPS
Physician Group 1	.9	.2	.55
Physician Group 2	−.9	−1.2	−1.05
Physician Group 3	2.2	1.2	1.70

We could develop an exchange function in which we translated the TPS into a unique value-based payment modifier for each group of physicians. This method would be similar to the approach we use in the Hospital Value-Based Purchasing program where we use a linear exchange function to develop a unique payment for each

hospital. This approach results in a continuous array of unique value-based payment modifiers such that there are no longer cut-off points between high and low performing groups of physicians. Rather, each group of physicians' payment would be modified under this approach.

We believe the quality-tiering approach may better compare the quality of care furnished to costs. We also believe that the quality-tiering approach is more transparent because groups of physicians may be more aware of the level at which quality and cost performance is likely to result in payment adjustment. However, we seek comment on these observations and whether to use the total performance score methodology rather than the quality-tiering methodology for the value-based payment modifier. If we were to use a total performance score methodology, we also seek comment on the weights to be given to quality and cost composites.

i. Proposed Informal Review and Inquiry Process

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the value-based payment modifier;
- The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care;
- The evaluation of costs composite, including establishment of appropriate measures of costs;
- The dates of implementation of the value-based payment modifier;
- The specification of the initial performance period and any other performance period;
- The application of the value-based payment modifier; and
- The determination of costs.

Despite the prohibition of administrative and judicial review, we believe it is useful for groups of physicians to understand how their payment under the PFS could be changed by the value-based payment modifier. We also believe that a mechanism is needed for groups of physicians to review and to identify any possible errors prior to application of the value-based payment modifier.

Therefore, we intend to disseminate Physician Feedback reports containing calendar year 2013 data in the fall of 2014 that encompass all physicians (individually or in groups of physicians, as applicable); these reports would be the basis of the value-based payment modifier in 2015. We propose that these reports would contain, among other things, the quality and cost measures and measure performance and benchmarks used to score the composites, and quality of care and cost composite scores, and the value-based payment modifier amount.

After the dissemination of the Physician Feedback reports in the fall of 2014, we propose that physicians would be able to email or call a technical help desk to inquire about their report and the calculation of the value-based payment modifier. We envision this process to help educate and inform physicians about the value-based payment modifier, especially for those groups of physicians that have elected that their value-based payment modifier be calculated using a quality-tiering approach. We note that because we have proposed to align our proposals with the PQRS satisfactory reporting criteria, groups of physicians will be able to avail themselves of the informal review process regarding the PQRS payment adjustment as well. We do not envision providing opportunities for review of a value-based payment modifier.

In anticipation of the reports that we would produce in 2014, in the fall of 2013 we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals based on 2012 data. These reports will include a ''first look'' at the methodologies we are proposing in this rule for the value-based payment modifier. We view these reports as a way to help educate groups of physicians about how the value-based payment modifier could affect their payment under the PFS.

j. Physician Scenario and the Value-Based Payment Modifier Proposals

The following example summarizes and pulls together our proposals for the payment modifier based on a group of physicians that satisfactorily reports quality measures through the PQRS GPRO web-interface and elects to have the value-based payment modifier calculated using the proposed quality-tiering methodology.

- *Quality measures:* A large medical practice group with more than 100 physicians each billing under the same TIN could choose to submit data on a common set of quality measures via the PQRS web-interface. This group of physicians would need to meet the applicable and proposed self-nomination requirements under the PQRS to report data under this option. After approval to participate, CMS would provide the group of physicians in early 2014 a list of patients pre-loaded into the GPRO web-interface on which they would be required to report the measures to CMS. They would complete the web-interface during the first calendar quarter of 2014.
- *Composite quality score:* To arrive at the quality composite score, we would create a standardized score for each quality measure included in the GPRO web-interface and then combine these scores into the quality composite. Specifically, for each measure we would divide the difference between the group's performance rate and the benchmark (the national mean computed across all groups of physicians and individual physicians submitting data on the quality measure) by the measure's standard deviation to create a standardized unit. Standardized units representing each measure are then combined into quality domains with each measure weighted equally. We would then equally weight the domains to form the quality composite score.
- *Composite cost score:* CMS will calculate five cost measures for the attributed beneficiaries. The standardized cost score composite is comprised of two cost domains: total per capita cost and condition-specific per capita costs. Each domain is weighted equally. For each cost measure, the difference between the group's performance and the national mean is divided by the standard deviation computed across all groups of physicians.
- *Payment modifier:* Using the quality composite, we would identify groups of physicians that have quality composite scores that are significantly different from the mean quality composite score of all groups of physicians. We would classify the groups of physicians into high, average, and low quality based on whether they are statistically above, not different from, or below the mean.

We would also identify groups of physicians that have cost composite scores that are significantly different from the mean cost composite score and classify groups of physicians into high, average, and low cost. We would then compare the quality of care composite classification with the cost composite classification to determine the payment modifier according to the amounts in Table 70.

Assuming the group of physicians had high quality and average cost, it would be eligible for an upward payment adjustment of +1x on each of its claims submitted for payment under the PFS during 2015. If the beneficiaries attributed to the group of physicians had an average risk score that was in the

top 25 percent of all beneficiary risk scores, the upward payment adjustment would be increased to +2x. We would indicate the exact amount of the upward payment adjustment in the Physician Feedback report that we produced in the fall of 2014.

(4) Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries. In September 2011, we produced and disseminated confidential feedback reports to physician groups that participated in the PQRS Group Practice Reporting Option (GPRO) in 2010, and in March 2012 we produced and disseminated reports to physicians practicing in the following States: Iowa, Kansas, Missouri, and Nebraska.

(a.) CY 2010 Physician Group Feedback Reports Based on 2010 Data and Disseminated in 2011

In September 2011, we produced and distributed confidential Physician Feedback reports to each of the 35 medical group practices that participated in the 2010 GPRO of the PQRS. Each report provided information on the quality of care and resource use for Medicare FFS beneficiaries treated by the medical groups in 2010. More information about the methodologies used in these reports and the aggregate findings from these reports is available at *http://www.cms.gov/physicianfeedbackprogram*.

To participate in the 2010 PQRS GPRO, a group practice had to be a single provider entity, identified by its TIN, with at least 200 eligible professionals. Thirty-five groups, encompassing 24,823 eligible professionals, participated in the 2010 PQRS GPRO reporting option. On average, each group practice contained the following type of medical professionals: Primary care (27 percent), medical specialties (20 percent), surgeons (13 percent), other medical professionals (36 percent) and ER physicians represented less than 1 percent. Despite the average group practice profile, five group practices were composed of substantially more medical specialists and surgeons than primary care professionals. A professional's medical specialty was determined based on the CMS medical specialty code listed most often on their 2010 Part B claims.

For each of the 35 participating group practices, we attributed Medicare FFS beneficiaries to the group practice if eligible professionals in the group practice billed for at least two office visits or other outpatient E&M services and the group practice had the plurality of E&M charges for that beneficiary. The average beneficiary population attributed to a group practice was 12,550 beneficiaries with the smallest group practice attributed 2,424 beneficiaries and the largest with 31,006 beneficiaries.

In 2010, each beneficiary that was attributed to a group practice had an average of 10 total E&M visits in 2010 (both to physicians in and outside the group practice), ranging from a low of nine visits per group practice to a high of 14 visits per group practice. Seven of these E&M visits, on average, were with physicians in the group practice, ranging from a low of five E&M visits to a high of nine E&M visits with physicians in the group practice. Thus, the GPRO groups provided not only the plurality, but the large majority, of E&M visits to the beneficiaries attributed to that group practice. On average, the group practices accounted for 78 percent of attributed beneficiaries' E&M visits.

Primary care physicians, on average among all 35 groups, furnished over half (53 percent) of the plurality of E&M visits within the group practice, followed by medical specialists at 27 percent. Surgeons provided 11 percent of the plurality of E&M visits and other physicians furnished 9 percent. We note that for five group practices medical specialists, rather than primary care providers, furnished the plurality of care for the attributed beneficiaries.

Table 72 shows the mean performance rate and the performance rates for the 10th, 50th, and 90th percentiles for each of the 26 quality measures that were included in the PQRS GPRO measure set for 2010. We calculated the performance rates based on the data submitted by each of the group practices. Table 72 also shows the mean performance rate for those 19 measures that were included in the PQRS GPRO that eligible professionals also reported at an individual level through the PQRS. The mean group practice performance rate was equal to or higher than the individual performance rate for 16 of the 19 measures.

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TABLE 72: Performance Rates on 26 Quality Measures for Individual Eligible Physicians and Groups

Measure Number	Measure Title	2010 Average Individual Performance Rate/Eligible Professional	Performance Rate for All 2010 GPROs			
			Mean	Percentile		
				10th	50th	90th
DIABETES						
GPRO DM-1	Diabetes Mellitus: Hemoglobin A1C Testing	NA	93%	88%	94%	98%
GPRO DM-2*	Diabetes Mellitus: Hemoglobin A1C Poor Control in Diabetes Mellitus	22%	22%	11%	21%	39%
GPRO DM-3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	59%	58%	49%	57%	67%
GPRO DM-5	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus	57%	54%	41%	55%	66%
GPRO DM-6	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients	74%	89%	82%	89%	96%
GPRO DM-8	Diabetes Mellitus: Foot Exam	72%	61%	16%	69%	86%
GPRO DM-9	Diabetes Mellitus: Lipid Profile	NA	84%	75%	84%	93%
HEART FAILURE						
GPRO HF-1	Heart Failure: Left Ventricular (LVF) Assessment	46%	86%	68%	93%	97%
GPRO HF-2	Heart Failure: Left Ventricular (LVF) Testing	NA	86%	68%	90%	98%
GPRO HF-3	Heart Failure: Weight Measurement	NA	86%	79%	88%	96%
GPRO HF-5	Heart Failure: Patient Education	43%	77%	54%	83%	97%
GPRO HF-6	Heart Failure: Beta Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	83%	92%	86%	95%	99%
GPRO HF-7	Heart Failure: Angiotenson-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	86%	90%	82%	91%	97%
GPRO HF-8	Heart Failure: Warfarin Therapy For Patients With Atrial Fibrillation	72%	79%	62%	82%	94%
CORONARY ARTERY DISEASE						
GPRO CAD-1	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for patients with CAD	85%	85%	50%	93%	97%
GPRO CAD-2	Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL- Cholesterol	75%	90%	85%	92%	97%
GPRO CAD-3	Coronary Artery Disease (CAD): Beta Blocker Therapy for CAD Patients with Prior Myocardial Infarction	71%	87%	76%	88%	95%
GPRO CAD-7	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and /or Left Ventricular Systolic Dysfunction (LVSD)	67%	83%	75%	84%	91%
HYPERTENSION						
GPRO HTN-1	Hypertension (HTN): Blood Pressure Measurement	NA	92%	72%	98%	100%
GPRO HTN-2	Hypertension (HTN): Blood Pressure Control	NA	68%	58%	68%	76%
GPRO	Hypertension (HTN): Plan of Care	NA	56%	21%	61%	79%

Measure Number	Measure Title	2010 Average Individual Performance Rate/Eligible Professional	Performance Rate for All 2010 GPROs			
			Mean	Percentile		
				10th	50th	90th
HTN-3						
	PREVENTIVE CARE AND SCREENING					
GPRO PREV-5	Preventive Care and Screening: Screening Mammography	54%	74%	63%	76%	85%
GPRO PREV-6	Preventive Care and Screening: Colorectal Cancer Screening	52%	60%	37%	64%	76%
GPRO PREV-7	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	51%	67%	50%	67%	79%
GPRO PREV-8	Preventive Care and Screening: Pneumonia Vaccination for Patients	55%	62%	40%	62%	86%

- DM-2 is a measure of poorly controlled blood sugar: Higher scores (and percentile rankings) on this measure reflect worse performance.

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The group practice performance rates were statistically reliable at a high level across the vast majority of the measures. We examine reliability because the clinical measures are derived from samples of the group practice's attributed beneficiaries. In this context, reliability means the group practices' performance rates would be similar or the same if a different sample population of the group practice were used for quality measurement. The average reliability score for the group practices' quality measures related to coronary artery disease ranged from 0.86 to 0.99, for diabetes from 0.87 to 0.99, for heart failure from 0.79 to 0.99, for hypertension from 0.89 to 1.00, and for the preventive measures from 0.94 to 0.98. All groups' quality measures achieved at least a 0.50 score with most group practices well above that level.

The percentage of primary care physicians in a group practice did not correlate with higher performance on the clinical care measures, even though the 26 quality measures focused on effective primary care. As noted above, in five group practices, medical specialists rather than primary care providers furnished care to the majority of attributed beneficiaries. Two of these five group practices were among the top five group practices overall across all quality measures.

In addition to the 26 quality measures included in the GPRO, the reports also contained each group practice's performance on measures of avoidable hospitalizations for six ambulatory care sensitive conditions (ACSCs). These are conditions for which outpatient care can potentially prevent a hospital admission. The measures were based on measures developed by the Agency for Healthcare Research and Quality (AHRQ) and more information can be found at *http://www.qualityindicators.ahrq.gov/modules/pqi_overview.aspx*.

The six ambulatory care sensitive conditions include: (1) Bacterial pneumonia; (2) urinary tract infection (UTI); (3) dehydration; (4) heart failure (HF); (5) chronic obstructive pulmonary disease (COPD); and (6) diabetes—a composite measure based on short-term diabetes complications, uncontrolled diabetes, long-term diabetes complications, and lower extremity amputation for diabetes. Table 73 shows the mean, as well as minimum, and maximum performance rate (as expressed in events per 1,000 beneficiaries) for each of the six ACSC measures of potentially preventable hospitalizations.

TABLE 73—PERFORMANCE RATES FOR THE ACSCS

(ACSC)	Mean	Minimum	Maximum
Diabetes	25	7	39
COPD	95	53	142
CHF	122	66	200
Bacterial Pneumonia	12	7	20
UTI	8	4	13
Dehydration	3	0	11

We also examined five measures of cost: total per capita costs for beneficiaries attributed to the group practice and total per capita for beneficiaries that had the following four chronic conditions: Diabetes, heart failure, chronic obstructive pulmonary disease, and coronary artery disease.

In calculating these measures, we first standardized the Medicare payments to ensure fair comparisons. Geographic variations in Medicare payments to providers can reflect factors unrelated to the care provided to beneficiaries. All Medicare payments have been standardized such that a given service is priced at the same level across all providers within the same facility type or setting, regardless of geographic location or differences in Medicare payment rates among facilities. More information about how CMS standardized payments can be found in the September 2011 document describing the methodologies used in the 2010 QRURs, which can be accessed at *http://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_GPRO_QRUR_Detailed_Methodology.pdf*.

The standardized total per capita costs for the 35 group practices for attributed beneficiaries was on average, $13,135. Thus on average, Medicare paid providers $13,135 per beneficiary attributed to each group practice. The range of total per capita costs was $9,124 to $24,480 and an absolute difference of $15,536 per beneficiary.

We applied a risk adjustment methodology to adjust these total per capita costs for patient demographics, socioeconomic factors, and prior health conditions, recognizing that physiologic differences among beneficiaries can affect their medical costs, regardless of the care provided. This risk adjustment methodology is based on the CMS' Hierarchical Condition Categories (HCC) model that assigns ICD–9 diagnosis codes (each with similar disease characteristics and costs) to 70 clinical conditions to capture medical condition risk. The HCC risk scores also incorporate patient age, general reason for Medicare eligibility (aged or

disabled), and Medicaid eligibility. The risk adjustment model also included the beneficiary's end stage renal disease (ESRD) status. More information about how CMS risk adjusted per capita costs can be found in the September 2011 document describing the methodologies used in the 2010 QRURs, which can be accessed at *http://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_GPRO_QRUR_Detailed_Methodology.pdf.*

After risk adjustment, the adjusted average total per capita costs was $12,652 with a range of $9,932 to $16,736 and an absolute difference of $6,804. Thus the risk adjustment methodology had the effect of reducing the absolute difference between the groups with the lowest and highest total per capita range 55.7 percent. In particular, the lowest third of the groups were adjusted upward by an average of 6.2 percent and the most expensive third were lowered by 10.4 percent. The middle third, on average, were adjusted downward by 0.1 percent, but the range of adjustments was −10.3 to +8.2 percent.

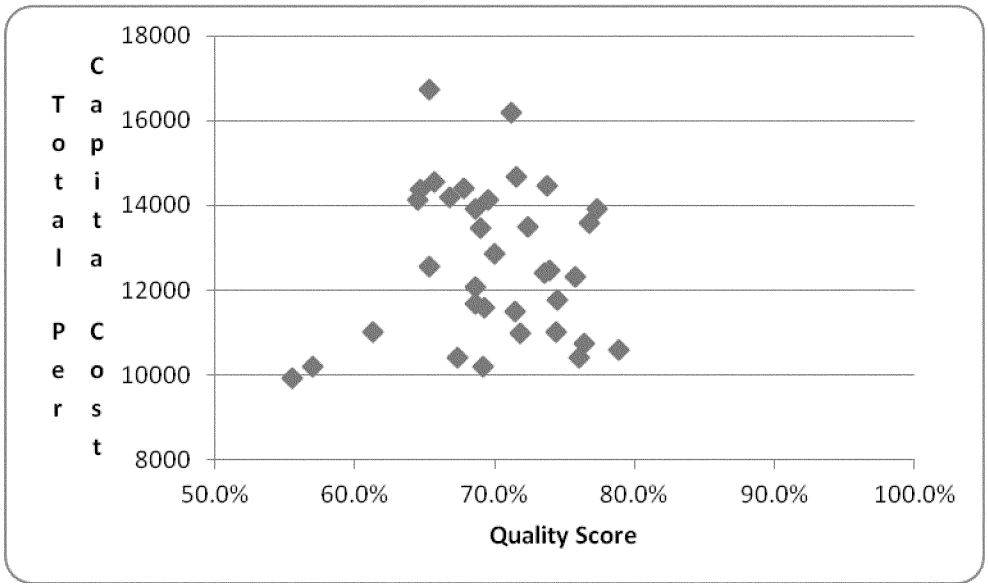
Moreover, three of the five group practices for which medical specialists provided the plurality of care to attributed beneficiaries had their costs risk adjusted downward. Two of these five groups had their unadjusted per capita costs adjusted upward.

The physician feedback reports also showed the percentage of professionals who did not bill under the group practice's TIN who treated the beneficiaries attributed to the group practice. On average, 42 percent of the professionals that cared for attributed patients were outside the group practice. The range was from 18 to 84 percent. We also found a weak association between the percent of professionals who did not bill under the group practice's TIN and total per capita costs for the attributed beneficiaries. The correlation was 0.12.

All 35 group practices achieved statistical reliability scores greater than 0.70 for the overall per capita cost measures and the four subgroup-specific cost measures. In particular, the group practices achieved an average reliability score of 0.99 for the overall per capita cost measure. In addition, all 35 group practices achieved a reliability of greater than 0.70 across all sub cost categories. The average reliabilities were 0.93 for heart failure, 0.91 for COPD, 0.95 for diabetes, and 0.96 for CAD.

Although the sample of group practices was small (35), we found almost no association between quality of care furnished and the total risk-adjusted per capita cost for each group practice. We constructed a simple quality score by taking the average of the 32 performance rates (26 clinical quality measures and six ACSC rates). We translated the ACSC rates into percentages with the lowest ACSC rate equal to 100.0 percent (because lower rates are better) and the highest ACSC rate equal to 0.0 percent. Table 74 shows a scatter diagram of the relationship between the quality of care furnished by each group practice and the total risk-adjusted per capita cost. The correlation between the two variables is 2.0 percent.

TABLE 74: Quality of Care Compared To Cost



(b.) Individual Physician Feedback Reports Based on 2010 Data and Disseminated in 2012

In March 2012, we produced and made available for download confidential individual Physician Feedback reports for 23,730 physicians enrolled in Medicare and practicing in Iowa, Kansas, Missouri, and Nebraska. Each report provided information on the quality of care and resource use for Medicare FFS beneficiaries treated by the physician in 2010. Each report contained two sets of quality measures for Medicare beneficiaries: measures physicians reported in the PQRS via the claims-based reporting methodology, and quality measures calculated by CMS that relied solely on Medicare administrative claims data.

Approximately 25 percent (5,891) of the 23,730 physicians reported on one or more PQRS measure in 2010. The five specialties with the highest participation rates, as a percentage of the total number of physicians in that specialty, were Ophthalmology, Anesthesiology, Gynecology/Oncology, Pathology, and Geriatric Medicine. Physicians reported 3.7 PQRS measures on average. The maximum number of

measures reported was 30, by a family practitioner.

The PQRS performance rates were strongly skewed upward and compressed for the physicians in the four states. For approximately three quarters of the measures, the 50th percentile was 100 percent. For approximately one-third of the measures, the 25th percentile was 100 percent. The most frequently reported PQRS measure was ''Health Information Technology: Adoption/Use of Electronic Health Records'', reported by 1,494 physicians (6.3 percent). The 2010 Reporting Experience report has more information on PQRS performance rates nationwide and it is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRI*.

The reports also contained information on up to 28 administrative claims-based quality measures (and 13 sub-measures for a total of 41 measures) depending upon whether the physician treated at least one beneficiary that was eligible for the measure, that assessed whether Medicare FFS beneficiaries received recommended primary care and preventive care services. We calculated these measure performance rates solely from Medicare FFS claims data. The measurement year used for calculating performance was January 1–December 31, 2010; claims were available for a one-year look-back period to January 1, 2009, for measures requiring a look-back period. Specifications for these measures are available at *http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf*.

On average, a physician's report contained information on 30 of 41 measures. The reports provided this information for any beneficiary to whom the physician furnished at least one service, even if the physician did not provide the treatment indicated by the quality measure. We provided this information because we believe it is critical to inform physicians about the quality of care that their beneficiaries received for primary care and preventive services from any Medicare FFS physician. Moreover, physicians may be unaware of the care that their beneficiaries receive. Table 75 shows the percentage of Medicare FFS patients who received the treatment indicated by the quality measure. There is room for improvement for physicians to provide basic recommended services in many clinical areas, especially those where the percentage of beneficiaries receiving the indicated treatment is less than 50 percent.

TABLE 75: Physician Performance on Medicare Claims–Based Quality Measures for 2010 QRUR Physicians (Iowa, Kansas, Missouri, Nebraska)

Clinical Condition and Measure Specifications for these clinical measures are posted at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf.	Mean Performance Rate Physicians in Iowa, Kansas, Missouri, and Nebraska	
	Number of Physicians Included	Percentage of Medicare Patients Who Received the Service
Chronic Obstructive Pulmonary Disease (COPD)		
Pharmacotherapy Management of COPD Exacerbation		
1. Dispensed Systemic Corticosteroid Within 14 Days of Event	18,472	66%
2. Dispensed Bronchodilator Within 30 Days of Event	18,472	66%
Use of Spirometry Testing to Diagnose COPD	22,290	33%
Bone, Joint, and Muscle Disorders		
Osteoporosis Screening for Chronic Steroid Use	17,046	58%
Osteoporosis Management in Women ≥ 67 Who Had a Fracture	19,678	14%
Disease-Modifying Antirheumatic Drug Therapy for Rheumatoid Arthritis	18,094	77%
Cancer		
Breast Cancer Surveillance for Women with a History of Breast Cancer	15,550	78%
PSA Monitoring for Men with Prostate Cancer	17,598	89%
Diabetes		
Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes	23,012	71%
HbA1c Testing for Beneficiaries ≤ 75 with Diabetes	23,012	87%
Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes	23,012	74%
Lipid Profile for Beneficiaries ≤ 75 with Diabetes	23,012	77%
Gynecology		
Endometrial Sampling or Hysteroscopy with Biopsy Before Endometrial Ablation Procedure	3,704	53%
Heart Conditions		
Statin Therapy for Beneficiaries with Coronary Artery Disease		
1. Percentage Prescribed Statin Therapy	20,909	71%
2. Average Medication Possession Ratio*	20,172	80%
3. Percentage with Medication Possession Ratio ≥ 0.80*	20,172	64%
Persistence of Beta Blocker Treatment After Heart Attack	10,381	57%
Lipid Profile for Beneficiaries with Ischemic Vascular Disease	22,130	44%
Human Immunodeficiency Virus (HIV)		
Monitoring for Disease Activity for Beneficiaries with HIV	13,345	39%
Mental Health		
Antidepressant Treatment for Depression		
1. Acute Phase Treatment (at least 12 weeks)	16,224	54%
2. Continuation Phase Treatment (at least 6 months)	16,224	39%
Follow-Up After Hospitalization for Mental Illness		
1. Percentage of Patients Receiving Follow-Up Within 30 Days	18,562	63%
2. Percentage of Patients Receiving Follow-Up Within 7 Days	18,562	33%
Prevention		
Breast Cancer Screening for Women ≤ 69	23,021	64%

Clinical Condition and Measure Specifications for these clinical measures are posted at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf.	Mean Performance Rate Physicians in Iowa, Kansas, Missouri, and Nebraska	
	Number of Physicians Included	Percentage of Medicare Patients Who Received the Service
Medication Management		
Viral Load Testing for Beneficiaries with Antiviral Therapy for Hepatitis C	1,212	93%
Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications	22,632	41%
Annual Monitoring for Beneficiaries on Persistent Medications		
1. Angiotensin Converting Enzyme (ACE) Inhibitors or Angiotensin Receptor Blockers (ARB)	22,010	93%
2. Digoxin	15,167	93%
3. Diuretics	21,905	93%
4. Anticonvulsants	1,712	39%
5. Total Rate (sum of 4 previous numerators divided by sum of 4 previous denominators)	22,385	92%
Anticoagulation Treatment ≥ 3 Months After Deep Vein Thrombosis	14,787	43%
Anticoagulation Treatment ≥ 3 Months After Pulmonary Embolism	10,298	44%
International Normalized Ratio (INR) Testing for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications	14,006	14%
*NOTE: For the measures shown below, **lower** percentages reflect better performance*		
Drugs to Be Avoided for Beneficiaries ≥ 65		
1. Patients Who Receive at Least One Drug to Be Avoided	23,085	27%
2. Patients Who Receive at Least Two Different Drugs to Be Avoided	23,085	16%
Potentially Harmful Drug-Disease Interactions for Beneficiaries ≥ 65		
1. Prescription for Tricyclic Antidepressants, Antipsychotics, or Sleep Agents for Patients with a History of Falls	21,132	18%
2. Prescription for Tricyclic Antidepressants or Anticholinergic Agents for Patients with Dementia	21,443	29%
3. Prescription for Nonaspirin NSAIDs or Cox-2 Selective NSAIDs for Patients with Chronic Renal Failure	16,902	8%
4. Total Rate (sum of 3 previous numerators divided by sum of 3 previous denominators)	22,232	22%
Lack of Monthly INR Monitoring for Beneficiaries on Warfarin	21,967	48%

*Unlike the other measures in this table, these values represent a ratio, not a percentage of patients receiving the service.

The reports also provided information on five measures of per capita cost. Total per capita costs for beneficiaries attributed to the physician and total per capita costs for beneficiaries that had the following four chronic conditions: diabetes; heart failure; chronic obstructive pulmonary disease (COPD); and coronary artery disease (CAD). As discussed earlier, we standardized and risk adjusted the total per capita cost measures.

To assess per capita cost measures, we attributed beneficiaries to physicians. To attribute beneficiaries, the reports classified each physician's Medicare FFS beneficiaries into three groups based upon the degree of the physician's involvement with the patient:

- *Directed:* The physician billed for 35 percent or more of the patient's office or other outpatient Evaluation and Management (E&M) visits.
- *Influenced:* The physician billed for fewer than 35 percent of the patient's outpatient E&M visits, but for 20 percent or more of the patient's total professional costs.
- *Contributed:* The physician billed for fewer than 35 percent of the patient's outpatient E&M visits, and for less than 20 percent of the patient's total professional costs.

As discussed with reference to the value-based payment modifier, this attribution methodology assigns the same patient to all physicians who treated the patient, but classifies the patient based on how involved the physician was with the care provided to the patient.

Table 76 shows the number of beneficiaries attributed, on average, to physicians under each of these rules. We wish to highlight two observations. First, that primary care physicians generally furnished services to fewer patients than surgeons/specialists and other types of physicians (which included radiologists, anesthesiologists, and pathologists) and that primary care physicians directed care more often

than other types of physicians. Second, there were several physicians in all categories who only contributed to care, meaning that care can frequently be fragmented. This finding highlights the importance of coordinating care among physicians.

TABLE 76—BENEFICIARIES IN IOWA, KANSAS, MISSOURI, AND NEBRASKA ATTRIBUTED BY PHYSICIAN TYPE: AVERAGE NUMBER OF BENEFICIARIES

Type of physician	Average number of attributed beneficiaries	Average number of directed beneficiaries	Average number of influenced beneficiaries	Average number of contributed beneficiaries
Primary care	279	105	13	181
Medical specialist	471	59	51	381
Surgeons	309	36	64	217
Emergency medicine	367	35	14	350
Other	860	18	34	840

We calculated total per capita costs for each type of attribution of patients. As discussed above and shown in Table 77, the beneficiaries who receive care under the ''contributed only'' attribution have substantially higher per capita costs and accounted for 20 percent of those beneficiaries covered by the 2010 individual reports.

TABLE 77—MEAN TOTAL PER CAPITA COSTS IN THE QRURS

Type of physician	Overall	Directed	Influenced	Contributed
Primary care	$16,580	$9,733	$6,780	$19,019
Medical specialist	19,765	11,256	9,219	21,276
Surgeons	17,535	11,482	15,182	18,313
Emergency medicine	20,729	10,389	3,675	21,217
Other	23,704	11,442	8,987	23,980

(c.) Physician Feedback Program Dissemination Strategy

Based on our previous dissemination of individual Physician Feedback reports, we have learned that the overwhelming factor that prevents physicians from accessing their reports is lack of knowledge of their availability. We undertook several steps this year to increase awareness of the Physician Feedback reports. First, we increased the information we provided to physicians about the feedback reports, performance reporting, the value-based payment modifier, and our methodology via *www.cms.gov/physicianfeedbackprogram*, fact sheets, FAQs, video, slides, national provider calls, targeted conference calls with report recipients, meetings with national and local medical associations and specialties, and multiple physician fee for service list serve announcements. We also partnered with the J5 Medicare Administrative Contractor (MAC), WPS, for Iowa, Kansas, Nebraska, and Missouri, to develop a secure internet portal where physician could easily obtain their reports. As of June 10, 2012, 7,484 of approximately 24,000 (31 percent) individual Physician Feedback reports have been accessed electronically. This is a substantial increase from earlier phases of the Physician Feedback program in which only 1 percent of physicians obtained their reports.

We also have aggressively solicited feedback from physicians and physician groups, including the American Medical Association, on how to increase the usefulness of the reports so that physicians and groups of physicians would actively seek this type of information from CMS. We invited report recipients (via several conference calls directed first to medical practice groups and then individual physicians) to provide us input on the usefulness and credibility of the performance measures, and other information contained in the reports so that we can improve the reports for future years.

Following the September 26, 2011 distribution of reports to physician groups, we hosted two conference calls for the 35 large medical practice groups. In addition to ''walking through'' a sample template of the group performance report, we responded to questions and followed up with an aggregation of questions/issues raised by groups and corresponding answers and explanations from CMS. These reports represent the first time performance on a wide-range of quality and cost measures can be viewed in the same report for Medicare beneficiaries in large group practices across the country.

After the March 2012 dissemination of individual reports, we conducted National Provider Calls on April 3, 2012 and April 5, 2012 at which time we reported some initial observations, reviewed a report template page by page, and answered questions from the call participants. On May 8, 2012 and June 4, 2012, we held another call in conjunction with the MAC, WPS, to obtain targeted feedback on the feedback reports and how they could be improved and made more useful. We view the physician feedback reports as a way to test various methods of analyzing and displaying comparative performance information and previewing methods that will be further developed for use in the value-based payment modifier. In addition, we have responded to over 50 requests for more information from the Help Desk we established for the program.

(d.) Future Plans for the Physician Feedback Reports

In the fall of 2012, we plan to disseminate Physician Feedback reports to all physicians in nine states (California, Iowa, Illinois, Kansas, Michigan, Minnesota, Missouri, Nebraska, and Wisconsin) based on 2011 data. These reports will contain the PQRS measures that physicians in these states submitted via enhanced claims, as well as information on 28 administrative claims measures included in the 2010 reports. We also will produce and disseminate Physician Feedback reports to the groups of

physicians that reported measures through the PQRS GPRO web interface in 2011. We have adjusted and improved the content and organization of the Physician Feedback reports that we plan to produce later this year based on the comments we received from the Program Year 2010 report recipients. We plan to increase our outreach efforts to encourage physicians to view their reports, to begin to understand the methodologies we have proposed for the value-based payment modifier and that are included in the 2011 reports, and to provide suggestions on how we can make these reports more meaningful and actionable in the future.

In the fall of 2013, we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals and to individual physicians that satisfactorily reported measures through PQRS in 2012 using any of the PQRS reporting mechanisms. These reports will include a ''first look'' at the methodologies that we are proposing in this rule for the value-based payment modifier.

In addition, section 1848(n) of the Act requires that we use the episode-based costs in the Physician Feedback reports beginning in 2013 for the reports based on 2012 data. As discussed above in relation to the value-based payment modifier, we plan to include episode-based cost measures for several episode types in these Physician Feedback reports. In addition, we plan to consider adjusting the format and organization of the reports, to the extent practicable, to address the best practices outlined in the AMA's Guidelines for Reporting Physician Data. We believe that this dissemination plan satisfies our obligations under the section 1848(p)(4)(B)(ii)(II) of the Act to provide information to physicians and groups of physicians about the quality of care furnished to Medicare FFS beneficiaries.

In the fall of 2014, we plan to disseminate Physician Feedback reports based on 2013 data that show the amount of the value-based payment modifier and the basis for its determination. We plan to provide these reports to all groups of physicians (at the TIN level) with 25 or more eligible professionals. We are examining whether we can provide reports to groups of physicians with fewer than 25 eligible professionals and to individual level reports as well. These reports will contain, among other things, performance on the quality and cost measures used to score the composites and the value-based payment modifier amount. As discussed above, we anticipate providing an opportunity for review and correction as outlined in our value-based payment modifier proposals above.

L. Medicare Coverage of Hepatitis B Vaccine

1. Modification of High Risk Groups Eligible for Medicare Part B Coverage of Hepatitis B Vaccine

a. Background and Statutory Authority—Medicare Part B Coverage of Hepatitis B Vaccine

Section 1861(s)(10)(B) of the Act authorizes Medicare Part B coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. High and intermediate risk groups are defined in regulations at § 410.63.

On December 23, 2011, the United States Centers for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report, which included an article entitled ''Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP).'' The article stated that ''In the United States, since 1996, a total of 29 outbreaks of HBV [Hepatitis B virus] infection in one or multiple long-term care (LTC) facilities, including nursing homes and assisted-living facilities, were reported to CDC; of these, 25 involved adults with diabetes receiving assisted blood glucose monitoring. These outbreaks prompted the Hepatitis Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes.''

''HBV is highly infectious and environmentally stable; HBV can be transmitted by medical equipment that is contaminated with blood that is not visible to the unaided eye. Percutaneous exposures to HBV occur as a result of assisted monitoring of blood glucose and other procedures involving instruments or parenteral treatments shared between persons. Lapses in infection control during assisted blood glucose monitoring that have led to HBV transmission include multipatient use of finger stick devices designed for single-patient use and inadequate disinfection and cleaning of blood glucose monitors between patients. Breaches have been documented in various settings, including LTC facilities, hospitals, community health centers, ambulatory surgical centers, private offices, homes, and health fairs.'' Additionally, in analyses of persons without hepatitis B-related risk behaviors (that is, injection-drug use, male sex with a male, and sex with multiple partners), persons aged 23 through 59 years with diabetes had 2.1 times the odds of developing acute hepatitis B as those without diabetes; and the odds for hepatitis B infection were 1.5 times as likely for persons aged 60 and older. (MMWR, December 23, 2011).

Based on the Hepatitis Vaccines Work Group findings, ACIP recommended that:

- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years.
- Hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged 60 years and older.

b. Implementation

Based on the ACIP recommendations, we propose to modify § 410.63(a)(1), High Risk Groups, by adding new paragraph ''(viii) persons diagnosed with diabetes mellitus.'' Since HBV can be transmitted by medical equipment (that is, finger stick devices and blood glucose monitors) that is contaminated with blood that is not visible to the unaided eye, we believe that persons diagnosed with diabetes mellitus should be added the high risk group. Since lapses in infection control have been reported in both community and facility settings, the increased risk of contracting HBV is not limited to the facility setting. We believe that expanding coverage of Hepatitis B vaccinations and administration to those diagnosed with diabetes mellitus is supported by the findings and evidence reviewed by the Hepatitis Vaccines Work Group and the ACIP recommendations. Hepatitis B vaccination is a preventive measure that needs to occur before exposure. It is difficult to predict which diabetics will eventually be exposed in the circumstances that we discussed above. Therefore, we are proposing to expand coverage for hepatitis B vaccine and its administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, for example, in nursing homes.

M. Updating Existing Standards for E-Prescribing Under Medicare Part D and Lifting the LTC Exemption

1. Background

a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Social Security Act (the Act) to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Social Security Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

(a) Adopting and updating:

CMS utilized several rounds of rulemaking to adopt standards for the e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the ''foundation'' standards. One of these standards, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004 (excluding the Prescription Fill Status Notification Transaction and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), hereafter referred to as the NCPDP SCRIPT 5.0, is the subject of several of the proposals in this rule. CMS issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are referred to as ''final'' standards. One of these standards, version 1.0 of the NCPDP Formulary and Benefit standard, Implementation Guide, Version 1, Release 0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) is also one of the subjects of this proposed rule. Please see the ''Initial Standards Versus Final Standards'' discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about ''foundation'' and ''final'' standards.

(b) Exemption From the NCPDP SCRIPT Standard in Long Term Care Settings (LTC)

While prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are generally required to comply with any applicable standards that are in effect at the time of their transmission, the early versions of the NCPDP SCRIPT standard did not support the complexities of the prescribing process for patients in long term care facilities where the prescribing process involves not only a prescriber and a pharmacy, but also a facility and its staff. As such, we exempted such entities from use of the NCPDP SCRIPT standard. That exemption, currently found at § 423.160(a)(3)(iv), provides an exemption for entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser.

For a more detailed discussion, see the November 7, 2005 final rule (70 FR 67583).

(2) Updating e-Prescribing Standards

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating process'' when a standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, however, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**. CMS utilized this streamlined process when it published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, CMS used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard. Finally, on July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).

In contrast to the extensive updating that was done to the NCPDP SCRIPT standard in the Part D e-prescribing program, the original NCPDP Formulary and Benefit 1.0 is still in place as the official Part D e-prescribing standard.

2. Proposals for Calendar Year 2013

a. Proposed Finalization of NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, Retirement of NCPDP SCRIPT 8.1 and Adoption of NCPDP SCRIPT 10.6 as the Official Part D E-Prescribing Standard

As described in greater detail below, we propose to finalize our recognition of NCPDP SCRIPT 10.6 as a backward compatible version of the official Part D e-prescribing standard NCPDP SCRIPT 8.1, effective from the effective date of the final rule through October 31, 2013, but, in response to the comments that were received to the interim final rule with comment, we also propose to retire NCPDP SCRIPT 8.1 effective October 31, 2013, and we propose to adopt NCPDP SCRIPT 10.6 as the official Part D e-

prescribing standard effective November 1, 2013.

On July 1, 2010, we published an interim final rule with comment (75 FR 38026) which named NCPDP SCRIPT 10.6 as a backward compatible update to NCPDP SCRIPT 8.1. We received 7 timely public comments on this interim final rule with comment. The comments came from a standards setting organization, two national industry associations, two healthcare organizations and, two health information intermediaries. All commenters supported the voluntary use of NCPDP SCRIPT version 10.6 as a backward compatible version of the adopted NCPDP SCRIPT 8.1 standard. Five of the commenters recommended that Version 10.6 be adopted as the official standard for the Medicare Part D e-Prescribing Program with a time frame of full implementation of January 1, 2013. One commenter recommended that CMS adopt version 10.6 as the official Part D e-prescribing standard, and retire version 8.1, but did not suggest a date by which that should happen. Another commenter recommended that CMS adopt version 10.6 as early as January 1, 2012. All commenters agreed that version 8.1 should be retired when version 10.6 was adopted.

As we discussed in the July 1, 2010 interim final rule with comment (75 FR 38026) NCPDP SCRIPT 10.6 has a number of new functionalities that, if users elect to use them will mesh with their use of the adopted NCPDP SCRIPT 8.1, which was adopted in the April 7, 2008 e-prescribing final rule (73 FR 18918). These new functions would allow users drug NDC source information, pharmacy prescription fill numbers and date of sale information that could then be used in a medication history response. These added functionalities would therefore be expected to facilitate better record matching, the identification and elimination of duplicate records, and the provision of richer information to the prescriber between willing trading partners. We therefore agree with commenters that NCPDP SCRIPT 10.6 would be appropriate as an official standard for the Medicare Part D e-Prescribing Program. At the time of this rule's drafting, however, the suggested dates for the adoption of SCRIPT Version 10.6 as the official Part D e-prescribing standard and the retirement of NCPDP SCRIPT 8.1 have either passed or are too near in the future to be a reasonable implementation date. Furthermore, since the time of these comments, industry stakeholders have worked with NCPDP, a standards development organization, and reached out to CMS with additional suggestions for appropriate implementation dates in light of the current state of the standards development process. Stakeholders working though NCPDP currently recommend retiring NCPDP SCRIPT 8.1 on October 31, 2013 and adoption of NCPDP Script 10.6 as the official Part D e-prescribing standard on November 1, 2013. We believe that this is a realistic timetable to retire NCPDP SCRIPT 8.1 and the adopt NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard on the dates described.

As such, we propose to revise § 423.160(b)(2)(ii) so as to limit its application to transactions on or before October 31, 2013 and add a new § 423.160(b)(2)(iii) to require that, as of November 1, 2013, providers and dispensers use NCPDP SCRIPT 10.6 for the following electronic transactions that convey prescription or prescription related information:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.
- Fill status notification.

Furthermore, we propose to amend § 423.160(b)(1) by adding a new 423.160(b)(1)(iii) to amend the information about which subsequent requirements in the section are applicable to which timeframes and amend § 423.160(b)(1)(ii) to limit its application to transactions on or before October 31, 2013.

As considerable time has passed since we solicited comments on the retirement of NCPDP SCRIPT 8.1, we are soliciting additional comments regarding the retirement of version 8.1 on October 31, 2013. We also are soliciting comments on the adoption of Version 10.6 as the official Part D e-prescribing standard for the e-prescribing functions that will be outlined in § 423.160(b)(1)(iii) and (b)(2)(iii), effective November 1, 2013.

b. Proposed Recognition of NCPDP Formulary and Benefit Standard 3.0 as a Backward Compatible Version of the NCPDP Formulary and Benefit Standard 1.0, Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and Proposed Adoption of NCPDP Formulary and Benefit Standard 3.0

Formulary and Benefits standards provide a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

The NCPDP Formulary and Benefits Standard 1.0 enables the prescriber to consider this information during the prescribing process, and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the health plan.

As discussed above, the November 7, 2005 final rule (70 FR 67579) established the process of updating an official Part D e-prescribing standard with the recognition of ''backward-compatible'' versions of the official standard in instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification. In these instances, notice and comment rulemaking could be waived, and use of either the new or old version of the adopted standard would be considered compliant with the adopted standard upon the effective date of the newer version's incorporation by reference in the **Federal Register**. This ''Backward Compatible'' version updating process allows for the standards' updating/maintenance to correct technical errors, eliminate technical inconsistencies, and add optional functions that provide optional enhancements to the specified e-prescribing transaction standard. Since the adoption of the NCPDP Formulary and Benefits 1.0 standard in the Part D e-prescribing program, NCPDP has updated its Formulary and Benefits standard. Changes were based upon industry feedback and business needs and ranged in complexity from creating whole new fields or lists within the standard to simply changing a

particular field designation from mandatory to optional. Each time a change is made to a standard it is given a new version number. The current version of the Formulary and Benefits standard is version 3.0.

One of the major improvements between version 1.0 and 3.0 involved the addition of Text message support for ''Coverage and Copay Information,'' the addition of the ''Text Message Type (A46–1S)'' field and the addition of ''Optional Prior Authorization Lists.'' Theses list were added for use in conveying prior authorization requirements.

Other improvements included conversion of certain elements from optional to mandatory. Version 3.0 also provides for ''Formulary Status List Headers,'' which are fields that allow the sender to specify a default formulary status for non-listed drugs. Subsequent versions also allowed for the omission of ''Formulary Status Detail'' records when the non-listed formulary policies are used exclusively to convey the status of a drug on a formulary.

Changes to a standard may also involve removing fields that are not widely used in industry. The removed fields are often replaced by new fields that better serve the business needs of the industry. For example, the following items have been removed through the various updates that led up to version 3.0: ''Classification List'' and references to it (such as Drug Classification Information), ''Coverage Information Detail—Medical Necessity (MN),'' ''Coverage Information Detail—Resource Link—Summary Level (RS),'' and the Classification ID in the Cross Reference Detail.

In place of these deleted fields, the following fields were added or amended to ultimately result in Version 3.0: The ''Formulary Status existing value 2'' field was changed to ''On Formulary/ Non-Preferred,'' The following has been clarified from '' The file load also enables payers to specify a single coverage-related text message for each drug'' field was changed to ''A payer may send multiple quantity limits, step medications, text messages and resource links for the same drug.''

We have reviewed Version 3.0, and based on our findings, we have determined that Formulary and Benefits 3.0 maintains full functionality of the official adopted Part D e-prescribing standard Formulary and Benefits 1.0, and would permit the successful communication of the applicable transaction with entities that continue to use Version 1.0.

While we would usually use the ''backward compatible'' waiver of notice and comment procedures that are described above to recognize Version 3.0 as a backward compatible version of the officially adopted Version 1.0, this would have to be done in an interim final rule with comment. As we cannot combine proposals and elements of a final rule in one rule, we are electing this one time to formally propose recognizing a subsequent standard as a backward compatible version of an adopted standard through full notice and comment rulemaking in order to avoid having to publish two rules contemporaneously. We therefore propose to recognize the use of either Version 1.0 or 3.0 as compliant with the adopted Version 1.0 effective 60 days after the publication of a final rule.

As noted above, according to the November 7, 2005 final rule (70 FR 67580), entities that voluntarily adopt later versions of standards that are recognized as backward compatible versions of the official Part D e-prescribing standard must still accommodate the earlier official Part D e-prescribing standard without modification. Therefore, as we are using full notice and comment in place of the backward compatible methodology in this one instance, we also propose to require users of 3.0 to support users who are still using Version 1.0 until such time as Version 1.0 is officially retired as a Part D e-prescribing standard and Version 3.0 is adopted as the official Part D e-prescribing standard.

To effectuate these proposals, we also propose to revise § 423.160(b)(5) by placing the existing material in a new subsection (b)(5)(i), and creating a second new subsection ((b)(5)(ii)) to reflect the use of Version 3.0. as a backward compatible version of the official Part D e-prescribing standard [i from 60 days from the publishing of the final rule through October 31, 2013 We seek comment on this proposal as well.

We also seek comment on timing and when to retire Version 1.0 as the official Part D e-prescribing standard, and the proposal to adopt Formulary and Benefit Version 3.0. as the official Part D e-prescribing standard.

c. Proposed Elimination of the Exemption for Non-Prescribing Providers (Long Term Care)

In our November 16, 2007 proposed rule (72 FR 64902–64906), we discussed the inability of NCPDP SCRIPT versions 5.0 and 8.1 to support the workflows and legal responsibilities in the long-term care setting, that is, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser (''three-way prescribing communications'' between facility, physician, and pharmacy). As such, such entities were provided with an exemption from the requirement to use the NCPDP SCRIPT standard in transmitting such prescriptions or prescription-related information. On July 1, 2010 we published an IFC (75 FR 38029) in which we conveyed that we would consider removing the LTC exemption when there was an NCPDP SCRIPT standard that could address the unique needs of long-term care settings. We noted that NCPDP SCRIPT Version 10.6 was available, and that we believed that it addressed the concerns of the LTC industry regarding their ability to successfully support their workflows when e-prescribing. We solicited comments on the impact and timing of adopting version 10.6 as the official Part D e-prescribing standard and the removal of the long-term care facility exemption from the NCPDP SCIPT standard.

LTC enhancements were first made to the NCPDP SCRIPT version 10.2, and were subsequently further enhanced in subsequent versions of the SCRIPT Standard.

In a July 1, 2009 recommendation letter to the Secretary, (*http://www.ncvhs.hhs.gov/090701lt.pdf*) NCVHS recommended the adoption of Version 10.6, the retirement of Version 8.1 and the lifting of the current exemption at § 423.160(a)(3)(iv) from the requirement to use the NCPDP SCRIPT standard for providers in long-term care settings. During the NCVHS testimony that preceded the recommendation letter, members of the industry testified that the changes that were present in NCPDP SCRIPT 10.6 created an environment where long-term care (LTC) facilities could carry out e-prescribing using NCPDP SCRIPT 10.6 if it were to be adopted as the official Part D e-prescribing standard. More information on the testimony given to, and the recommendations given by NCVHS, can be found at the NCVHS Web site *http://www.ncvhs.hhs.gov/*.

We considered the recommendations of the industry and NCVHS and concluded that it would be appropriate to retire Version 8.1, adopt Version 10.6 and eliminate the LTC exemption from the NCPDP SCRIPT standard. Since the LTC industry currently is exempt from the requirement to use the NCPDP SCRIPT Version 8.1 standard, Medicare Part D e-prescribing operators, providers, and vendors have been utilizing proprietary e-prescribing

solutions and interfaces in the form of electronic medication administration records and internet communications, which are likely not interoperable. As the use of Part D e-prescribing standards would promote our administrative priorities of promoting interoperability and harmonization among IT systems, we therefore propose to retire Version 8.1, adopt Version 10.6 and eliminate the current exemption at § 423.160(a)(3)(iv) for entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser.

We are soliciting comments on lifting the Long Term Care exemption, effective November 1, 2013 in conjunction with the effective date of NCPDP SCRIPT 10.6. We solicit comments regarding the impact of these proposed effective dates on industry and other interested stakeholders, and whether an earlier or later effective date should be adopted.

IV. Technical Corrections

A. Waiver of Deductible for Surgical Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test and Colorectal Cancer Screening Test Definition

Section 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic in the course of the procedure or visit. Specifically, section 1833(b)(1) of the Act waives the deductible for colorectal screening tests regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. To implement this statutory provision, we proposed that ''all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be considered to be furnished in connection with, as a result of, and in the same clinical encounter as the screening test.'' After receiving public comment, this proposal was finalized in the CY 2011 final rule with comment period (75 FR 73431). However, we neglected to amend our regulations to reflect this policy.

When a screening test becomes a diagnostic service, practitioners are to append a modifier to the diagnostic procedure code that is reported instead of the HCPCS code for screening colonoscopy or screening flexible sigmoidoscopy or as a result of the barium enema. By use of this modifier, practitioners signal that the procedure meets the criteria for the deductible to be waived.

To reflect this policy in our regulations, we propose to amend § 410.160 Part B annual deductible to include colorectal screening tests that become diagnostic services in the list of services for which the deductible does not apply. Specifically, we propose to add a new § 410.160(b)(8) to read, ''Beginning January 1, 2011, a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.''

Section 103 of the BIPA amended section 1861(pp)(1)(C) of the Act to permit coverage of screening colonoscopies for individuals not at high risk for colorectal cancer who meet certain requirements. In order to conform our regulations to section 1861(pp)(1)(C) of the Act, we propose to modify § 410.37(a)(1)(iii) to define ''Screening colonoscopies'' by removing the phrase ''In the case of an individual at high risk for colorectal cancer'' from this paragraph.

We also propose to delete paragraph (g)(1) from this section since Medicare no longer receives claims for dates of service between January 1, 1998 and June 30, 2001, making this paragraph obsolete. We also propose to redesignate paragraphs (g)(2) through (g)(4) and make technical changes to newly redesignated paragraph (g)(1) by replacing the reference to paragraph (g)(4) with a reference to newly redesignated paragraph (g)(3).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§ 410.32)

Proposed § 410.32(d)(2)(i) would require that the physician or qualified nonphysician practitioner (as defined in § 410.32(a)(2)) who orders the service maintain documentation of medical necessity in the beneficiary's medical record. In addition, both the medical record and the laboratory requisition (or order) would be required to be signed by the physician or qualified nonphysician practitioner who orders the service. The burden associated with these requirements would be the time and effort necessary for a physician or qualified nonphysician practitioner to sign the medical record or laboratory requisition (or order). There would also be a recordkeeping requirement associated with maintaining the documentation of medical necessity in the beneficiary medical record. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned information collection requirements would be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practices.

B. ICRs Regarding Durable Medical Equipment Scope and Conditions (§ 410.38(g))

In § 410.38(g), we would require (as a condition of payment for certain covered items of DME) that a physician must have documented and communicated to the DME supplier that the physician or a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

We propose that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record (portions containing sufficient information to document that the face-to-face encounter meets our requirements) would be considered sufficient and valid documentation of

the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. While we believe that many of the practitioners addressed in this proposed rule are already conducting a needs assessment and evaluating or treating the beneficiary for conditions relevant to the covered item of DME, this proposed rule may require some changes in their procedures to ensure that their documentation fulfills Medicare's regulatory requirements. Suppliers should already be receiving written orders and documentation to support the appropriateness of certain items of DME.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud, and abuse, we propose that as a condition of payment a written order must include: (1) The beneficiaries' name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; (5) the date of the order; (6) the diagnosis; and (7) necessary proper usage instructions, as applicable.

In order to determine costs associated with the impact we utilized the Bureau of Labor Statistics mean hourly rates for the professional, analyzed for the year that the original data was received. The hourly rate for a physician, including fringe benefits and overhead is estimated at $118 per hour. The hourly rate, including fringe benefits and overhead, for a NP, PA, CNS is estimated at $55 per hour. The hourly rate for administrative assistant, including fringe benefits and overhead, is estimated at $23 per hour.

Physicians are now required to document the face-to-face encounter if it was performed by a PA, NP, or CNS. In order to allow payment for this documentation, a G code is established for this service. There are approximately 10 million DME users and it was assumed that roughly 5 percent of face-to-face encounters are actually performed by these other provider types, thereby requiring documentation of the encounter. Therefore, it was assumed that about 500,000 of these documentation services would be billed. We estimate the time for a physician to review each one of these encounters that results in an order is 10 minutes. Therefore, we estimate that the physician documentation burden to review and document when a PA, NP or CNS performed the face-to-face encounter in year 1 would be nearly 83,333 hours and a total of 700,000 million hours over 5 years. The associated cost in year 1 is nearly $9.8 million and over 5 years has associated costs of nearly $82.6 million based on the growth rate of the Medicare population. The increase is slightly more than five-fold because the number of Medicare beneficiaries would increase over time.

TABLE 78—PHYSICIAN TIME TO DOCUMENT OCCURRENCE OF A FACE-TO-FACE ENCOUNTER

	Year 1	5 Years
Number of claims affected	500,000	4,200,000.
Time for physician review of each claim	10 min	10 min.
Total Time	83,333 hours	700,000 hours.
Estimated Total Cost (Hours times $118)	$9,833,333	$82,600,000.

We assume it will take 3 minutes for a PA, NP, or CNS to prepare the medical record for the review of the face-to-face encounter. For the 500,000 orders used in the previous estimate, this creates a total of 25,000 hours at a cost of about $1.4 million in year 1 and nearly 210,000 hours over 5 years at a cost of nearly $11.6 million based on the growth rate of the Medicare population. Though consistent with previous estimates, we believe that using a PA, NP, or CNS hourly rate creates a high burden impact estimate since most of these tasks would more than likely be completed by administrative personnel. We welcome comments on the appropriateness of these estimates.

TABLE 79—PHYSICIAN ASSISTANT, NURSE PRACTITIONER OR CLINICAL NURSE SPECIALIST TIME

	Year 1	5 Years
Number of claims affected	500,000	4,200,000.
Time for PAs, NPs, or CNSs to gather and provide each claim.	3 min	3 min.
Total Time	25,000 hours	210,000 hours.
Estimated Total Cost (Hours times $55)	$1,375,000.00	11,550,000.

This proposed rule would create only a minimal change in the normal course of business activities in regards to recordkeeping. Although we believe the documentation of a needs assessment, evaluation, and or treatment of a beneficiary for a condition relevant to an item of DME is a common practice, it is possible that some practitioners may not be documenting the results of all encounters; and therefore, there may be additional impact for some practitioners.

This regulation requires that the supplier have access to the documentation of the face-to-face encounter, which is required when CMS conducts an audit. CMS already accounts for the audit burden associated with the exchange of documentation for claims subject to prepayment review (approved under OCN 0938–0969). As a business practice we recognize that some suppliers may receive the documentation of the face-to-face for all applicable claims, voluntarily.

We believe that the requirements expressed in this proposed rule meet the utility and clarity standards. We welcome comment on this assumption and on ways to minimize the burden on affected parties. The proposed recordkeeping requirement in § 410.38(g)(5) and the requirement to maintain and make the supplier's order/additional documentation available to CMS upon request is subject to the PRA, but we believe that these requirements are usual and customary business practices as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

C. ICRs Regarding Physician Quality Reporting System—Definitions (§ 414.90(b))

While § 414.90(b) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–1083, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

D. ICRs Regarding Physician Quality Reporting System—Use of Consensus-Based Quality Measures (§ 414.90(e))

We are proposing to revise § 414.90(e), redesignated as to broadly define our use of consensus-based quality measures. The current regulation at § 414.90(e) states that we will publish a final list of measures every year. However, we are proposing measures for 2013 and beyond this year.

While § 414.90(e) contains information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–1083, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

E. ICRs Regarding Physician Quality Reporting System—Requirements for the Incentive Payments (§ 414.90(g))

While § 414.90(g) contains information collection requirements regarding the PQRS incentive payments, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–1083, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

F. ICRs Regarding Physician Quality Reporting System—Requirements for the Payment Adjustments (§ 414.90)

While § 414.90 contains information collection requirements regarding the PQRS payment adjustments, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions, except for the proposed criteria for reporting via claims for the 2015 and 2016 PQRS payment adjustments and the provisions that would allow the administrative claims reporting option. Otherwise, all of the requirements and burden estimates are currently approved by OMB under OCN 0938–1083 and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

With respect to the proposed reporting criteria for the 2015 and 2016 PQRS payment adjustments using the claims-based reporting mechanism, we note below that we anticipate that approximately 320,000 eligible professionals would use the claims-based reporting mechanism for CYs 2013 and 2014. This is a difference of 120,000 from the 200,000 that participated in PQRS using the claims-based reporting mechanism in 2010. We believe that these 120,000 eligible professional would use the 2015 and 2016 PQRS payment adjustment claims-based payment adjustment criteria to meet the criteria for satisfactory reporting for the 2015 and 2016 payment adjustments.

We estimate the cost for an eligible professional and group practices to review the list of PQRS quality measures or measures group, identify the applicable measures or measures group for which they can report the necessary information, incorporate reporting of the selected measures or measures group into the office work flows, and select a PQRS reporting option to be approximately $200 per eligible professional ($40 per hour × 5 hours). Based on our experience with the Physician Voluntary Reporting Program PVRP, we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for a measure) on claims will range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. At an average labor cost of $40/hour per practice, the cost associated with this burden would range from $0.17 in labor to about $8.00 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.67.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we are proposing to reduce the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional or eligible professional in a group practice associated with claims-based reporting would range from 4.5 minutes (0.25 minutes per measure × 3 measures × 6 cases per measure) to 180 minutes (12 minutes per measure × 3 measures × 6 cases per measure), with the burden to the median practice being 31.5 minutes (1.75 minutes per measure × 3 measures × 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims-based reporting would range from $3.06 ($0.17 per measure × 3 measures × 6 cases per measure) to $144.00 ($8.00 per measure × 3 measures × 6 cases per measure), with the cost to the median practice being $30.06 per eligible professional ($1.67 per measure × 3 measures × 6 cases per measure).

With respect to reporting using the administrative claims reporting option, we estimate that the burden associated with reporting using the administrative claims option is the time and effort associated with reporting. We note that the burden for eligible professionals and group practices using the administrative claims-based reporting mechanism

G. Summary of Annual Burden Estimates for Codified Requirements (Proposed)

TABLE 80—SUMMARY OF ANNUAL BURDEN ESTIMATES

Regulation section(s)	OCN	Respondents	Responses	Burden per response (hr)	Total burden (hr)
410.38(g) re: Physician	0938–New	500,000	500,000	10 min	83,333
410.38(g) re: PA, NP, or CNS	0938–New	500,000	500,000	3 min	25,000
414.90(h)	0938–1083	120,000	120,000 (120,000 responses × 1 measure).	0.5 (31.5 minutes—the median).	60,000

H. Additional Information Collection Requirements

While this proposed rule would impose collection of information requirements that are set out in the regulatory text (see above), this rule also sets out information collection requirements that are set out only in the preamble. Following is a discussion of the preamble-specific information collections, some of which have already received OMB approval.

1. Part B Drug Payment

The discussion of average sales price (ASP) issues in section XXX of this proposed rule does not contain any new information collection requirements with respect to payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. The ASP reporting requirements are set forth in section 1927(b) of the Act. The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. All of the requirements and burden estimates are currently approved by OMB under OCN 0938–0921, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

2. Physician Quality Reporting System (PQRS)

The preamble of this proposed rule discusses the background of the PQRS, provides information about the proposed measures and reporting mechanisms that would be available to eligible professionals and group practices who choose to participate in the 2013 and 2014 PQRS, and provides the proposed criteria for satisfactory reporting in CYs 2013 and 2014 (for the 2013 and 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustments).

a. Participation in the 2013 and 2014 PQRS

According to the 2010 Reporting Experience Report, a total of $391,635,495 in PQRS incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (i.e., a bonus payment equal to 2.0 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional in the reporting period) for satisfactory reporting under PQRS. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in PQRS would rise to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014 respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimate that we would distribute approximately $162 million ($539 × 300,000 eligible professionals) and $216 million ($539 × 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to eligible professionals participating in PQRS for the applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in PQRS will cease and payment adjustments for not satisfactorily reporting will commence.

We note that the total burden associated with participating in PQRS is the time and effort associated with indicating intent to participate in PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The requirements for reporting for PQRS 2013 and 2014 incentives and 2015 and 2016 payment adjustments would be established as proposed in this 2013 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, that the eligible professional or group practice would report on 3 measures.
- With respect to labor costs, we believe that a billing clerk would handle the administrative duties associated with participating, while a computer analyst would handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

b. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS—New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS would be approximately $80 ($16/hour × 5 hours).

c. Burden Estimate on Participation in the 2013 and 2014 PQRS via the Claims-Based Reporting Mechanism—Individual Eligible Professionals

In 2010, approximately 200,000 of the roughly 245,000 eligible professionals (or 84 percent) of eligible professionals used the claims-based reporting mechanism. We believe that although the number of eligible professionals or group practices using the claims-based reporting mechanism will increase in CYs 2013 and 2014, we anticipate that the percentage of eligible professionals or group practices using the claims-based reporting mechanism will decrease slightly as eligible professionals and group practices transition towards using the EHR-based reporting mechanism. Therefore, although we estimate that the participation rate for PQRS will double from participation rates in 2010, we note that, although we believe the claims-based reporting mechanism will be the most widely used, the percentage of PQRS participants using the claims-based reporting mechanism will decrease as we anticipate that more eligible professionals would use the registry and EHR-based reporting mechanisms. For these reasons, we estimate that approximately 320,000 eligible professionals, whether participating individually or in a group practice, will participate in PQRS in CY 2014.

With respect to an eligible professional who participates in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN 0938–0999). Based on our experience with Physician Voluntary Reporting Program PVRP, we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims would range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 3 measures would range from 0.75 minutes to 36 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims will range from $0.50 (0.75 minutes × $40/hour) to $24.00 (36 minutes × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional will report will vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are proposing to reduce the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimate that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($0.50/per reported case × 6 reported cases) $3.00 to ($24.00/reported case × 6 reported cases) $144.

We note that, for the 2015 and 2016 PQRS payment adjustments, we are proposing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register to participate in PQRS as an administrative claims reporter. Therefore, we estimate that the cost of undergoing the GPRO selection process will be ($16/hour × 2 hours) $32. With respect to reporting, we note that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submit. Rather, CMS would bear the burden of reporting with respect to selecting which measures to report. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

d. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS via the Registry-Based or EHR-Based Reporting Mechanism

In 2010, approximately 40,000 of the roughly 245,000 eligible professionals (or 16 percent) of eligible professionals used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using the registry based reporting mechanism will remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a registry solely for PQRS reporting by CY 2014. In 2010, only 14 of the roughly 245,000 eligible professionals (or >1 percent) of eligible professionals used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will increase as eligible professionals become more familiar with EHR products. In particular, we believe eligible professionals and group practices will transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 40,000 eligible professionals (4 percent), whether participating as an individual or part of a group practice, will use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participates in PQRS via a qualified registry, direct EHR product, or EHR data submission vendor product, we believe there would be little to no burden associated for an eligible professional to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. While we note that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

e. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS—Group Practices

Unlike eligible professionals who choose to report individually, we note that we are proposing that eligible professionals choosing to participate as part of a group practice under the GPRO would need to indicate their intent to participate in PQRS as a GPRO. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface would be the time and effort associated with submitting this data. To submit quality

measures data for PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in PQRS as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process will be ($16/hour × 6 hours) $96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for an applicable year would be ($40/hour × 79 hours) $3,160.

Eligible professionals who wish to qualify for an additional 0.5 percent Maintenance of Certification Program incentive will need to ''more frequently'' than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2012 and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification Board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive will depend on what a certification board establishes as ''more frequently'' and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in 2012, the time an individual spends to complete the practice assessment component of the Maintenance of Certification ranges from 8–12 hours.

f. Burden Estimate on Vendor Participation in the CYs 2013 and 2014 PQRS

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that registry and EHR vendor products incur costs associated with participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimate that approximately 50 additional registries would self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries, the total burden for qualified registries who submit PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimate that it would take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimate that it would cost a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS quality measures data will be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that since we are proposing not to continue to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data, there is no burden associated with qualification of direct EHR products and EHR data submission vendor products. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional would need to submit to CMS will depend on the vendor's familiarity with PQRS and the vendor's system and programming capabilities. Since we believe that an EHR vendor would be submitting data for reasons other than reporting under PQRS, we believe there would be no additional burden for an EHR vendor to submit quality measures data for PQRS reporting.

g. Summary of Burden Estimates on Participation in the 2013 and 2014 PQRS—Eligible Professionals and Vendors

TABLE 81—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation.	5.0	1	N/A	$16	$80.
Individual EP: Claims	0.2	6	3	$40	$144.

TABLE 81—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS—Continued

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual EP: Administrative Claims	2	1	N/A	$16	$32.
Individual EP: Registry	N/A	1	N/A	N/A	Minimal.
Individual EP: EHR	N/A	1	N/A	N/A	Minimal.
Group Practice: Self-Nomination	6.0	1	N/A	$16	$96.
Group Practice: Reporting	79	1	N/A	$40	$3,160.

TABLE 82—ESTIMATED COSTS TO VENDORS TO PARTICIPATE IN PQRS

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$160	$160
EHR: Programming	0	0	0

3. Electronic Prescribing (eRx) Incentive Program

The requirements for the eRx Incentive Program for 2012–2014 were established in the CY 2012 Medicare PFS final rule. Although we are making proposals related to the eRx Incentive Program in the CY 2013 Medicare PFS, these proposals have no additional burden or impact on the public. Therefore, this rule would not revise the requirements or burden estimates approved by OMB under OCN: 0938–1083.

4. Physician Quality Reporting System-Medicare EHR Incentive Pilot

The Physician Quality Reporting System-Medicare EHR Incentive Pilot is a Pilot that provides a method whereby an eligible professional participating in both PQRS and Medicare EHR Incentive Program may submit one set of data and satisfy the reporting requirements for both programs. We believe any burden or impact associated with the Pilot would be absorbed in the burden and impact estimates provided for PQRS (OCN: 0938–1083) and the EHR Incentive Program.

I. Submission of PRA-Related Comments

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–1590–P] Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA), the Affordable Care Act, and other statutory changes. This proposed rule also is necessary to make changes to Part B drug payment policy and other related Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2012), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year (for details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an

explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers including IDTFs are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis for the remaining provisions and addresses comments received on these issues.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This proposed rule would have no consequential spending effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2012 with proposed payment rates for CY 2013 using CY 2011 Medicare utilization as the basis for the comparison. To the extent that there are year-to-year changes in the volume and mix of services furnished by physicians, the actual impact on total Medicare revenues will be different from those shown in Tables 83 (CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty) and 84 (CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal). The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 85 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Tables 83 and 84 show the payment impact on PFS services. We note that these impacts do not include the effect of the January 2013 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with section 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. While the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to permanently reform the SGR methodology for Medicare PFS updates. We provide our most recent estimate of the SGR and physician update for CY 2013 on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/*.

The following is an explanation of the information represented in Table 83:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2011 utilization and CY 2012 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been

summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.

- *Column C (Impact of Work and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Combined Impact):* This column shows the estimated CY 2013 combined impact on total allowed charges of all the changes in the previous columns.

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TABLE 83: CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty*

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work and MP RVU Changes	(D) Impact of PE RVU Changes	(E) Combined Impact
TOTAL	$ 86,000	0%	0%	0%
01-ALLERGY/ IMMUNOLOGY	$ 198	-1%	1%	0%
02-ANESTHESIOLOGY	$ 1,970	-1%	-3%	-3%
03-CARDIAC SURGERY	$ 366	-1%	-2%	-2%
04-CARDIOLOGY	$ 6,568	-1%	-2%	-3%
05-COLON AND RECTAL SURGERY	$ 153	-1%	1%	1%
06-CRITICAL CARE	$ 261	-1%	0%	0%
07-DERMATOLOGY	$ 3,008	-1%	0%	0%
08-EMERGENCY MEDICINE	$ 2,819	-1%	0%	-1%
09-ENDOCRINOLOGY	$ 434	-1%	1%	1%
10-FAMILY PRACTICE	$ 5,879	3%	4%	7%
11-GASTROENTEROLOGY	$ 1,885	-1%	0%	0%
12-GENERAL PRACTICE	$ 579	-1%	1%	0%
13-GENERAL SURGERY	$ 2,261	-1%	0%	0%
14-GERIATRICS	$ 217	1%	3%	4%
15-HAND SURGERY	$ 134	-1%	0%	0%
16-HEMATOLOGY/ ONCOLOGY	$ 1,900	-1%	0%	-1%
17-INFECTIOUS DISEASE	$ 623	-1%	1%	0%
18-INTERNAL MEDICINE	$ 11,058	2%	3%	5%
19-INTERVENTIONAL PAIN MGMT	$ 534	-1%	0%	-1%
20-INTERVENTIONAL RADIOLOGY	$ 203	-1%	-2%	-3%
21-MULTISPECIALTY CLINIC/OTHER PHY	$ 202	-1%	-1%	-1%
22-NEPHROLOGY	$ 2,065	-1%	0%	-1%
23-NEUROLOGY	$ 1,601	-1%	2%	1%
24-NEUROSURGERY	$ 681	-1%	0%	-1%
25-NUCLEAR MEDICINE	$ 49	-1%	-3%	-3%
27-OBSTETRICS/ GYNECOLOGY	$ 698	-1%	0%	1%
28-OPHTHALMOLOGY	$ 5,621	-1%	1%	1%
29-ORTHOPEDIC SURGERY	$ 3,622	-1%	0%	-1%
30-OTOLARNGOLOGY	$ 1,070	-1%	1%	0%
31-PATHOLOGY	$ 1,185	-1%	-1%	-2%
32-PEDIATRICS	$ 64	2%	3%	5%
33-PHYSICAL MEDICINE	$ 990	-1%	1%	1%
34-PLASTIC SURGERY	$ 351	-1%	0%	0%
35-PSYCHIATRY	$ 1,149	-1%	0%	0%
36-PULMONARY DISEASE	$ 1,691	-1%	1%	0%
37-RADIATION ONCOLOGY	$ 1,983	-1%	-14%	-14%
38-RADIOLOGY	$ 4,791	-1%	-3%	-4%
39-RHEUMATOLOGY	$ 545	-1%	0%	0%
40-THORACIC SURGERY	$ 340	-1%	-1%	-2%
41-UROLOGY	$ 1,909	-1%	-1%	-2%
42-VASCULAR SURGERY	$ 882	-1%	-2%	-3%
43-AUDIOLOGIST	$ 57	-1%	-4%	-5%
44-CHIROPRACTOR	$ 738	-1%	1%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work and MP RVU Changes	(D) Impact of PE RVU Changes	(E) Combined Impact
45-CLINICAL PSYCHOLOGIST	$ 567	-1%	-2%	-3%
46-CLINICAL SOCIAL WORKER	$ 400	-1%	-2%	-3%
47-DIAGNOSTIC TESTING FACILITY	$ 875	-1%	-7%	-8%
48-INDEPENDENT LABORATORY	$ 1,064	-1%	-1%	-1%
49-NURSE ANES / ANES ASST	$ 1,142	-1%	-3%	-4%
50-NURSE PRACTITIONER	$ 1,606	1%	3%	5%
51-OPTOMETRY	$ 1,048	-1%	2%	1%
52-ORAL/MAXILLOFACIAL SURGERY	$ 44	-1%	1%	0%
53-PHYSICAL/OCCUPATIONAL THERAPY	$ 2,613	-1%	3%	3%
54-PHYSICIAN ASSISTANT	$ 1,219	1%	2%	3%
55-PODIATRY	$ 1,898	-1%	2%	1%
56-PORTABLE X-RAY SUPPLIER	$ 104	-1%	2%	2%
57-RADIATION THERAPY CENTERS	$ 71	-1%	-18%	-19%
98-OTHER	$ 19	-1%	1%	0%

* Table 83 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law.

Table 84 shows the estimated impact of selected policy proposals on total allowed charges, by specialty. The following is an explanation of the information represented in Table 84:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2011 utilization and CY 2012 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Baseline (PPIS transition, Updated Claims Data, and All Other Factors)):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs due to the final year of the PPIS transition, proposed multiple procedure payment reduction for the TC of cardiovascular and ophthalmology diagnostic tests furnished on the same day (section II.B.4. of this proposed rule), all other proposals that result in minimal redistribution of payments under the PFS, the use of CY 2011 claims data to model payment rates, and other factors.
- *Column D (Updated Equipment Interest Rate Assumption):* This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs resulting from our proposed update to the equipment interest rate assumption as discussed in section II.A.2.f. of this proposed rule.
- *Column E (Primary Care and Care Coordination: Post-Discharge Transitional Care Management Services):* This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our proposed policy to pay for post-discharge transitional care management services in the 30 days following an inpatient hospital, outpatient observation or partial hospitalization, skilled nursing facility (SNF), or community mental health center (CMHC) discharge as discussed in section II.H.1. of this proposed rule. We would expect a negative impact on all non-primary care specialties due to the application of a BN adjustment to reflect the discharge transitional care management policy.
- *Column F (Input Changes for Certain Radiation Therapy Procedures):* This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our proposal to revise the procedure times for certain radiation therapy procedures discussed in section II.B.3.b. of this proposed rule.
- *Column G (Cumulative Impact):* This column shows the estimated CY 2013 combined impact on total allowed charges of all the proposed changes in the previous columns.

TABLE 84: CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal*

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Specialty	**Allowed Charges (mil)**	**Baseline (PPIS transition, new utilization and other factors)**	**Updated Equipment Interest Rate Assumption**	**Discharge Transition Care Manage-ment**	**Input Changes for Certain Radiation Therapy Procedures**	**Total (Cumulative Impact)**
TOTAL	$ 85,485	0%	0%	0%	0%	0%
01-ALLERGY/ IMMUNOLOGY	$ 198	0%	1%	-2%	1%	0%
02-ANESTHESIOLOGY	$ 1,969	-2%	0%	-1%	0%	-3%
03-CARDIAC SURGERY	$ 366	-1%	0%	-1%	0%	-2%
04-CARDIOLOGY	$ 6,565	-1%	0%	-1%	0%	-3%
05-COLON AND RECTAL SURGERY	$ 153	1%	0%	-1%	0%	1%
06-CRITICAL CARE	$ 261	1%	0%	-1%	0%	0%
07-DERMATOLOGY	$ 3,008	0%	1%	-2%	0%	-1%
08-EMERGENCY MEDICINE	$ 2,819	0%	0%	-1%	0%	-1%
09-ENDOCRINOLOGY	$ 434	1%	0%	-1%	0%	0%
10-FAMILY PRACTICE	$ 5,872	2%	0%	5%	0%	7%
11-GASTROENTEROLOGY	$ 1,885	1%	0%	-1%	0%	0%
12-GENERAL PRACTICE	$ 577	1%	0%	-1%	0%	0%
13-GENERAL SURGERY	$ 2,261	1%	0%	-1%	0%	0%
14-GERIATRICS	$ 217	2%	0%	2%	0%	4%
15-HAND SURGERY	$ 134	1%	0%	-1%	0%	0%
16-HEMATOLOGY/ ONCOLOGY	$ 1,891	0%	1%	-2%	0%	-1%
17-INFECTIOUS DISEASE	$ 623	2%	0%	-1%	0%	1%
18-INTERNAL MEDICINE	$ 11,049	1%	0%	3%	0%	5%
19-INTERVENTIONAL PAIN MGMT	$ 533	0%	0%	-1%	0%	-1%
20-INTERVENTIONAL RADIOLOGY	$ 202	-2%	0%	-1%	0%	-3%
21-MULTISPECIALTY CLINIC/OTHER PHY	$ 201	-1%	0%	-1%	0%	-2%
22-NEPHROLOGY	$ 2,064	0%	0%	-1%	0%	-1%
23-NEUROLOGY	$ 1,596	2%	0%	-1%	0%	1%
24-NEUROSURGERY	$ 680	0%	0%	-1%	0%	-1%
25-NUCLEAR MEDICINE	$ 48	-2%	-1%	-1%	0%	-4%
27-OBSTETRICS/ GYNECOLOGY	$ 698	1%	0%	-1%	0%	0%
28-OPHTHALMOLOGY	$ 5,621	2%	0%	-1%	0%	1%
29-ORTHOPEDIC SURGERY	$ 3,609	0%	0%	-1%	0%	-1%
30-OTOLARNGOLOGY	$ 1,069	1%	1%	-1%	0%	0%
31-PATHOLOGY	$ 1,185	-1%	0%	-1%	0%	-2%
32-PEDIATRICS	$ 64	1%	0%	3%	0%	5%
33-PHYSICAL MEDICINE	$ 980	2%	0%	-1%	0%	1%
34-PLASTIC SURGERY	$ 351	1%	0%	-1%	0%	0%
35-PSYCHIATRY	$ 1,149	1%	0%	-1%	0%	0%
36-PULMONARY DISEASE	$ 1,691	1%	0%	-1%	0%	0%
37-RADIATION ONCOLOGY	$ 1,982	-3%	-3%	-2%	-7%	-15%

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Specialty	**Allowed Charges (mil)**	**Baseline (PPIS transition, new utilization and other factors)**	**Updated Equipment Interest Rate Assumption**	**Discharge Transition Care Manage-ment**	**Input Changes for Certain Radiation Therapy Procedures**	**Total (Cumulative Impact)**
38-RADIOLOGY	$ 4,724	-2%	-1%	-1%	0%	-4%
39-RHEUMATOLOGY	$ 544	0%	1%	-2%	0%	0%
40-THORACIC SURGERY	$ 340	-1%	0%	-1%	0%	-2%
41-UROLOGY	$ 1,905	-1%	0%	-1%	0%	-2%
42-VASCULAR SURGERY	$ 881	-2%	0%	-1%	0%	-3%
43-AUDIOLOGIST	$ 57	-3%	0%	-1%	0%	-5%
44-CHIROPRACTOR	$ 738	2%	0%	-1%	0%	0%
45-CLINICAL PSYCHOLOGIST	$ 567	-2%	0%	-1%	0%	-3%
46-CLINICAL SOCIAL WORKER	$ 400	-2%	0%	-1%	0%	-3%
47-DIAGNOSTIC TESTING FACILITY	$ 848	-5%	-2%	-2%	1%	-8%
48-INDEPENDENT LABORATORY	$ 1,064	-2%	1%	-2%	1%	-2%
49-NURSE ANES / ANES ASST	$ 1,142	-3%	0%	-1%	0%	-4%
50-NURSE PRACTITIONER	$ 1,606	2%	0%	3%	0%	5%
51-OPTOMETRY	$ 1,048	2%	0%	-1%	0%	1%
52-ORAL/MAXILLOFACIAL SURGERY	$ 44	1%	1%	-1%	0%	0%
53-PHYSICAL/OCCUPATIONAL THERAPY	$ 2,263	3%	0%	-1%	0%	3%
54-PHYSICIAN ASSISTANT	$ 1,219	1%	0%	2%	0%	3%
55-PODIATRY	$ 1,897	2%	1%	-2%	0%	1%
56-PORTABLE X-RAY SUPPLIER	$ 104	2%	1%	-2%	1%	2%
57-RADIATION THERAPY CENTERS	$ 71	-4%	-5%	-2%	-8%	-19%
98-OTHER	$ 19	1%	0%	-1%	0%	0%

*Table 84 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law

2. CY 2012 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to several factors. First, as discussed in section II.A.2. of this proposed rule, we are currently implementing the final year of the 4-year transition to new PE RVUs using the PPIS data that were adopted in the CY 2010 PFS final rule with comment period. The impacts of the final year of the transition are generally consistent with the impacts that would be expected based on the impacts displayed in the CY 2012 final rule with comment period. The second factor is the post-discharge transitional care management proposal, under which we would pay separately for care coordination in the 30 days following an inpatient hospital, outpatient hospital observation services or partial hospitalization, SNF, or CMHC discharge from the treating physician in the hospital to the beneficiary's primary physician in the community.

Table 83 also reflects updates to the proposed interest rate assumption used in the medical equipment calculation in the PE RVU methodology, the proposed multiple procedure payment reduction policy for the technical component of diagnostic cardiovascular and ophthalmological procedures, and proposed changes to the inputs for certain radiation therapy procedures.

Table 84 shows the same information as provided in Table 83, but rather than isolating the policy impact on physician work, PE, and malpractice separately, Table 84 shows the impact of varied proposed policies on total RVUs.

b. Combined Impact

Column E of Table 83 and column G of Table 84 display the estimated CY 2013 combined impact on total allowed charges by specialty of all the proposed RVU and MPPR changes. These impacts range from an increase of 7 percent for family practice to a decrease of 19 percent for radiation therapy centers. Again, these impacts are estimated prior to the application of the negative CY

2013 Conversion Factor (CF) update applicable under the current statute.

Table 85 (Impact of Proposed Rule on CY 2013 Payment for Selected Procedures (Based on the March 2012 Preliminary Physician Update)) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included CY 2013 payment rates with and without the effect of the CY 2013 negative PFS CF update for comparison purposes. We selected these procedures because they are the most commonly furnished by a broad spectrum of physician specialties. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this proposed rule.

TABLE 85: Impact of Proposed Rule on CY 2013 Payment for Selected Procedures (Based on the March 2012 Preliminary Physician Update)*

CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2012[2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)	CY 2012 [2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)
11721		Debride nail 6 or more	$25.19	$24.37	-3%	$17.79	-29%	$43.57	$44.00	1%	$32.12	-26%
17000		Destruct premalg lesion	$56.16	$56.19	0%	$41.01	-27%	$81.01	$81.23	0%	$59.29	-27%
27130		Total hip arthroplasty	$1,445.58	$1,433.42	-1%	$1,046.26	-28%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,231.48	$1,223.23	-1%	$892.84	-27%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,544.29	$1,530.22	-1%	$1,116.91	-28%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,950.35	$1,897.80	-3%	$1,385.21	-29%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,112.35	$1,085.81	-2%	$792.54	-29%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.61	$172.62	-1%	$126.00	-28%	$351.61	$348.96	-1%	$254.71	-28%
66821		After cataract laser surgery	$307.70	$315.79	3%	$230.50	-25%	$326.08	$334.07	2%	$243.84	-25%
66984		Cataract surg w/iol 1 stage	$760.74	$775.43	2%	$565.99	-26%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$504.10	$507.37	1%	$370.33	-27%	$523.84	$524.63	0%	$382.93	-27%
71010		Chest x-ray	NA	NA	NA	NA	NA	$23.83	$23.02	-3%	$16.80	-29%
71010	26	Chest x-ray	$8.85	$8.80	-1%	$6.42	-27%	$8.85	$8.80	-1%	$6.42	-27%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$112.32	$110.68	-1%	$80.79	-28%
77056	26	Mammogram both breasts	$42.55	$41.63	-2%	$30.39	-29%	$42.55	$41.63	-2%	$30.39	-29%
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.35	$78.86	-3%	$57.56	-29%
77057	26	Mammogram screening	$34.38	$33.51	-3%	$24.46	-29%	$34.38	$33.51	-3%	$24.46	-29%
77427		Radiation tx management x5	$177.00	$182.77	3%	$133.41	-25%	$177.00	$182.77	3%	$133.41	-25%
88305	26	Tissue exam by pathologist	$36.08	$35.20	-2%	$25.69	-29%	$36.08	$35.20	-2%	$25.69	-29%
90801		Psy dx interview	$119.81	$116.10	-3%	$84.74	-29%	$152.49	$150.62	-1%	$109.94	-28%

CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2012 [2]	CY 2013 [3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)	CY 2012 [2]	CY 2013 [3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)
90862		Medication management	$44.25	$43.66	-1%	$31.87	-28%	$58.54	$58.89	1%	$42.99	-27%
90935		Hemodialysis one evaluation	$72.84	$70.74	-3%	$51.63	-29%	NA	NA	NA	NA	NA
92012		Eye exam established pat	$51.40	$52.46	2%	$38.29	-25%	$82.71	$84.62	2%	$61.76	-25%
92014		Eye exam & treatment	$78.29	$79.20	1%	$57.81	-26%	$119.81	$122.53	2%	$89.43	-25%
92980		Insert intracoronary stent	$837.67	$804.20	-4%	$586.99	-30%	NA	NA	NA	NA	NA
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$19.06	$17.94	-6%	$13.09	-31%
93010		Electrocardiogram report	$8.51	$8.12	-5%	$5.93	-30%	$8.51	$8.12	-5%	$5.93	-30%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$88.50	$83.94	-5%	$61.27	-31%
93307	26	Tte w/o doppler complete	$45.95	$44.34	-4%	$32.36	-30%	$45.95	$44.34	-4%	$32.36	-30%
93458	26	L hrt artery/ventricle angio	$315.87	$315.12	0%	$230.00	-27%	$315.87	$315.12	0%	$230.00	-27%
98941		Chiropractic manipulation	$30.63	$30.46	-1%	$22.23	-27%	$36.08	$36.22	0%	$26.43	-27%
99203		Office/outpatient visit new	$74.88	$74.46	-1%	$54.35	-27%	$105.18	$106.28	1%	$77.57	-26%
99213		Office/outpatient visit est	$49.69	$49.76	0%	$36.32	-27%	$70.46	$71.76	2%	$52.37	-26%
99214		Office/outpatient visit est	$76.24	$76.49	0%	$55.83	-27%	$104.16	$105.26	1%	$76.83	-26%
99222		Initial hospital care	$133.09	$133.70	0%	$97.58	-27%	NA	NA	NA	NA	NA
99223		Initial hospital care	$195.38	$196.99	1%	$143.78	-26%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.12	$37.91	-1%	$27.67	-27%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$69.78	$70.06	0%	$51.14	-27%	NA	NA	NA	NA	NA
99233		Subsequent hospital	$100.07	$100.53	0%	$73.37	-27%	NA	NA	NA	NA	NA

CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2012[2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)	CY 2012 [2]	CY 2013[3] (pre update)	% Change (pre update)	CY 2013 [4] (post update)	% Change (post update)
		care										
99236		Observ/hosp same date	$212.05	$211.88	0%	$154.65	-27%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$103.13	$103.91	1%	$75.84	-26%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$60.25	$59.57	-1%	$43.48	-28%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$114.71	$113.73	-1%	$83.01	-28%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.16	$216.62	0%	$158.11	-27%	$267.20	$268.75	1%	$196.16	-27%
99292		Critical care addl 30 min	$108.92	$108.65	0%	$79.30	-27%	$119.47	$119.82	0%	$87.46	-27%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.03	$81.57	-1%	$59.54	-27%
99350		Home visit est patient	NA	NA	NA	NA	NA	$171.21	$172.96	1%	$126.24	-26%
G0008		Immunization admin	NA	NA	NA	NA	NA	$24.17	$25.05	4%	$18.28	-24%

*The CY 2013 payment rates are likely to differ from those shown in 85, as the CY 2013 CF is not yet final.

1 CPT codes and descriptions are copyright 2012American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

2 Payments based on the 2012conversion factor of 34.0376

3 Payments based on the 2012 conversion factor of 34.0376, adjusted to 33.8572 to include the BN adjustment.

4 Payments based on the 2013conversion factor of 24.7124, which includes the BN adjustment.

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D. Effect of Proposed Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E.3 of this proposed rule, we are proposing to add several new codes to the list of Medicare telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Effect of Proposed Definition of Certified Registered Nurse Anesthetists' (CRNA) Services

As discussed in section II.K.1. of this proposed rule, we propose to define ''anesthesia and related care'' as used in the statutory benefit category for CRNAs under section 1861(bb)(2) of the Act to include those services that are related to anesthesia and included within the state scope of practice for CRNAs in the state in which the services are furnished. CMS has been requested to clarify the definition with regard to chronic pain management services. Contractors have reached different conclusions as to whether the statutory definition of ''anesthesia services and related care'' encompasses the chronic pain management services delivered by CRNAs. Given variations in state scopes of practice, we expect that differences on whether CRNAs can bill Medicare directly for these services will continue to exist. In addition, current Medicare policies do not prohibit CRNAs from furnishing these services in states where the scope of practice allows them to do so, but only prohibit them from billing Medicare directly. As a result of these two factors, we do not expect a significant change in how many services are billed to Medicare and therefore, we estimate no significant budgetary impact from this proposed change.

F. Effects of Proposed Change to Ordering Requirements for Portable X-Ray Services Under the PFS

As discussed in section III.K.2. of this proposed rule, we are proposing to revise our current regulation that limits ordering of portable x-ray services to only a doctor of medicine or a doctor of osteopathy to allow other physicians and nonphysician practitioners (acting within the scope of State law and their Medicare benefit) to order portable x-ray services. We estimate no significant impact on PFS expenditures from the proposed additions.

G. Geographic Practice Cost Indices (GPCIs)

As discussed in section II.E. of this proposed rule, we are required to review and revise the GPCIs at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2013, we are not proposing any revisions related to the data or methodologies used to calculate the GPCIs. However, since the 1.0 work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2013 PFS, the proposed CY 2013 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS proposed rule do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848(e)(1)(G) and section 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier States are applicable in CY 2013.

H. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule

As discussed in section III.A. of this proposed rule, section 306 of the TPTCCA and section 3007 of the MCTRJCA require the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2012. As further discussed in section III.A. of this proposed rule, this legislation is self-implementing, and we are proposing to amend the regulation text at § 414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we are not making any policy proposals associated with these legislative provisions and there is no associated regulatory impact.

2. Part B Drug Payment: ASP Issues

As discussed in section III of this proposed rule, we are proposing to update the AMP-based price substitution policy that would allow Medicare to pay based off lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Our impact analysis is unchanged from last year (76 FR 73462): Based on estimates published in various OIG reports cited in the CY 2012 PFS final rule with comment period (76 FR 73290–1), we believe that this proposal will generate minor savings for the Medicare program and its beneficiaries since any substituted prices would be for amounts less than the calculated 106 percent of the ASP.

Our policy clarification regarding Pharmacy Billing for Part B Drugs Administered Incident to a Physician's Services which is discussed in section III of this proposed rule states that only physicians and not pharmacies (or DME suppliers) are allowed to bill Medicare under Part B for drugs administered in physicians' offices. We do not believe that this clarification will significantly impact the quantity or payment amount for part B drugs that are administered through implanted DME and or the procedures used to refill such pumps.

3. Medicare Program; Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

a. Overall Impact

We estimate the overall economic impact of this provision on the health care sector to be a cost of $49.95 million in the first year and $285.2 million over 5 years. This overall impact is comprised of additional administrative paperwork costs to private sector providers; a slight increase in Medicare spending, consisting of additional costs and some offsetting savings; and additional opportunity and out-of-pocket costs to Medicare beneficiaries. We believe there are likely to be other benefits and cost savings result from the DME face-to-face requirement, however, many of those benefits cannot be quantified. For instance, we expect to see savings in the form of reduced fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (note that not all improper payments are fraudulent). Our detailed cost and benefit analysis is explained below. We are specifically soliciting comment on the potential increased costs and benefits associated with this provision.

TABLE 86—OVERALL ECONOMIC IMPACT TO HEALTH SECTOR

[In millions]

	Year 1	5 Years
Private Sector (Paperwork Cost)	$11.2	$94.2
Net Medicare impact of additional visits and G code billings	5	30
Beneficiaries	29.75	161
Total Economic Impact to Health Sector	49.95	285.2

The definition of small entity in the RFA includes non-profit organizations. Most suppliers and providers are small entities as that term is used in the RFA. Likewise, the vast majority of physician and NP practices are considered small businesses according to the Small Business Administration's size standards with total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this rule are substantial in the aggregate, the economic impacts on individual entities will be relatively small. We estimate that 90 to 95 percent of DME suppliers and practitioners who order DME are small entities under the RFA definition. Physicians and other professionals would receive extra payments for some of the costs imposed, and other costs (for example, for additional practitioner visits) would be reimbursed by Medicare under regular payment rules. The rationale behind requiring a face-to-face encounter is to reduce inappropriate claims from those DME suppliers who have been abusing or defrauding the program. The impact on these suppliers could be significant, however since the purpose of the statute and this regulation is to reduce abusive and fraudulent DME sales, we do not view the burden placed on those providers in the form of lost revenues as a condition that we must mitigate. We believe that the effect on legitimate suppliers and practitioners would be minimal.

Anticipated Effects

b. Costs

(1) Private Sector Paperwork Costs

We believe that most practitioners are already seeing the beneficiary no more than 90 days prior to the written order or within 30 days after the order is written in certain circumstances. However this regulation potentially requires increased documentation.

Although we have no quantitative data for a specific dollar figure for the additional DME that may now be authorized in accordance with § 410.38(g), nor can we determine if there would be cost avoidance and a reduction of unnecessary DME, we acknowledge the potential for this provision to surpass the economically significant threshold. We do not believe that this proposed rule would significantly affect the number of legitimate written orders for DME. However, we would expect a decline in fraudulent, wasteful and abusive orders, thereby causing a decrease in the amount paid for DME overall.

The covered items of DME as outlined in the M Pages, including the proposed list of Specified Covered Items, contains items that meet at least one of the criteria. The four criteria are as follows: (1) Items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the DME MACs, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, the Government Accountability Office or other oversight entities. We are requesting comments on our criteria.

We also have estimated the number of different covered Medicare items subject to this proposed rule at approximately 164 HCPCS codes for items of DME. As new products enter the market this number could increase, which could increase the impact. In addition, we propose a G-code to pay physicians' for documenting the encounter conducted by a PA, a NP, or a CNS.

We anticipate there would be an impact as a result of additional office visits for the face-to-face encounter and the additional time spent by physicians to document the face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS.

In our estimate of overall cost we include the estimates from section III, of this proposed rule (Collection of Information Requirements section). These are estimated at $11.2 million in year 1 and $ 94.2 million over 5 years. These are driven by the physician documenting face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS, including the time to communicate the practitioners findings to physicians so they can complete the necessary documentation.

TABLE 87—PRIVATE SECTOR PAPERWORK COSTS

	Year 1 (in millions)	5 Years (in millions)
Physician time to document occurrence of a face-to-face encounter cost	$9.8	$82.6
PA, NP, or CNS costs	1.4	11.6
Total Cost	11.2	94.2

(2) Medicare Costs

Medicare would incur additional costs associated with this proposed rule related to additional face-to-face encounters in the form of office visits, and additional payment for time spent documenting the face-to-face encounter if furnished by the PA, NP or CNS and not by the physician directly. Subsequently, a G–Code is being created to allow Medicare payment to physicians for documenting the face-to-face encounters that are furnished by a PA, NP, and CNS, and is included in this proposed rule.

From a programmatic standpoint we believe that there would be 750,000

additional office visits billed and 500,000 G code claims for the documentation. It is difficult to determine how many PAs, NPs or CNSs wrote orders for covered items of DME, and while we lack exact empirical data, in order to provide an estimate, we assumed that 5 percent of the orders for covered items of DME were written by a PA, NP or CNS. For the purpose of this estimate we assume that each order requires a separate face-to-face encounter, recognizing fully that the estimate might be inflated.

While we believe that currently the majority of practitioners evaluate beneficiaries before ordering DME, some may not, and therefore, a certain number of beneficiaries would be required to have a new visit in order to fulfill the face-to-face encounter requirement. Actuarial estimates indicate approximately 5 percent of those obtaining covered items of DME in a given year did not see a practitioner in the 90 days preceding the order or in the 30 days after the order was written. We estimate that 500,000 beneficiaries would not see their practitioners in the 90 days prior to the written order for the covered item or in the 30 days after the order is written. We assume that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face-to-face requirement. The range would be about one to three; possibly less than one if many beneficiaries choose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame. To estimate the impact of the additional office visits we assumed 750,000 additional office visits (1.5 visits * 500,000 beneficiaries). We also assumed that the average cost for these office visits is around $65, which is consistent with a mid-level office visit under the PFS. This represents the total amount that the practitioners would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Physicians are now required to document the face-to-face encounter if it was furnished by a PA, NP, or CNS. In order to allow payment for this documentation, a G code is established for this service. There are approximately 10 million DME users and it was assumed that roughly 5 percent of face-to-face encounters are actually furnished by these other practitioner types, thereby requiring documentation of the encounter. Therefore, it was assumed that about 500,000 of these documentation services would be billed. We cannot predict with any certainty the cost of this new service, but believe that $15 is a reasonable estimate. This represents the total amount that the physician would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Therefore the estimated gross cost is estimated to be $45 million in year 1 and $250 million over 5 years; note that there are also savings to Medicare that must be netted against the cost of additional practitioner office visits, which are described later in the Benefits section. There is a high degree of uncertainty surrounding this estimate because it is difficult to predict how physicians and beneficiaries would respond to the new requirement.

This provision would assist in providing better documentation which may help to lower the error rate and thus reduce improper payments, including those stemming from waste, fraud and abuse. Since there is a large amount of potential variation in the amount of time that a face-to-face encounter may take for an item of DME, as a proxy our estimate is based on the amount of time needed for a mid-level visit to evaluate a beneficiary (E&M code 99213). The time allotted for this visit to furnish the face-to-face evaluation under a 99213 is 15 minutes. We welcome comments as to the appropriateness of E&M Code 99213 as a proxy measure of time required for a face-to-face encounter.

Based on actual data, projecting these historical patterns in light of the draft regulation is not straight-forward. Some line items may be bundled (perhaps because they are used together). Beneficiaries may also change their behavior in response to the regulation. For example, beneficiaries would be required to visit a physician in order for Medicare to pay for a new piece of equipment may substitute this visit for a later visit that would have been for a routine service. In this situation, the overall number of visits would not increase. Moreover, some beneficiaries may choose not to pursue the DME item at that time. On the other hand, the proposed rule points out that some of the encounters reported on the practitioner claim now may not qualify to support the need for the item of DME. We assume that beneficiaries would decide not to schedule 10 percent of the additional visits required as a result of not needing the DME item and that some would substitute a required service for a later planned visit.

TABLE 88—MEDICARE 5-YEAR COSTS FOR ADDITIONAL FACE-TO-FACE VISITS AND G CODE BILLINGS

2013	2014	2015	2016	2017
$45	$45	$50	$50	$60

*These costs represent 80 percent of the allowed charges for the additional visits and the new G codes.

The requirement for a face-to-face encounter with a beneficiary in a certain time period as a condition of payment for DME is a new statutory requirement. It is not subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. However, by regulation, we are proposing to make an additional payment through a new G-code for physician work documenting the face-to-face encounters that are performed by a PA, NP, and CNS. This additional regulatory spending is subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act.

(c) Beneficiary Cost Impact

From a programmatic standpoint, approximately 5 percent of those obtaining covered items of DME in that year did not see a practitioner in the 90 days preceding the order or in the 30 days after the order was written. We estimate that 500,000 beneficiaries would not see their practitioners in the 90 days prior to the written order for the covered item or in the 30 days after the order is written. As mentioned above, we assume that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face to face requirement. The range would be about one to three; possibly less than one if many beneficiaries choose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame. There are effects on travel time and cost for these beneficiaries. If it takes a beneficiary 1.25 hours to go to a practitioner, the total estimate is approximately 937,500 hours of time for this proposed rule. We assume that an

average trip requires one hour and 15 minutes (45 minutes of round trip travel time and 30 minutes in the doctor's office—half for waiting and half for time with the staff). As a proxy we use $20 to estimate the cost per hour including loss of leisure time and travel cost for a beneficiary to see a practitioner. This is consistent with previous estimates of beneficiary leisure time as proposed in the May 4, 2011 proposed rule entitled ''Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Medicare & Medicaid Participating Providers and Suppliers'' 76 FR 25469. This creates an economic cost of nearly $18.75 million in year 1. Over 5 years this cost could reach $105 million. There will be additional out of pocket expenses at the 20 percent Medicare Part B coinsurance. We estimated this cost to be $10 million in year 1 and $56 million over 5 years.

TABLE 89—BENEFICIARY COST IMPACT RESULTING FROM ADDITIONAL FACE-TO-FACE VISITS TO OBTAIN DME SERVICES

	Year 1	5 Years
Total beneficiaries visits impacted	750,000	4.2 million.
Time per beneficiary	1.25 hours	1.25 hours.
Total Time	937,500	5.25 million.
Beneficiary Time Cost ($20)	$18.75 million	$105 million.
Out of Pocket Expense	$10 million	$56 million.
Estimated Total Beneficiary Cost Impact	$29.75 million	$161 million.

*These costs represent 20 percent of the allowed charges for the additional visits and the new G codes.

b. Benefits

There would be quantifiable benefits from an expected reduction in Medicare DME services provided. In addition, we anticipate additional, qualitative benefits from a decrease in waste, fraud, and abuse, which would decrease the number of services. Further, requiring that there be a face-to-face evaluation of the beneficiary helps ensure appropriate orders based on the individual's medical condition, which increases the quality of care that the beneficiary receives. It is difficult to measure how much waste, fraud, and abuse will be prevented as a result of this proposed rule since it is impossible to determine what would have happened in the absence of the proposed rule. This provision is expected to improve physician's documentation of DME, and therefore, will help reduce improper payments and move the agency towards its strategic goal to reduce the Medicare fee-for-service error rate for DME items which has a higher error rate than other Medicare services. The Comprehensive Error Rate Testing (CERT) program error rate for DME is high. Fraud is an improper payment, but not all improper payments are fraud.

Therefore, creating a measure of how much this proposed rule would save in terms of a reduction in waste, fraud and abuse is not possible. With that stated, in 2009 Medicare paid $1.7 billion for DME items covered by this proposed rule, and we estimate that $1.9 billion will be paid for covered items in 2012, and $9.9 billion over 5 years. Preventing waste, fraud and abuse by changing behavior that results in just a small percentage reduction in inappropriate or unnecessary ordering of DME services will generate Medicare savings. This is an area where savings can be found through increased oversight, such as this regulation proposes. We believe that the cost of the visits will be offset by the savings produced by this provision.

We project Medicare savings from reduced DME services; these savings partially offset the costs of additional physician office visits and documentation payments described earlier in the impact analysis. The year-to-year Medicare savings from reduced DME services is as follows:

TABLE 90—YEAR-TO-YEAR MEDICARE SAVINGS FROM REDUCED DME SERVICES

	2013	2014	2015	2016	2017
DME savings	−$40	−$40	−$45	−$45	−$50

Based on an analysis of 2007 DME claims, approximately 2 percent of total DME spending was for those beneficiaries who had little contact with their physician during the year. For this subset of spending we assumed that there would be a 20 percent reduction in spending due to the face-to-face requirement. We found similar reductions in DME expenditures among managed care enrollees compared to fee for service (FFS) beneficiaries in the Medical Expenditure Panel Survey. This assumption is fairly speculative but we think it is modest compared to the estimates of fraud and abuse reported elsewhere. The savings occurs because some beneficiaries will not choose to go to the physician to authorize the DME item, some physicians will not order the items that would otherwise have been provided in the absence of the regulation, and some suppliers will not be able to achieve a payment that might have occurred through an unnecessary sale or outright fraud.

The overall net impact to Medicare of the DME face-to-face encounter policy is $5 million in the first year and $30 million over the first 5 years.

This regulation produces an extra benefit that is difficult to quantify, but is an extremely positive one in terms of greater practitioner involvement. By increasing practitioner interactions with beneficiaries before ordering DME, beneficiaries would receive more appropriate DME and benefiting from higher quality care. Beneficiaries would also benefit from reduced out-of-pockets costs by not having to pay for unnecessary DME. This accomplishes the objective of achieving greater practitioner accountability noted in the provisions of and the amendments made by section 6407 and other sections of the Affordable Care Act. We welcome public comment on the benefits of the DME face-to-face requirement, including any data that could help quantify the expected reduction in fraud, improper payments, or improved beneficiary quality of care.

Alternatives Considered

In this proposed rule, we consider a variety of options and have sought

comments on these options in other sections of this proposed rule. We expect public comment on the way in which the supplier should be notified that a face-to-face has occurred wanting to limit the potential burden. We proposed several options for the physician documentation of a face-to-face encounter furnished by that physician. We believe just submitting the medical record for the applicable date of service would create the least cost while still producing the desired benefits. In this proposed rule we have also set forth different options of what physician documentation of a face-to-face encounter furnished by a PA, NP or CNS could look like, in the hope of receiving comments on determining the method that will create the least potential burden.

There are also options to change the list of covered DME, either by expanding it to cover more items or by minimizing it to cover fewer items with low unit costs. We welcome comment on our selection criteria.

Finally, there are other possible periods of time that could be set as the window within which face-to-face encounters must occur. We believe that the consistency with the home health rule benefits providers of services and suppliers, and beneficiaries but welcome comment on this proposal.

4. Non-Random Prepayment Review

We estimate no significant budgetary impact. We believe that the overall costs for most providers and suppliers would remain the same unless they are subject to non-random prepayment complex medical review for an extended period of time.

5. Ambulance Coverage—Physician Certification Statement

We estimate no significant budgetary impact.

6. Physician Compare Web Site

Section IV.N.2. of this proposed rule discusses the background of the Physician Compare Web site. As described in section IV.N.2. of this proposed rule, we propose to develop aspects of the Physician Compare Web site in stages. In the first stage, which was completed in 2011, we posted the names of those eligible professionals who satisfactorily participated in the 2009 Physician Quality Reporting System. The second phase of the plan, which was completed in 2012, included posting the names of eligible professionals who were successful electronic prescribers under the 2009 eRx Incentive Program, as well as eligible professionals (EPs) who participate in the EHR Incentive Program. The next phase of the plan includes posting of performance information with respect to the 2012 Physician Quality Reporting System GPRO measures which will be completed no sooner than 2013.

We are proposing to include performance information for the 2013 Physician Quality Reporting System GPRO web interface measures data no sooner than 2014, in addition to 2013 patient experience data for group practices participating in the 2013 Physician Quality Reporting System GPRO. As reporting of physician performance rates and patient experience data on the Physician Compare Web site will be performed directly by us using the data that we collect under the 2012 Physician Quality Reporting System GPRO and other data collection methods, we do not anticipate any notable impact on eligible professionals with respect to the posting of information on the Physician Compare Web site.

7. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

According to the 2010 Reporting Experience Report, a total of $391,635,495 in Physician Quality Reporting System incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (i.e., a bonus payment equal to 2.0 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting under the Physician Quality Reporting System. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010,which is the latest year in which PQRS has full participation data, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the Physician Quality Reporting System would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimate that the Physician Quality Reporting System would distribute approximately $162 million ($539 × 300,000 eligible professionals) and $216 million ($539 × 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to eligible professionals for participating in the Physician Quality Reporting System for the applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in the Physician Quality Reporting System will cease and payment adjustments for not satisfactory reporting will commence.

We note that the total burden associated with participating in the Physician Quality Reporting System is the time and effort associated with indicating intent to participate in the Physician Quality Reporting System, if applicable, and submitting Physician Quality Reporting System quality measures data. When establishing these burden estimates, we assume the following:

- The requirements for reporting for the Physician Quality Reporting System 2013 and 2014 incentives and payment adjustments for 2015 and beyond would be established as proposed in this 2013 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would report on 3 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting Physician Quality Reporting System quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

For an eligible professional who wishes to participate in the Physician Quality Reporting System as an individual, the eligible professional need not indicate his/her intent to participate. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the Physician Quality Reporting System are

based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the Physician Quality Reporting System measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the Physician Quality Reporting System would be approximately $80 ($16/hour × 5 hours).

With respect to an eligible professional who participates in the Physician Quality Reporting System via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The Physician Quality Reporting System collects QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims will range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 3 measures would range from 0.75 minutes to 36 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims would range from $0.50 (0.75 minutes × $40/hour) to $24.00 (36 minutes × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are proposing to reduce the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimate that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($0.50/per reported case × 6 reported cases) $3.00 to ($24.00/reported case × 6 reported cases) $144.

We note that, for the 2015 and 2016 PQRS payment adjustments, we are proposing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register for to participate in PQRS as an administrative claims reporter. Therefore, we estimate that the cost of undergoing the GPRO selection process will be ($16/hour × 2 hours) $32. With respect to reporting, we note that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submit. Rather, CMS would bear the burden of reporting with respect to selecting which measures to report. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

With respect to an eligible professional or group practice who participates in the Physician Quality Reporting System via a qualified registry, direct EHR product, or EHR data submission vendor product, we believe there would be little to no burden associated for an eligible professional to report Physician Quality Reporting System quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. While we note that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting Physician Quality Reporting System quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

Unlike eligible professionals who choose to report individually, we note that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the Physician Quality Reporting System as a group practice. The total burden for group practices who submit Physician Quality Reporting System quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the Physician Quality Reporting System, a group practice would need to (1) be selected to participate in the Physician Quality Reporting System GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the Physician Quality Reporting System as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decode to participate in the Physician Quality Reporting System as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in the Physician Quality Reporting System GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96. With respect to reporting, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit Physician Quality Reporting System quality measures data for the proposed reporting options in an applicable year would be ($40/hour × 79 hours) $3,160.

Eligible professionals who wish to quality for an additional 0.5% Maintenance of Certification Program incentive must ''more frequently'' than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2013 and/or 2014 and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in

a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive would depend on what a certification board establishes as ''more frequently'' and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in 2012, the time an individual spends to complete the practice assessment component of the Maintenance of Certification ranges from 8–12 hours.

Aside from the burden of eligible professionals and group practices participating in the Physician Quality Reporting System, we believe that registry, direct EHR, and EHR data submission vendor products incur costs associated with participating in the Physician Quality Reporting System.

With respect to qualified registries, the total burden for qualified registries who submit Physician Quality Reporting System Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years for Physician Quality Reporting System, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimate that it will take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report Physician Quality Reporting System quality measures data. Therefore, we estimate that it would cost a registry approximately ($16.00/hour x 10 hours) $160 to become qualified to submit Physician Quality Reporting System quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in the Physician Quality Reporting System. Therefore, we believe there would be little to no additional burden associated with reporting Physician Quality Reporting System quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the Physician Quality Reporting System.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit Physician Quality Reporting System Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years under the Physician Quality Reporting System, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we are not proposing to continue to require direct EHR products and EHR data submission vendors to become qualified to submit Physician Quality Reporting System quality measures data. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional must submit to CMS would depend on the vendor's familiarity with the Physician Quality Reporting System and the vendor's system and programming capabilities. We believe it would take a vendor approximately 40 hours (for experienced vendors) to 200 hours (for first-time vendor participants) to submit Physician Quality Reporting System quality measures data. Therefore, we estimate that it would cost an EHR vendor ($40/hour x 40 hours) $1,600 to $8,000 to submit Physician Quality Reporting System quality measures data for its eligible professionals.

TABLE 91—ESTIMATED COSTS FOR REPORTING PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80
Individual EP: Claims	0.2	6	3	40	144
Individual EP: Administrative Claims	2	1	N/A	16	32
Individual EP: Registry	N/A	1	N/A	N/A	*
Individual EP: EHR	N/A	1	N/A	N/A	*
Group Practice: Self-Nomination	6.0	1	N/A	16	96
Group Practice: Reporting	79	1	N/A	40	3,160

* Minimals.

TABLE 92—ESTIMATED COSTS TO VENDORS TO PARTICIPATE IN THE PHYSICIAN QUALITY REPORTING SYSTEM

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$40	$400
EHR: Programming	40–200	40	1,600–1,800

8. Electronic Prescribing (eRx) Incentive Program

Please note that the requirements for becoming a successful electronic prescriber for the 2013 incentive and 2014 payment adjustment were established in the CY 2012 MPFS final rule with comment period. The proposed provisions contained in this CY 2013 MPFS proposed rule would make additional changes to the requirements for the 2013 incentive and 2014 payment adjustment for group practices. Specifically, CMS is proposing to add a new criterion for being a successful electronic prescriber for the 2013 incentive and 2014 payment adjustments for group practices of 2–24 eligible professionals given that CMS is proposing to modify the definition of group practice. However, we note that any additional impact a result of this proposal would be minimal, as it is our understanding the eligible professionals who would use this new reporting option are already participating in the eRx Incentive Program as individual eligible professionals.

For the reasons stated, the proposals would have no additional impact other than the impact of the 2013 and 2014 payment adjustments described in the CY 2012 MPFS final rule with comment period.

9. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule for the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67962). The proposals for the Medicare Shared Savings Program set forth in the CY 2013 MPFS proposed rule impose requirements that eligible professionals in group practices within accountable care organizations would need to satisfy for purposes of the PQRS payment adjustment under the Medicare Shared Savings Program as the proposals related to the ACOs for the PQRS payment adjustment mirror the requirements that were established for earning the PQRS incentives.

10. Medicare EHR Incentive Program

Please note that the requirements for reporting clinical quality measures (CQMs) to achieve meaningful use under Stage 1 for the EHR Incentive Program were established in a standalone final rule published on July 28, 2010 (75 FR 44544). The proposals contained in this CY 2013 MPFS proposed rule merely propose methods to report CQMs to meet the CQM objective for achieving meaningful use under Stage 1 for the EHR Incentive Program. Therefore, the impacts to the proposal we are making to extend the use of attestation and the Physician Quality Reporting System-Medicare EHR Incentive Pilot to report CQMs were absorbed in the impacts discussion published in the EHR Incentive Program final rule published on July 28, 2010.

11. Chiropractic Services Demonstration

As discussed in section III of this rule with comment period, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fourth year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to the PFS for all chiropractors in CY s 2010 through 2014. To implement this required BN adjustment, we are recouping $10 million in CY 2013 by reducing the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

11. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The proposed changes to the Physician Feedback Program in section IV.I. of this proposed rule would not impact CY 2013 physician payments under the PFS. However, we expect that our proposals to use the Physician Quality Reporting System (PQRS) quality measures in the Physician Feedback reports and in the value modifier to be implemented in CY 2015 may result in increased participation in the PQRS in CY 2013. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the PQRS to determine and understand how the value modifier could affect their payments.

12. Medicare Coverage of Hepatitis B Vaccine: Modification of High Risk Groups Eligible for Medicare Part B Coverage of Hepatitis B Vaccine

As discussed in section III of this proposed rule, section 1861(s)(10)(B) of the Act authorizes Medicare coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B, as determined by the Secretary under regulations. Our current regulations are established at 42 CFR 410.63. We are proposing to modify § 410.63(a)(1) by adding persons diagnosed with diabetes mellitus to the high risk group. While it is estimated that approximately 23 percent of non-institutionalized Medicare beneficiaries are diagnosed with diabetes mellitus, it is unclear how many of these beneficiaries will obtain these services. Therefore, the estimated impact of adding persons diagnosed with diabetes mellitus to the high risk group eligible for coverage of hepatitis B vaccine and its administration is unknown for CY 2013.

13. Existing Standards for E-prescribing Under Medicare Part D and Identification and Lifting the LTC Exemption

The e-prescribing standard updates that are proposed in this section of the proposed rule imposes no new requirements as the burden in using the updated standards is anticipated to be the same as using the old standards. We believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 8.1 in favor of NCPDP SCRIPT 10.6 will result in significant costs. We also believe the same holds true for the standard updates for NCPDP Formulary and Benefits 3.0. The backward compatible Formulary and Benefits 3.0 imposes no new requirements on entities that are already e-prescribing. Entities that choose to use Formulary and Benefits 3.0 would be doing so voluntarily.

The proposed removal of the LTC exception to the NCPDP SCRIPT standard would impose a small burden on the LTC industry. LTC entities who use and developed proprietary solutions may need to invest in software programming updates if they had not already incorporated the Part D e-prescribing standards in their solutions. It is reasonable to assume that a small number of proprietary solutions would have to modify their software in order to adhere to the adopted e-prescribing standards. Other cost may be incurred though staff training on the use of the e-prescribing standards and the use of an e-prescribing solution if adopted by a LTC facility. Additional training cost may involve prescribers and dispensers learning the new workflows that an electronic prescription may or may not require.

I. Alternatives Considered

This proposed rule contains a range of policies, including some provisions

related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

J. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of the proposed changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; creating a separate payment for post-discharge transitional care management services in the 30 days after a beneficiary has been discharged from an inpatient hospital admission, from outpatient observation services and partial hospitalization program, from a SNF, or from a CMHC; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS for certain radiation therapy services; capital interest rate assumptions; multiple procedure payment reduction for ophthalmology and cardiovascular diagnostic tests; and revisions to payment for Part B drugs will have a positive impact and improve the quality and value of care furnished to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 85, the CY 2012 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $105.18 which means that in CY 2012 a beneficiary would be responsible for 20 percent of this amount, or $21.04. Based on this proposed rule, using the current (CY 2012) CF of 34.0376, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 85, is $106.31, which means that, in CY 2013, the proposed beneficiary coinsurance for this service would be $21.26

K. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 93 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this proposed rule. This estimate includes the estimated FY 2012 cash benefit impact associated with certain Affordable Care Act and MCTRJCA provisions, and the CY 2013 incurred benefit impact associated with the estimated CY 2013 PFS conversion factor update based on the Mid-Session Review of the FY 2013 President's Budget baseline.

TABLE 93—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2013 Annualized Monetized Transfers	Estimated decrease in expenditures of $23.5 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2013 Annualized Monetized Transfers	Estimated increase in payment of 162 millions.
From Whom To Whom?	Federal Government to eligible professionals participated in (Physician Quality Reporting System (PQRS).

TABLE 94—ACCOUNTING STATEMENT:
CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

[$ In Millions]

Category	Benefit
Qualitative (unquantified) benefits of fraud, waste, and abuse prevented, and of improved quality of services to patients improved quality of services to patients.	No precise estimate available.
Category	**Cost**
CY 2013 Annualized monetized costs of beneficiary travel time	$9.37 millions.
Category	**Transfer**
CY 2013 Annualized Monetized Transfers of beneficiary cost coinsurance.	$10 millions.
From Whom To Whom?	Beneficiaries to Federal Government.
Category	**Transfer**
CY 2013 Medicare face-to-face visit and G-code payments	$16.2 millions.
From Whom To Whom?	Federal Government to DME providers.

L. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial ''Regulatory Flexibility Analysis.'' The previous analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO). Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapters 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, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

2. Section 410.32 is amended by—

A. Revising paragraphs (b)(2)(iii) introductory text, (d)(2)(i), and (e).

B. Redesignating paragraphs (c)(2) and (c)(3) as paragraphs (c)(3) and (c)(4), respectively.

C. Adding new paragraph (c)(2)

The revisions and addition read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(2) * * *

(iii) Diagnostic psychological and neuropsychological testing services when—

* * * * *

(c) * * *

(2) These services are ordered by a physician as provided in (a) or by a nonphysician practitioner as provided in (a)(2) of this section.

(d) * * *

(2) * * *

(i) *Ordering the service.* The physician or (qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

* * * * *

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

§ 410.37 [Amended]

3. Amend § 410.37 by—

A. Revising paragraph (a)(1)(iii) by removing the phrase ''In the case of an individual at high risk for colorectal cancer,''.

B. Removing paragraph (g)(1).

C. Redesignating paragraphs (g)(2) through (g)(4) as paragraph (g)(1) through (g)(3), respectively.

D. In newly redesignated paragraph (g)(1), removing the reference ''(g)(4)'' and adding in its place the reference ''(g)(3)''.

4. Section 410.38 is amended by revising paragraph (g) to read as follows:

§ 410.38 Durable medical equipment: Scope and conditions.

* * * * *

(g)(1) *Items requiring a written order.* As a condition of payment, Specified Covered Items (as described in paragraph (g)(2) of this section) require a written order that meets the requirements in paragraphs (g)(3) and (4) of this section before delivery of the item.

(2) *Specified covered items.* (i) Specified Covered Items are items of durable medical equipment that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A list of these items is updated annually in the **Federal Register**.

(ii) The list of Specified Covered Items includes the following:

(A) Any item described by a *Healthcare Common Procedure Coding System (HCPCS)* code for the following types of durable medical equipment:

(*1*) Transcutaneous electrical nerve stimulation (TENS) unit.

(*2*) Rollabout chair.

(*3*) Wheelchair accessories.

(*4*) Oxygen and respiratory equipment.

(*5*) Hospital beds and accessories.

(*6*) Traction-cervical.

(B) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling at or greater than $1,000.

(C) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

(iii) The list of specific covered items excludes the following:

(A) Any item that is no longer covered by Medicare.

(B) Any HCPCS code that is discontinued.

(3) *Face-to-face encounter requirements.* (i) For orders issued in accordance with paragraphs (g)(1) and (2) of this section, as a condition of payment for the Specified Covered Item, all of the following must occur:

(A) The physician must document and communicate to the DME supplier that the physician or a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the beneficiary on the date of the written order or during either of the following:

(*1*) Up to 90 days before the date of the written order.

(*2*) Within 30 days after the date that the order is written.

(B) During the face-to-face encounter the physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must conduct a needs assessment, evaluate, or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered.

(C) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination,

diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate).

(i) For purposes of paragraph (g), a face-to-face encounter does not include DME items and services furnished from an ''incident to'' service.

(ii) For purposes of paragraph (g), a face-to-face beneficiary encounter may occur via telehealth in accordance with all of the following:

(A) Section 1834(m) of the Act.

(B)(*1*) Medicare telehealth regulations in § 410.78 and § 414.65 of this chapter; and

(*2*) Subject to the list of payable Medicare telehealth services established by the applicable PFS.

(4) *Written order issuance requirements.* Written orders issued in accordance with paragraphs (g)(1) and (2) of this section must include all of the following:

(i) Beneficiary's name.

(ii) Item of DME ordered.

(iii) Prescribing practitioner NPI.

(iv) Signature of the prescribing practitioner.

(v) The date of the order.

(vi) The beneficiary's diagnosis.

(vii) Necessary proper usage instructions, as applicable.

(5) *Supplier's order and documentation requirements.* (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with § 424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

5. Section 410.40 is amended by—

A. In paragraph (c)(3)(ii), the word ''fro'' is revised to read ''from.''

B. Redesignating paragraph (d)(2) as (d)(2)(i).

C. Adding paragraph (d)(2)(ii).

The addition reads as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(d) * * *

(2) * * *

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed physician certification statement does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

6. Section 410.59 is amended by adding paragraph (a)(4) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

7. Section 410.60 is amended by adding paragraph (a)(4) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

8. Section 410.61 is amended by revising paragraph (c) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals that are consistent with the patient function reporting on claims for services.

* * * * *

9. Section 410.62 is amended by adding paragraph (a)(4) to read as follows:

§ 410.62 Outpatient speech-language-pathology services: Conditions and exclusions.

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

10. Section 410.63 is amended by adding paragraph (a)(1)(viii) to read as follows:

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

* * *

(a) * * *

(1) * * *

(viii) Persons diagnosed with diabetes mellitus.

* * * * *

11. Section 410.69 is amended by adding the definition ''Anesthesia and related care'' to paragraph (b) in alphabetical order to read as follows:

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

* * * * *

(b) * * *

Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished.

* * * * *

12. Section 410.78 is amending by revising the introductory text of paragraph (b) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, and behavioral counseling for obesity furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

13. Section 410.105 is amended by—

A. Revising paragraph (c)(1)(ii).

B. Adding new paragraph (d).

The revision and addition read as follows:

§ 410.105 Requirement for coverage of CORF services.

* * * * *

(c) * * *

(1) * * *

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals that are consistent with the patient function reporting on the claims for services.

* * * * *

(d) Claims submitted for physical therapy, occupational therapy or speech-language-pathology services, contain prescribed information on patient functional limitations.

14. Section 410.160 is amended by—

A. Redesignating paragraphs (b)(8) through (b)(13) as paragraphs (b)(9) through (b)(14).

B. Adding new paragraph (b)(8).

The addition reads as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(8) Beginning January 1, 2011, a surgical service furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal screening test. A surgical service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal screening test means—a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37 of this part.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

15. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

16. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, and behavioral counseling for obesity furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Emergency department or initial inpatient telehealth consultations.* The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

17. Section 414.90 is amended by—

A. In paragraph (b), revising the definitions ''Group practice'' and ''Qualified registry.''

B. Removing the term ''Qualified electronic health record product''.

C. Adding the definitions ''Administrative claims,'' ''Direct electronic health record (EHR) product,'' ''Electronic health record (EHR) data submission vendor product,'' and ''Group practice reporting option (GPRO) web-interface'' in alphabetical order.

D. Revising paragraphs (c) and (d).

E. Redesignating paragraphs (e), (f), (g), (h), (i), and (j) as paragraphs (f), (g), (i), (j), (k), and (l), respectively.

F. Adding new paragraphs (e) and (h).

G. Revising newly designated paragraphs (f), (g), and (k).

The revisions and additions read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on the proposed PQRS quality measures. Under this reporting mechanism, CMS determines which measures an eligible professional or group practice reports.

Direct electronic health record (EHR) product means an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS.

Electronic health record (EHR) data submission vendor product means an electronic health record vendor's product or version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice.

* * * * *

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web-interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on Physician Quality Reporting System quality measures.

* * * * *

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the Physician Quality Reporting System qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide Physician Quality Reporting

System data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the following year.

* * * * *

(c) *Incentive payments.* For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if—

(1) There are any quality measures that have been established under the Physician Quality Reporting System that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i of this section for the group practice) to the Secretary data on such quality measures in accordance with the Physician Quality Reporting System for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

(i) For 2007 and 2008, 1.5 percent.

(ii) For 2009 and 2010, 2.0 percent.

(iii) For 2011, 1.0 percent.

(iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph—

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Physician Quality Reporting System to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the Physician Quality Reporting System group practice reporting option, the eligible professional cannot individually qualify for a Physician Quality Reporting System incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(d) *Additional incentive payment.* Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(i) and (ii) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d)(1) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program (as defined in paragraph (b) of this section) that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program (as defined in paragraph (b) of this section) for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment (as defined in paragraph (b) of this section) for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(2)(ii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Payment Adjustments.* For 2015 and subsequent years, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection.

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent; and

(ii) For 2016 and each subsequent year, 98 percent.

(2) [Reserved]

(f) *Use of consensus-based quality measures.* For measures selected for inclusion in the Physician Quality Reporting System quality measure set, CMS will use consensus-based quality measures that meet one of the following criteria:

(1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act.

(2) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and

practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(3) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Requirements for the incentive payments.* In order to qualify to earn a Physician Quality Reporting System incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, (or in the case of a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (g)(1) of this section and using one of the reporting mechanisms specified in paragraph (g)(2) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual Physician Quality Reporting System quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of Physician Quality Reporting System measures groups by eligible professionals.

(2) *Reporting mechanisms.* For program year 2011 and subsequent program years, an eligible professional who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS in one of the following manners:

(i) *Claims.* Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Web-interface.* For a group practices defined in paragraph (b) of this section, reporting individual Physician Quality Reporting System quality measures to CMS using a CMS web-interface in the form and manner and by the deadline specified by CMS.

(3) Although an eligible professional may attempt to qualify for the Physician Quality Reporting System incentive payment by reporting on both individual Physician Quality Reporting System quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one Physician Quality Reporting System incentive payment per TIN/NPI combination for a program year.

(h) *Requirements for the payment adjustments.* In order to satisfy the requirements for the Physician Quality Reporting System payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination (or in the case of a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section and using one of the reporting mechanisms specified in paragraph (h)(2) of this section.

(1) For purposes of this paragraph, the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls two years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1–December 31 that fall two years prior to the year in which the payment adjustment is applied, is also available.

(ii) [Reserved]

(2) An eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System measures or Physician Quality Reporting System measures groups identified by CMS using one of the following reporting mechanisms:

(i) *Claims.* Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) Medicare Part B claims may not be reprocessed or reopened for the sole purpose or reporting on individual

Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) *Qualified registry.* Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *GPRO web-interface.* For a group practices defined in paragraph (b) of this section that are comprised of 25 or more eligible professionals, reporting individual Physician Quality Reporting System quality measures to CMS using a CMS web-interface in the form and manner and by the deadline specified by CMS.

(vi) *Administrative claims.* For the 2015 and 2016 payment adjustments, reporting certain administrative claims individual Physician Quality Reporting System quality measures during the applicable reporting period. Eligible professionals and (or in the case of a group practice under paragraph (i) of this section) that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Register to participate in the Physician Quality Reporting System using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional or group practice has performed services applicable to certain individual Physician Quality Reporting System quality measures.

(3) Although an eligible professional or group practice may attempt to meet the criteria for satisfactory reporting for the Physician Quality Reporting System payment adjustment by reporting on individual Physician Quality Reporting System quality measures or measures groups using more than one reporting mechanism (as specified in paragraph (h)(2) of this section), the eligible professional or group practice must satisfy the criteria for satisfactory reporting for the Physician Quality Reporting System payment adjustment under one reporting mechanism per TIN/NPI combination for a program year.

(i) *Requirements for group practices.* Under the Physician Quality Reporting System, a group practice (as defined in paragraph (b) of this section) must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option.

(2) Be selected by CMS to participate in the Physician Quality Reporting System group practice reporting option.

(3) Report measures in the form and manner specified by CMS.

(4) Meet other requirements for satisfactory reporting specified by CMS.

(5) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the Physician Quality Reporting System group practice reporting option for a program year, then for that program year the eligible professional must participate in the Physician Quality Reporting System via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System as part of a group practice (as identified by the TIN) that is not selected to participate in the Physician Quality Reporting System group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

18. Section 414.92 is amended by—

A. Revising paragraphs (c)(2)(ii)(A)(*5*) and (c)(2)(ii)(A)(*6*).

B. Adding paragraph (f)(2)(i)(A) and reserving paragraph (f)(2)(i)(B).

C. Redesignating paragraph (g) as paragraph (h), and adding new paragraph (g).

The revision and addition reads as follows:

§ 414.92 Electronic Prescribing Incentive Program.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(A) * * *

(*5*) Eligible professionals who achieve meaningful use during the respective 6- or 12-month payment adjustment reporting period.

(*6*) Eligible professionals who have registered to participate in the EHR Incentive Program and adopted Certified EHR Technology prior to application of the respective payment adjustment.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure.

(B) [Reserved]

Informal review. Eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (e) of this section, group practices) did not meet the requirements for the 2013 incentive or the 2013 and 2014 payment adjustments.

(1) To request an informal review for the 2013 incentive, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) To request an informal review for the 2013 and 2014 payment adjustments, an eligible professional or group practices must submit a request to CMS by January 31 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(3) CMS will provide a written response of CMS' determination within 90 days of the receipt of the request.

(i) All decisions based on the informal review are final.

(ii) There is no further review or appeal.

* * * * *

19. Section 414.610 is amended by revising paragraphs (c)(1)(ii), (c)(5)(ii), and (h) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2012, ambulance services originating in—

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section; and

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2012, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2012.

20. Section 414.904 is amended by revising paragraphs (d)(3)(ii), (d)(3)(iii) and (d)(3)(iv).

B. The revisions read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(3) * * *

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not a critical or medically necessary drug identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

* * * * *

21. Subpart N is added to Part 414 to read as follows:

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

Sec.

414.1200 Basis and scope.
414.1205 Definitions.
414.1210 Application of the value-based payment modifier.
414.1215 Performance and payment adjustment periods for the value-based payment modifier.
414.1220 Reporting mechanisms for the value-based payment modifier under the physician fee schedule.
414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.
414.1230 Additional measures for groups of physicians.
414.1235 Cost measures.
414.1240 Attribution for quality of care and cost measures.
414.1245 Scoring methods for the value-based payment modifier.
414.1250 Benchmarks for quality of care measures.
414.1255 Benchmarks for cost measures.
414.1260 Composite scores.
414.1265 Reliability of measures.
414.1270 Payment adjustments.
414.1275 Payment modifier scoring methodology.
414.1280 Limitation of review.
414.1285 Inquiry process.

Subpart N—Value-Based Payment Modifier Under the Physician Fee Schedule

§ 414.1200 Basis and scope.

(a) *Basis.* This part/section implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians under the Medicare physician fee schedule based on the quality of care furnished compared to cost during a performance period.

(b) *Scope.* This subpart sets forth the following:

(1) The application of the value-based payment modifier.

(2) Performance and payment adjustment periods.

(3) Reporting mechanisms for the value-based payment modifier.

(4) Alignment of PQRS quality of care measures with the quality composite of the value-based payment modifier.

(5) Additional measures for groups of physicians.

(6) Cost measures.

(7) Attribution for quality of care and cost measures.

(8) Scoring methods for the value-based payment modifier.

(9) Benchmarks for quality of care measures.

(10) Benchmarks for cost measures.

(11) Composite scores.

(12) Reliability of measures.

(13) Payment adjustments.

(14) Payment modifier scoring methodology.

(15) Limitation of review.

(16) Inquiry process.

§ 414.1205 Definitions.

As used in this section, unless otherwise indicated—

Accountable care organization (ACO) has the same meaning given this term under § 425.20 of this chapter.

Critical access hospital has the same meaning given this term under § 400.202 of this chapter.

Electronic health record (EHR) has the same meaning given this term under § 414.92 of this chapter.

Eligible professional has the same meaning given this term under section1848(k)(5)(B) of the Act.

Federally Qualified Health Center has the same meaning given this term under § 405.2401(b) of this chapter.

Group of physicians means a single Tax Identification Number (TIN) with 2

or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN, as determined at the time the group of physicians is selected to participate under the Physician Quality Reporting System GPRO.

Performance rate mean the calculated rate for each quality or cost measure such as the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

Physician has the same meaning given this term under section 1861(r) of the Act.

Physician Fee Schedule has the same meaning given this term under part 410 of this chapter.

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Risk score means the beneficiary risk score derived from the CMS Hierarchical Condition Categories (HCC) model.

Taxpayer Identification Number (TIN) has the same meaning given this term under § 425.20 of this chapter.

Value-based payment modifier means the percentage by which amounts paid to a physician or group of physicians under the physician fee schedule are adjusted.

Value-based payment modifier satisfactory reporting criteria means the criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures for the 2013 and 2014 incentive or the criteria for satisfactory reporting using the Physician Quality Reporting System administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment.

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable to the items and services furnished under the Medicare Part B physician fee schedule by physicians in groups of physicians with 25 or more eligible professionals starting on January 1, 2015.

(b) *Exceptions:*

(1) Groups of physicians with 25 or more eligible professionals that are participating in the Medicare Shared Savings Program or the Pioneer ACO program.

(2) [Reserved]

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

(a) The performance period is calendar year 2013 for payment adjustments to be made in the calendar year 2015 payment adjustment period.

(b) The performance period is calendar year 2014 for payment adjustments to be made in the calendar year 2016 payment adjustment period.

§ 414.1220 Reporting mechanisms for the value-based payment modifier under the physician fee schedule.

Groups of physicians may submit data on quality of care measures as specified under the Physician Quality Reporting System and in § 414.90(g).

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which groups of physicians are eligible to report under the Physician Quality Reporting System starting in 2013 are used to calculate the value-based payment modifier program to the extent the group of physicians submits data on such measures.

§ 414.1230 Additional measures for groups of physicians.

The value-based payment modifier includes the following additional quality measures for all groups of physicians:

(a) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes. The rate of potentially preventable hospital admissions for diabetes is a composite measure of uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes.

(b) A composite rates of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia.

(c) Rates of an all-cause hospital readmissions measure.

(d) A 30-day post-discharge visit measure.

§ 414.1235 Cost measures.

Costs for groups of physicians are assessed based on the following five cost measures:

(a) Total per capita costs for all attributed beneficiaries; and

(b) Total per capita costs for all attributed beneficiaries with diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure.

(c) Total per capita costs include all payments made under Medicare Part A and Part B.

(1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for each cost measure; that is—

(i) Total per capita costs; and

(ii) Total per capita costs for beneficiaries with the following conditions: Coronary artery disease, COPD, diabetes, and heart failure.

§ 414.1240 Attribution for quality of care and cost measures.

Beneficiaries are attributed to groups of physicians using the method specified under the Physician Quality Reporting System.

§ 414.1245 Scoring methods for the value-based payment modifier.

For each quality of care and cost measure, a standardized score is calculated for each group of physicians by dividing—

(1) The difference between their performance rate and the benchmark, by

(2) The measure's standard deviation.

§ 414.1250 Benchmarks for quality of care measures.

The benchmark for each quality of care measure is the national mean for that measure's performance rate during the performance period. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of cases used to calculate the group of physician's performance rate.

§ 414.1255 Benchmarks for cost measures.

The benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of cases used to calculate the group of physician's performance rate.

§ 414.1260 Composite scores.

(a)(1) The standardized score for each quality of care measure is classified into one of the following equally weighted domains to determine the quality composite:

(i) Patient safety.

(ii) Patient experience.

(iii) Care coordination.

(iv) Clinical care.

(v) Population/community health.
(vi) Efficiency.
(2) If a domain includes no measure or does not reach the minimum case size in § 414.1265, the remaining domains are equally weighted to form the quality of care composite.
(b)(1) The standardized score for each cost measure is grouped into two separate and equally weighted domains to determine the cost composite:
(i) Total per capita costs for all attributed beneficiaries (one measures); and
(ii) Total per capita costs for all attributed beneficiaries with specific conditions: diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure (four measures).
(2) Measures within each domain are equally weighted.

§ 414.1265 Reliability of measures.

To calculate a composite score for a quality or cost measure based on claims, a group of physicians must have 20 or more cases for that measure.
(a) Where a group of physicians has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.
(b) Where a reliable quality of care composite or cost composite cannot be calculated, payments are not adjusted.

§ 414.1270 Payment adjustments.

(a) *Downward payment adjustments.* For a group of physicians with 25 or more eligible professionals that:
(1) Does not meet the value-based payment modifier satisfactory reporting criteria, payments for items and services under the physician fee schedule will be adjusted downward by 1.0 percent.
(2) Does meet the value-based payment modifier satisfactory reporting criteria, elects that their value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs), payments for items and services under the physician fee schedule are adjusted downward by up to 1.0 percent as specified in § 414.1275.
(b) *Upward payment adjustments.* If a group of physicians with 25 or more eligible professionals does meet the value-based payment modifier satisfactory reporting criteria and elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under subsection (a) above and applied as specified in § 414.1275.

§ 414.1275 Payment modifier scoring methodology.

(a) The value-based payment modifier amount for a group of physicians that elects the quality-tiering approach is based upon a comparison of the composite of quality of care measures and a composite of cost measures.
(b) Groups of physicians' quality composite and cost composite are classified into high, average, and low categories based on whether the composites are statistically above, not different from, or below the mean composite scores.
(c) The following value-based payment modifier amounts apply:

VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR GROUPS OF PHYSICIANS REQUESTING THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	*+2.0x	*+1.0x	+0.0%
Average quality	*+1.0x	+0.0%	−0.5%
Low quality	+0.0%	−0.5%	−1.0%

*Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures through the GPRO using the web-interface, claims, registries, or EHRs, and average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

(d) Groups of physicians that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and that satisfactorily report data on quality measures through the Physician Quality Reporting System GPRO using the web-interface, claims, registries, or EHRs reporting mechanisms, receive a greater upward payment adjustment as follows:
(1) Groups of physicians classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x) and
(2) Groups of physicians classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

§ 414.1280 Limitation of review.

(a) There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of all of the following:
(1) The establishment of the value-based payment modifier.
(2) The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care.
(3) The evaluation of costs composite, including establishment of appropriate measures of costs.
(4) The dates of implementation of the value-based payment modifier.
(5) The specification of the initial performance period and any other performance period.
(6) The application of the value-based payment modifier.
(7) The determination of costs.

§ 414.1285 Inquiry process.

After the dissemination of the annual Physician Feedback reports, a group of physicians may contact CMS to inquire about its report and the calculation of the value-based payment modifier.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

22. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 415.130 [Amended]

23. In § 415.130(d)(1) and (d)(2), remove the reference to ''December 31, 2011'' and add in its place the reference to ''June 30, 2012.''

PART 421—MEDICARE CONTRACTING

24. The authority citation for part 421 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart F—[Removed and Reserved]

25. Subpart F is removed and reserved.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

26. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social

Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

27. Section 423.160 is amended by—

A. Revising paragraphs (a)(3)(iv), (b)(1)(ii), and (b)(2)(ii) introductory text.

B. Adding paragraphs (b)(1)(iii), (b)(2)(iii), (b)(5)(i), and (b)(5)(ii).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(3) * * *

(iv) Until November 1, 2013, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. After January 1, 2012, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser must utilize the NCPCP SCRIPT.

* * * * *

(b) * * *

(1) * * *

(ii) Before November 1, 2013 the standards specified in paragraphs (b)(2)(ii) and (b)(3) of this section.

(iii) On or after November 1, 2013, the standards specified in paragraphs (b)(2)(ii) and (b)(3) through (b)(6) of this section.

(2) * * *

(ii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

* * * * *

(iii) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 10 release 6 approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription related information between prescribers and dispensers.

* * * * *

(5) * * *

(i) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 3.0), January 2011(incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(ii) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors; or The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 3.0), January 2011 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

* * * * *

28. Subpart F, consisting of § 421.500 through § 421.505 is removed and reserved.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

29. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

30. Section 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) Results of claims based measures. Quality measures reported using the GPRO web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

31. Section 425.504 is amended by adding paragraph (b) to read as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.

* * * * *

(b) *Physician Quality Reporting System payment adjustment.*

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under Subpart F of this part during the reporting period for a year, as defined in paragraph (b)(6) of this section, according to the method of submission established by CMS under the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment, each ACO supplier/provider who is an eligible professional, will receive a payment adjustment, as described in paragraph (b)(5) of this section.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program.

(5) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act.

(i) The applicable percent for 2015 is 98.5 percent.

(ii) The applicable percent for 2016 and subsequent years is 98.0 percent.

(6) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

33. Section 486.106 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in § 410.32(a) of this chapter or by a nonphysician practitioner as provided in § 410.32(a)(2) and records are properly preserved.

(a) *Standard—referral by a physician or nonphysician practitioners.* Portable X-ray examinations are performed only on the order of a physician licensed to practice in the State or by a nonphysician practitioner acting within the scope of State law. Such nonphysician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

(1) The portable X-ray test was ordered by a licensed physician or a nonphysician practitioner acting within the State scope of law; and

(2) Such physician or nonphysician practitioner's written, signed order specifies the reason a portable X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

34. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

35. Section 495.8 is amended by revising paragraph (a)(2)(v) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(v) *Exception for Medicare EPs for PY 2012 and 2013—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–16814 Filed 7–6–12; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 476, 478, 480, and 495

[CMS–1589–P]

RIN 0938–AR10

Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations

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 2013 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, we are proposing updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We also are proposing revisions to the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program, and the various regulations governing Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical changes.

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 September 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1589–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–1589–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–1589–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.

Submission of comments on paperwork requirements: You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and new technology APCs.

Jennifer Bean, (410) 786–4827, for issues related to the Hospital Outpatient Quality Reporting Program.

Anita Bhatia, (410) 786–7236, for issues related to the ASCQR Program.

Douglas Brown, (410) 786–0028, for issues related to Electronic Health Record Incentive Program Electronic Reporting Pilot.

Carrie Bullock, (401) 786–0378, for issues related to device-dependent APCs, blood products, and no cost/full credit and partial credit devices.

Erick Chuang, (410) 786–1816, for issues related to OPPS APC weights, mean calculation, copayments, wage index, outlier payments, and rural hospital payments.

Caroline Gallaher, (410) 786–8705, for issues related to Inpatient Rehabilitation Facilities Quality Reporting Program.

Alpha-Banu Huq, (410) 786–8687, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, and packaged items/services.

Twi Jackson, (410) 786–1159, for issues related to hospital outpatient visits, extended assessment composite APC, and inpatient-only procedures.

Thomas Kessler, (410) 786–1991, for issues related to QIO regulations.

Marina Kushnirova, (410) 786–2682, for issues related to OPPS status indicators and comment indicators.

Barry Levi, (410) 786–4529, for issues related to OPPS pass-through devices, brachytherapy sources, intraoperative radiation therapy (IORT), brachytherapy composite APC, multiple imaging composite APCs, cardiac resynchronization therapy composite, and cardiac electrophysiologic evaluation and ablation composite APC.

Jana Lindquist, (410) 786–4533, for issues related to partial hospitalization and community mental health center issues.

Ann Marshall, (410) 786–3059, for issues related to OPPS supervision, proton beam therapy, and the Hospital Outpatient Payment (HOP) Panel.

John McInnes, (410) 786–0378, for issues related to new technology intraocular lenses (NTIOLs).

Char Thompson, (410) 786–2300, for issues related to OPPS CCRs and ambulatory surgical center (ASC) payments.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgery center payments not previously identified.

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 proposed rule, all of the Addenda will 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 will be 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*. Readers who experience any problems accessing any of the Addenda

that are posted on the CMS Web site identified above should contact Charles Braver at (410) 786–0378.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
APC Ambulatory Payment Classification
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
CAP Competitive Acquisition Program
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter associated urinary tract infection
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Public Law 109–171
DSH Disproportionate share hospital
EACH Essential access community hospital
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
ESRD End-stage renal disease
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
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HEU Highly enriched uranium
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5)
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD Implantable cardioverter defibrillator
ICU Intensive care unit
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IOM Institute of Medicine
IORT Intraoperative radiation treatment
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRF–PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument
LDR Low dose rate
LTCH Long-term care hospital
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
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
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
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NQF National Quality Forum
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
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PCR Payment-to-cost ratio
PE Practice expense
PHP Partial hospitalization program
PHS Public Health Service [Act], Public Law 96–88
PPI Producer Price Index
PPS Prospective payment system
PPV Pneumococcal pneumonia
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
TOPs Transitional Outpatient Payments
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Executive Summary and Background

A. Executive Summary of This Proposed Rule

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 and ASCs beginning January 1, 2013. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and conversion factor for services payable under the OPPS. 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 to establishing payment rates for CY 2013, we are proposing updates and new requirements under the Hospital OQR Program, the ASCQR Program, and the IRF Quality Reporting Program. We also are proposing certain revisions to the electronic reporting pilot for the EHR Incentive Program and to the regulations governing the Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical corrections.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2013, we are proposing to increase payment rates under the OPPS by an OPD fee schedule increase factor of 2.1 percent. This increase is based on the projected hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage points, and minus a 0.1 percentage point adjustment required by the Affordable Care Act. Under this proposal, we estimate that total payments, including beneficiary cost-sharing for CY 2013 to the more than 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), would be approximately $48.1 billion, an increase of approximately $4.6 billion compared to CY 2012 payments, or $700 million excluding our estimated changes in enrollment, utilization, and case-mix.

We are proposing to continue implementing the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting ratio of 0.980 to the OPPS payments and copayments for all applicable services.

- *Geometric Mean-Based Relative Payment Weights:* CMS has discretion under the statute to set OPPS payments based upon either the estimated mean or median costs of services within an Ambulatory Payment Classification

(APC) group, the unit of payment. To improve our cost estimation, for CY 2013, we are proposing to use the geometric mean costs of services within an APC to determine the relative payment weights of services, rather than the median costs that we have used since the inception of the OPPS. Our analysis shows that the proposed change to means would have a limited payment impact on most providers, with a small number experiencing payment gain or loss based on their service-mix.

• *Rural Adjustment:* We are proposing to continue an adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This 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 2013, we are proposing to continue our policy to provide additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data. Based on those data, a proposed target PCR of 0.91 would be used to determine the CY 2013 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment amount associated with the cancer hospital payment adjustment would be the additional payment needed to result in a proposed PCR equal to 0.91 for each cancer hospital.

• *Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources:* The Administration has established an agenda to eliminate domestic reliance on reactors outside of the United States that produce highly enriched uranium (HEU), and to promote the conversion of all medical isotope production to non-HEU sources. We are proposing to exercise our statutory authority to make payment adjustments necessary to ensure equitable payments, to provide an adjustment for CY 2013 to cover the marginal cost of hospital conversion to use of non-HEU sources to obtain radioisotopes used in medical imaging. The adjustment would cover the marginal cost of radioisotopes produced from non-HEU sources over the costs of radioisotopes produced by HEU sources.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2013, we are proposing to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at the statutory default of average sales price (ASP) plus 6 percent.

• *Supervision of Hospital Outpatient Therapeutic Services:* We are clarifying the application of the supervision regulations to physical therapy, speech-language pathology, and occupational therapy services that are furnished in OPPS hospitals and critical access hospitals (CAHs). We are proposing to extend the enforcement instruction for CAHs and certain small rural hospitals for one final year through CY 2013.

• *Outpatient Status:* We are concerned about recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving observation services. In addition, hospitals continue to express concern about Medicare Part B rebilling policies when a hospital inpatient claim is denied because the admission was not medically necessary. We are providing an update on the Part A to Part B Rebilling Demonstration that is in effect for CY 2012 through CY 2014, which was designed to assist us in evaluating these issues. In addition, we are soliciting public comments on potential clarifications or changes to our policies regarding patient status that may be appropriate.

• *Ambulatory Surgical Center Payment Update:* For CY 2013, we are proposing to increase payment rates under the ASC payment system by an MFP-adjusted CPI–U update factor of 1.3 percent. This increase is based on a projected CPI–U update of 2.2 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.9 percent. Based on this update, we estimate that total ASC payments, including beneficiary cost-sharing, for CY 2013 would be approximately $4.103 billion, an increase of approximately $211 million compared to estimated CY 2012 payments.

• *New Technology Intraocular Lenses:* We are proposing significant revisions to the regulations governing payments for new technology intraocular lens (NTIOLs), specifically § 416.195(a)(2) and § 416.195(a)(4). We are proposing to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available IOLs. We are proposing to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are seeking public comment on our approach for future measure selection and development as well as proposing certain measures for future inclusion in the ASCQR Program measure set. For the CY 2015 payment determination and subsequent years payment determinations, we are proposing requirements regarding the dates for submission, payment, and completeness for claims-based measures. We also are proposing how the payment rates would be reduced for ASCs that fail to meet program requirements beginning in CY 2014 and are clarifying our policy on updating measures.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing no new measures for CY 2013. We also are proposing no new targeting criteria to select hospitals for validation of medical records. We are confirming the suspension of data collection for specific measures. We are proposing that the criteria we would consider when determining whether to retire measures for the Hospital Inpatient Quality Reporting (IQR) Program are applicable likewise to the Hospital OQR Program. We are proposing that measures adopted in future rulemaking are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace them. We are proposing changes to administrative forms used in the program. We are proposing to extend the deadline for submitting a notice of participation form and to enter structural measures data.

• *Electronic Health Record (EHR) Incentive Program:* For the EHR Incentive Program, we are proposing to extend the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs through 2013, exactly as finalized for 2012. Other changes to the Medicare and Medicaid EHR Incentive Programs are proposed in a Notice of Proposed Rulemaking published in the **Federal Register** on March 7, 2012.

• *Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP):* We are proposing to: (1) Adopt updates on a previously adopted measure for the IRF QRP that will affect annual prospective payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is

actively removed, suspended, or replaced; and (3) adopt policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

• *Revisions to the Quality Improvement Organization (QIO) Regulations:* We are proposing to revise the QIO program regulations to: (1) Give QIOs the authority to send and receive secure transmissions of electronic versions of medical information; (2) provide more detailed and improved procedures for QIOs when completing Medicare beneficiary complaint reviews and general quality of care reviews, including procedures related to a new alternative dispute resolution process called ''immediate advocacy''; (3) increase the information beneficiaries receive in response to QIO review activities; (4) convey to Medicare beneficiaries the right to authorize the release of confidential information by QIOs; and (5) make other technical changes that are designed to improve the regulations. The technical changes to the QIO regulations that we are proposing to improve the regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

3. Summary of Costs and Benefits

In sections XXII. and XXIII. 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 include the following:

a. Impacts of the OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 45 in section XXII. of this proposed rule displays the distributional impact to various groups of hospitals and for CMHCs of all the proposed OPPS changes for CY 2013 compared to all estimated OPPS payments in CY 2012. We estimate that the proposals in this proposed rule would result in a 2.1 percent overall increase in OPPS payments to providers. We estimate that the increase in OPPS expenditures, including beneficiary cost-sharing, would be approximately $700 million, not taking into account potential changes in enrollment, utilization, and case mix. Taking into account estimated spending changes that are attributable to these factors, we estimate an increase of approximately $4.6 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2013 compared to CY 2012 OPPS expenditures. We estimate that total OPPS payments, including beneficiary cost-sharing, would be $48.1 billion for CY 2013.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs furnish only partial hospitalization services. Continuing the provider-specific structure that we adopted for CY 2011 and basing payment fully on the data for the type of provider furnishing the service, we estimate a 4.4 percent decrease in CY 2013 payments to CMHCs relative to their CY 2012 payments. This effect is largely attributable to a decline in the relative payment weight for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) using the proposed geometric mean-based relative payment weights as opposed to median-based relative payment weights.

(2) Impacts of Basing APC Relative Weights on Geometric Mean Costs

We estimate that our proposal to base the APC relative payment weights on the geometric mean costs rather than the median costs of services within an APC would not significantly impact most providers. Payments to low volume urban hospitals and to hospitals for which disproportionate share hospital (DSH) data are not available would increase by an estimated 2.1 and 4.0 percent, respectively. The increase to hospitals without available DSH data is largely attributable to payment increases for partial hospitalization and group psychotherapy services furnished in the hospital. These hospitals are largely non-IPPS psychiatric hospitals. In contrast, payments to CMHCs would decrease by an estimated 6.9 percent due primarily to lower payments for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs).

(3) Impacts of the Updated Wage Indices

We estimate no significant impacts related to updating the wage indices and applying the frontier State wage index. Adjustments to the wage indices other than the frontier State wage adjustment would not significantly affect most hospitals. Overall, urban hospitals would experience no change from CY 2012 to CY 2013, and rural hospitals would experience payment decreases of approximately 0.2 percent. Urban hospitals in the New England and Pacific regions would experience the most significant payment changes with a decrease of 1.2 percent in New England and an increase of 1.6 percent in the Pacific region.

We estimate that all facilities and all hospitals would experience a combined increase of 0.1 percent due to the frontier State wage index, which is not budget neutral. The frontier State wage index would only affect hospitals in the West North Central and Mountain regions, with rural hospitals in those regions experiencing slightly greater percentage payment increases than urban hospitals in those regions.

(4) Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our payment proposals for hospitals that are eligible for the proposed rural adjustment or for the proposed cancer hospital payment adjustment. We are not proposing any change in policies for determining the rural and cancer hospital payment adjustments, and the proposed adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(5) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 2.1 percent to the conversion factor would mitigate the small negative impacts of the budget neutrality adjustments. Certain low volume hospitals and hospitals for which DSH data are not available would experience larger increases ranging from 4.1 percent to 8.3 percent. We estimate that rural and urban hospitals would experience similar increases of approximately 2 percent as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar increases.

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 percentage change in estimated total payments by specialty groups under the proposed CY 2013 payment rates compared to estimated CY 2012 payment rates range between −2 percent for respiratory system procedures, integumentary system procedures, and cardiovascular system procedures to 5 percent for nervous system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposals to significantly affect the number of

hospitals that do not receive a full annual payment update.

d. Impacts of the EHR Incentive Program Proposal

There are no changes from the 2012 OPPS/ASC final rule to the costs or impact for the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs.

e. Impacts of the ASCQR Program

We do not expect our proposals to significantly affect the number of ASCs that do not receive a full annual payment update beginning in CY 2014.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the 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; and most recently the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012.

Under the OPPS, we pay for hospital outpatient 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 hospital services that are furnished to inpatients who are entitled to Part A and have exhausted their Part A benefits, or who are not so entitled.

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 exercised the authority granted under the statute to also exclude from the OPPS those 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 MPFS; 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 composite rate; 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 and entities that are excluded from payment under the OPPS. These excluded entities include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance

with section 1814(b)(3) of the Act; CAHs; 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) 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), Formerly Named the Advisory Panel on Ambulatory Payment Classification Groups (APC 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, at that time named the APC Panel. This expert panel, which may be composed of up to 19 representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) subject to the OPPS, reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. 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). Since its initial chartering, the Secretary has renewed the Panel's charter five times: on November 1, 2002; on November 1, 2004; on November 21, 2006; on November 2, 2008 and November 12, 2010. 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 current charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add CAHs to its membership.

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/FACA/05_Advisory_PanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on February 27–29, 2012. 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 (previously known as the Packaging Subcommittee).

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 SIs 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 APCs to be assigned to 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 that the subcommittees continue at the August 2012 Panel meeting. We accepted this recommendation. All subcommittee recommendations are discussed and voted upon by the full Panel.

Discussions of the other recommendations made by the Panel at the February 2012 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 hospital OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://fido.gov/facadatabase/public.asp*.

F. Public Comments Received on the CY 2012 OPPS/ASC Final Rule With Comment Period

We received approximately 61 timely pieces of correspondence on the CY 2012 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 24, 2011 (76 FR 74122), some of which contained multiple comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment

indicator ''NI'' in Addendum B to that final rule with comment period. We will present summaries of those public comments on topics open to comment in the CY 2012 OPPS/ASC final rule with comment period and our responses to them under the appropriate headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative 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 the CY 2013 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2013, and before January 1, 2014 (CY 2013), using the same basic methodology that we described in the CY 2012 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 2013, we used approximately 141 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, 2011, and before January 1, 2012. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 141 million final action claims for services provided in hospital outpatient settings used to calculate the proposed CY 2013 OPPS payment rates, approximately 113 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 113 million claims, approximately 5 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 108 million claims, we created approximately 110 million single records, of which approximately 74 million were ''pseudo'' single or ''single session'' claims (created from approximately 28 million multiple procedure claims using the process we discuss later in this section). Approximately 959,000 claims were trimmed out on cost or units in excess of +/− 3 standard deviations from the geometric mean, yielding approximately 110 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 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. Ultimately, we were able to use for CY 2013 ratesetting some portion of approximately 95 percent of the CY 2011 claims containing services payable under the OPPS.

The proposed APC relative weights and payments for CY 2013 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 2011 that were processed before January 1, 2012. While we have historically based the payments on median hospital costs for services in the APC groups, we are proposing to establish the cost-based relative payment weights of the CY 2013 OPPS using geometric mean costs, as discussed in section II.A.2.f. of this proposed rule. Therefore, on the CMS Web site, along with Addenda A and B, we are providing a file that presents payment information for the proposed CY 2013 OPPS payments based on geometric mean costs compared to those based on median costs. Under the proposed 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 2013 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2013, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights would be 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 enabled us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74132 through 74134). In addition, for CY 2008, we increased packaging and created the first composite APCs, and continued those policies through CY 2012. 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 2012, and are proposing to continue this policy for CY 2013. We refer readers to section II.A.2.e. of this proposed rule for a discussion of the use of claims in modeling the costs for composite APCs.

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 2013 OPPS. This methodology enabled us to create, for this proposed rule, approximately 74 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of this proposed rule for further discussion), to add to the approximately 36 million ''natural'' single procedure claims. For this proposed rule, ''pseudo'' single procedure and ''single session'' procedure bills represented approximately 67 percent of all single procedure bills used for ratesetting purposes.

For CY 2013, we are proposing to bypass 480 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 2013, data available for the February 27, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2011 claims processed through September 30, 2011, and CY 2010 claims data processed through June 30, 2011, used to model the payment rates for CY 2012) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2013, we are proposing to continue to bypass all of the HCPCS codes on the CY 2012 OPPS bypass list, with the exception of HCPCS codes that we are proposing to be deleted for CY 2013, which are listed in Table 1 of this proposed rule. 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. We also are proposing to add to the bypass list for CY 2013 HCPCS codes not on the CY 2012 bypass list that, using either the CY 2012 final rule data (CY 2010 claims) or the February 27, 2012 Panel data (first 9 months of CY 2011 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2013 proposal to develop OPPS relative payment weights based on geometric mean costs, we are proposing that the median cost of packaging criterion instead be based on the geometric mean cost of packaging. The entire list proposed for CY 2013 (including the codes that remain on the bypass list from prior years) is open to public comment. 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 we are proposing to establish the CY 2013 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. The proposal to develop the CY 2013 OPPS relative payment weights based on geometric mean costs is discussed in greater detail in section II.A.2.f. of this proposed rule.

In response to comments to 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. We are proposing for CY 2013, based on the same rationale described for the CY 2012 OPPS/ASC final rule with comment period (76 FR 74133), to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2012 market basket increase of 1.90 percent to the prior non-rounded dollar threshold of $52.76 (76 FR 74133), we determined that the threshold remains for CY 2013 at $55 ($53.76 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2011 claims at $55 for a code to be considered for addition to the CY 2013 OPPS bypass list.

- The code is not a code for an unlisted service. Unlisted codes do not describe a specific service, and thus 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 CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2013 OPPS proposal. Some of these codes were identified by CMS medical advisors 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) and the CPT codes for additional hours of drug administration to the bypass list (73 FR 68513 and 71 FR 68117 through 68118).

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 2013. The list of bypass codes contains codes that were reported on claims for services in CY 2011 and, therefore, includes codes that were in effect in 2011 and used for billing but were deleted for CY 2012. We retained these deleted bypass codes on the proposed CY 2013 bypass list because these codes existed in CY 2011 and were covered OPD services in that period, and CY 2011 claims data are used to calculate CY 2013 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 were 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 2013 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 2013 bypass list because these codes were either deleted from the HCPCS before CY 2011 (and therefore were not covered OPD services in CY 2011) or were not separately payable codes under the proposed CY 2013 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these proposed deleted codes are ''overlap bypass'' codes.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2013 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
76880	Us exam, extremity.
86903	Blood typing, antigen screen.
92135	Ophth dx imaging post seg.
93231	Ecg monitor/record, 24 hrs.
93232	ECG monitor/report, 24 hrs.
93236	ECG monitor/report, 24 hrs.

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2013, we are proposing to continue to use the hospital-specific overall ancillary and departmental 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 2013 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 2011 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2010. For the CY 2013 OPPS proposed rates, we used the set of claims processed during CY 2011. 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 2011 (the year of the claims data we used to calculate the proposed CY 2013 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2011 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). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim, as detailed in the CY 2007 OPPS/ASC final rule with comment period, is the calculation of blood costs, as discussed in section II.A.2.d.(2) of this proposed rule and which has been our standard policy since the CY 2005 OPPS.

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 for hospitals that filed outpatient claims in CY 2011 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, in most cases, cost reports with cost reporting periods beginning in CY 2010. 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 2013 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 in this section of this proposed rule 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 2013.

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 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-fxsp0;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,'' public comments, and our responses, 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 order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, we believe that it is necessary to have a critical mass of cost reports filed with data in this cost center. In preparation for the CY 2013 OPPS/ASC proposed rule, we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center using cost reports in the December 31, 2011 quarter ending update of HCRIS, which was the latest upload of the cost report data that we could use for the CY 2013 proposed rule. We determined that 2,063 hospitals, out of approximately 3,800 hospitals, utilized the ''Implantable Devices Charged to Patients'' cost center, and we believe that this is a sufficient amount of data from which to generate a meaningful analysis. Therefore, we are proposing to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative weights for CY 2013. Table 2 below contains a list of APCs that had either a greater than or less than 3.0 percentage point change in cost when the ''Implantable Devices Charged to Patients'' cost center is used to create a distinct CCR compared to a CCR created from the combination of the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers as was used in the CY 2012 OPPS/ASC final rule with comment period.

TABLE 2—PERCENTAGE CHANGE IN APC COST WHEN THE ''IMPLANTABLE DEVICES CHARGED TO PATIENTS'' COST CENTER IS USED TO CREATE DISTINCT CCR

APC	APC descriptor	Percentage change in cost
0654	Level II Insertion/Replacem of Permanent Pacemaker	6.99
0315	Level II Implantation of Neurostimulator Generator	5.71
0227	Implantation of Drug Infusion Device	5.65
0386	Level II Prosthetic Urological Procedures	4.92
0107	Insertion of Cardioverter-Defibrillator Pulse Generat	4.89
0089	Insertion/Replace of Perm Pacemaker and Electrodes	4.71
0108	Insertion/Replace/Repair of Cardioverter-Defibr Sys	4.42
0039	Level I Implantation of Neurostimulator Generator	4.35
0655	Insert/Replac/Conv of a Perm Dual Cham Pacemaker	4.20
0680	Insertion of Patient Activated Event Recorders	3.77
0090	Level I Insertion/Replacem of Permanent Pacemaker	3.68
0318	Implanta of Neurostimulator Pulse Gen and Electrode	3.64
0106	Insert/Replac of Pacemaker Leads and/or Electrodes	3.10
0387	Level II Hysteroscopy	−3.16
0100	Cardiac Stress Tests	−3.20
0269	Level II Echocardiogram Without Contrast	−3.21
8002	Level I Extended Assess & Management Composite	−3.31
0101	Tilt Table Evaluation	−3.34
0142	Level I Small Intestine Endoscopy	−3.49
0084	Level I Electrophysiologic Procedures	−3.61
8000	Cardiac Electrophysiologic Eval and Ablation Compo	−3.69
0165	Level IV Urinary and Anal Procedures	−3.73
0270	Level III Echocardiogram Without Contrast	−3.73
0679	Level II Resuscitation and Cardioversion	−3.76

TABLE 2—PERCENTAGE CHANGE IN APC COST WHEN THE ''IMPLANTABLE DEVICES CHARGED TO PATIENTS'' COST CENTER IS USED TO CREATE DISTINCT CCR—Continued

APC	APC descriptor	Percentage change in cost
0174	Level IV Laparoscopy	−3.78
0659	Hyperbaric Oxygen	−4.01
0085	Level II Electrophysiologic Procedures	−4.15
0111	Blood Product Exchange	−4.27
0381	Single Allergy Tests	−5.10
0370	Multiple Allergy Tests	−7.46
0012	Level I Debridement & Destruction	−8.15
0251	Level II ENT Procedures	−8.46

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 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, MRI, 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 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 are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. However, because cost reports that were filed on the revised cost report Form CMS–2552–10 are not currently accessible in the HCRIS, we were unable to calculate distinct CCRs for CT scans, MRI, and cardiac catheterization using the new standard cost centers for these services. We believe that we will have cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 OPPS rulemaking.

We believe that improved cost report software, the incorporation of new standard and nonstandard cost centers, and the elimination of outdated requirements will improve the accuracy of the cost data contained in the electronic cost report data files and, therefore, the accuracy of our cost estimation processes for the OPPS relative weights. We will continue our standard practice of examining ways in which we can improve the accuracy of our cost estimation processes.

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 OPPS payment rates for CY 2013. The Hospital OPPS page on our 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. Our 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 2011 claims that were used to calculate the proposed payment rates for the CY 2013 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 most recently 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 this proposed rule, we are proposing to use geometric mean costs to calculate the proposed relative weights on which the proposed CY 2013 OPPS payment rates are based. While this proposal would change the cost metric on which the relative payments are based, the data process in general would remain the same, under the methodologies that we use to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this proposed rule to calculate the geometric mean costs we use to establish the proposed relative weights used in calculating the proposed OPPS payment rates for CY 2013 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that we are providing a file comparing the CY 2013 proposed payments under the geometric mean cost-based OPPS, relative to what they would be under a CY 2013 median-based OPPS. We are providing this file so that the public can provide meaningful comment on our proposal to base the CY 2013 OPPS relative payment weights on geometric mean costs. We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC geometric mean costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2011 hospital outpatient claims processed before January 1, 2012, to calculate the geometric mean costs of APCs that underpin the proposed relative weights for CY 2013. To begin the calculation of the proposed relative weights for CY 2013, we pulled all claims for outpatient services furnished in CY 2011 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 services 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 113 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, of which we use a subset for the limited number of services in these claims that are paid under the OPPS.

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 and comment on our Web site: *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 claims from all 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 nothing but influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost and, 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.

In the past several years, we have developed payment policy for nonpass-through separately paid drugs and biologicals based on a redistribution methodology that accounts for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This 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 are proposing to pay 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. Therefore, under this proposal, we would not redistribute the packaged cost. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our proposed policy to pay for separately paid drugs and biologicals in CY 2013.

We then removed line-items that were not paid during claim 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,'' ''V,'' or ''X'' 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 proposed to come off the inpatient list for CY 2012 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 2013, we are proposing to continue the policy we implemented for CY 2012 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2011) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2011) 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 2012 OPPS/ASC final rule with comment period (76 FR 74141) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. 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.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2013 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 follow below.) For CY 2013, we are proposing to continue our current policy of defining major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' ''V,'' or ''X;'' defining minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and classifying ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2013, we are proposing to continue assigning status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STVX-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 2013 as we have treated them since CY 2008. Specifically, we are proposing to continue 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.e. 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,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STVX-packaged'') where there was no code with status indicator ''S,'' ''T,'' ''V,'' or ''X'' 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,'' ''V,'' or ''X,'' 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,'' ''V,'' or ''X''). 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'' (''STVX-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'' (''STVX-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' ''V,'' or ''X'' 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 or clinical laboratory tests, 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'' (''STVX-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.

(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).

We also are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on our 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 2013 ''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. Where 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.e.(5) of this proposed rule, were met. Where 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 proposed CY 2013 OPPS payment would be 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'' (''STVX-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 2012 relative weight, 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 2012 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2012 relative 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, where 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 2012 relative weight, 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 2012 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2012 relative 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.

Where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STVX-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative weight for CY 2012 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 2012 relative weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STVX-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We favor status indicator ''Q2'' over ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2012 relative weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2011

relative weight, it would become 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, where they meet the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XII.A.1. 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 modifier (Modifier 50 (Bilateral procedure)) 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 this methodology for the purpose of creating pseudo single procedure claims for the CY 2013 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 referenced in section XIX. of this proposed rule and 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 3 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

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 2013 to the revenue codes that the I/OCE will package for CY 2013 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 proposed 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 to the CY 2010 proposed list of packaged revenue codes.

For CY 2013, as we did for CY 2012, we reviewed the changes to revenue codes that were effective during CY 2011 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2013. We believe that the charges reported under the revenue codes listed in Table 3 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2013, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS code under the revenue codes displayed in Table 3 below for purposes of calculating the geometric mean costs on which the proposed CY 2013 OPPS/ASC payment rates are based.

TABLE 3—PROPOSED CY 2013 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0275	Medical/Surgical Supplies and Devices; Pacemaker.
0276	Medical/Surgical Supplies and Devices; Intraocular Lens.
0278	Medical/Surgical Supplies and Devices; Other Implants.
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices.
0280	Oncology; General Classification.
0289	Oncology; Other Oncology.
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
0370	Anesthesia; General Classification.
0371	Anesthesia; Anesthesia Incident to Radiology.

TABLE 3—PROPOSED CY 2013 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0372	Anesthesia; Anesthesia Incident to Other DX Services.
0379	Anesthesia; Other Anesthesia.
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
0623	Medical Supplies—Extension of 027X, Surgical Dressings.
0624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
0630	Pharmacy—Extension of 025X; Reserved.
0631	Pharmacy—Extension of 025X; Single Source Drug.
0632	Pharmacy—Extension of 025X; Multiple Source Drug.
0633	Pharmacy—Extension of 025X; Restrictive Prescription.
0681	Trauma Response; Level I Trauma.
0682	Trauma Response; Level II Trauma.
0683	Trauma Response; Level III Trauma.
0684	Trauma Response; Level IV Trauma.
0689	Trauma Response; Other.
0700	Cast Room; General Classification.
0710	Recovery Room; General Classification.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty services; Observation Hours.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Inpatient Renal Dialysis; Other Donor.
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis-Outpatient or Home; Maintenance—100%.
0825	Hemodialysis-Outpatient or Home; Support Services.
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis.
0942	Other Therapeutic Services (also see 095X, an extension of 094X); Education/Training.
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
0948	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 on or after July 1, 2004, 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 fiscal intermediary or MAC was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative 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 2013 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 and final rule 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.

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 108 million claims were left. Using these approximately 108 million claims, we created approximately 110 million single and ''pseudo'' single procedure claims, of which we used slightly more than 110 million single bills (after trimming out approximately 959,000 claims as discussed in section II.A.1.a. of this

proposed rule) in the CY 2013 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 CY 2013 OPPS, we are proposing to calculate the APC relative weights using geometric mean costs, and therefore the following discussion of the two times rule and relative weight development refers to geometric means. For more detail about the CY 2013 OPPS/ASC proposal to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this proposed rule.

We are proposing to use these claims to calculate the proposed CY 2013 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, as part of the CY 2013 proposal to develop the OPPS relative payment weights based on geometric mean costs, we also are proposing to apply the 2 times rule based on geometric mean costs. For a detailed discussion of the CY 2013 proposal to develop the APC relative payment weights based on geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule.

We note that, for purposes of identifying significant HCPCS 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 100 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 CY 2013 proposal 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 system. 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. Section III. of this proposed rule includes a discussion of many of the HCPCS code assignment changes that resulted from examination of the geometric mean costs and for other reasons. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d. and II.A.2.e. and in section 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 calculation of single APC criteria-based geometric mean costs. Section II.A.2.e. of this proposed rule discusses the calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the geometric mean costs for partial hospitalization services.

(2) Recommendations of the Advisory Panel on Hospital Outpatient Payment Regarding Data Development

At the February 27–28, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel), we provided the Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2012 OPPS final rule median costs based on CY 2010 claims processed through June 30, 2011, to those based on CY 2011 OPPS/ASC final rule data (CY 2009 claims processed through June 30, 2010). The Data Subcommittee reviewed the fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

At the February 27–28, 2012 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation 1: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response to Recommendation 1: We are accepting this recommendation.

Recommendation 2: The Panel recommends that Kari S. Cornicelli, C.P.A., FHFMA, serve as acting chairperson for the winter 2012 meeting of the Data Subcommittee.

CMS Response to Recommendation 2: We are accepting this recommendation.

d. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

Device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

For CY 2013, we are proposing to use the standard methodology for calculating costs for device-dependent APCs that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74148 through 74151). This methodology utilizes claims data that generally represent the full cost of the required device and the most recent cost report data. Specifically, we are proposing to calculate the costs for device-dependent APCs for CY 2013 using only the subset of single procedure claims from CY 2011 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; do not contain the ''FB'' modifier signifying that the device was

furnished without cost to the provider, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code. We continue to believe the standard methodology for calculating costs for device-dependent APCs gives us the most appropriate costs for device-dependent APCs in which the hospital incurs the full cost of the device.

Table 4A below lists the APCs for which we are proposing to use our standard device-dependent APC ratesetting methodology for CY 2013. We refer readers to Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed payment rates for these device-dependent APCs for CY 2013.

TABLE 4A—PROPOSED CY 2013 DEVICE-DEPENDENT APCS

Proposed CY 2013 APC	Proposed CY 2013 status indicator	Proposed CY 2013 APC title
0039	S	Level I Implantation of Neurostimulator Generator.
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082	T	Coronary or Non-Coronary Atherectomy.
0083	T	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity.
0084	S	Level I Electrophysiologic Procedures.
0085	T	Level II Electrophysiologic Procedures.
0086	T	Level III Electrophysiologic Procedures.
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090	T	Insertion/Replacement of Pacemaker Pulse Generator.
0104	T	Transcatheter Placement of Intracoronary Stents.
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107	T	Insertion of Cardioverter-Defibrillator.
0108	T	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes.
0115	T	Cannula/Access Device Procedures.
0202	T	Level VII Female Reproductive Procedures.
0227	T	Implantation of Drug Infusion Device.
0229	T	Level II Endovascular Revascularization of the Lower Extremity.
0259	T	Level VII ENT Procedures.
0293	T	Level V Anterior Segment Eye Procedures.
0315	S	Level II Implantation of Neurostimulator Generator.
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode.
0319	T	Level III Endovascular Revascularization of the Lower Extremity.
0384	T	GI Procedures with Stents.
0385	S	Level I Prosthetic Urological Procedures.
0386	S	Level II Prosthetic Urological Procedures.
0425	T	Level II Arthroplasty or Implantation with Prosthesis.
0427	T	Level II Tube or Catheter Changes or Repositioning.
0622	T	Level II Vascular Access Procedures.
0623	T	Level III Vascular Access Procedures.
0648	T	Level IV Breast Surgery.
0652	T	Insertion of Intraperitoneal and Pleural Catheters.
0653	T	Vascular Reconstruction/Fistula Repair with Device.
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker.
0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674	T	Prostate Cryoablation.
0680	S	Insertion of Patient Activated Event Recorders.

(2) 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 2013, 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 would then 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 calculated the costs upon which the proposed CY 2013 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 note that we used geometric mean unit costs for each blood and blood product to calculate the proposed payment rates, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of this proposed rule.

We continue to believe the hospital-specific, blood-specific CCR methodology best 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 believe that continuing with this methodology in CY 2013 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 refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2013 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).

(3) Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

For the CY 2011 update, the AMA's CPT Editorial Panel created 16 new CPT codes in the Endovascular Revascularization section of the 2011 CPT codebook to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71841 through 71845), we discussed the process and methodology by which we assigned the CY 2011 endovascular revascularization CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the services. Specifically, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for 12 of the 16 new separately payable codes for CY 2011. Because the endovascular revascularization CPT codes were new for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. As shown in Table 7 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71844), many of the new endovascular revascularization CPT codes were previously reported using a combination of CY 2009 CPT codes. In order to simulate costs, we selected claims that we believe met the definition for each of the new endovascular revascularization CPT codes. Table 7 showed the criteria we applied to select a claim to be used in the calculation of the costs for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71842), we developed these criteria based on our clinicians' understanding of services that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described by the new CPT codes for CY 2011.

After determining the simulated costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 new codes, we assigned 9 CPT codes to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and 5 CPT codes to APC 0229 (Transcatheter Placement of Intravascular Shunts), and created new APC 0319 (Endovascular Revascularization of the Lower Extremity) for 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71845) displayed their final CY 2011 APC assignments and CPT costs. We noted that, because these CPT codes were new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as a new interim APC assignment for CY 2011 and subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74156), for CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. Because previous endovascular revascularization CPT codes were in existence prior to CY 2011 and assigned to designated APCs, we continued to use existing hospital outpatient claims and cost report data from established codes to simulate estimated costs for the endovascular revascularization CPT codes in determining the appropriate APC assignments for CY 2012, as we did for CY 2011. In the CY 2012 OPPS/ASC final rule with comment period, we also revised the title of APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity''; the title of APC 0229 from ''Transcatheter Placement of Intravascular Shunts and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and the title of APC 0319 from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity''.

Because the endovascular revascularization of the lower extremity CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, review of the procedures with significant claims data in APCs 0083, 0229, and 0319 shows no 2 times rule violation in these APCs. We believe that the endovascular revascularization CPT codes in APCs 0083, 0229, and 0319 continue to be appropriately placed based on clinical homogeneity and resource costs. Therefore, for CY 2013, we are proposing to continue to assign the endovascular revascularization CPT codes to APCs 0083, 0229, and 0319, as listed in Table 4B below.

TABLE 4B—PROPOSED APCS TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WOULD BE ASSIGNED FOR CY 2013

CY 2012 CPT Code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0229	T	0229
37222	Iliac revasc add-on	T	0083	T	0083
37223	Iliac revasc w/stent add-on	T	0083	T	0083
37224	Fem/popl revas w/tla	T	0083	T	0083
37225	Fem/popl revas w/ather	T	0229	T	0229
37226	Fem/popl revasc w/stent	T	0229	T	0229
37227	Fem/popl revasc stnt & ather	T	0319	T	0319
37228	Tib/per revasc w/tla	T	0083	T	0083
37229	Tib/per revasc w/ather	T	0229	T	0229
37230	Tib/per revasc w/stent	T	0229	T	0229
37231	Tib/per revasc stent & ather	T	0319	T	0319
37232	Tib/per revasc add-on	T	0083	T	0083
37233	Tib/per revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

(4) Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA's CPT Editorial Panel restructured the Cardiac Catheterization section of the CPT codebook so that combinations of services that were previously reported using multiple codes are now reported with one CPT code. This revision deleted several non-congenital cardiac catheterization-related CPT codes from the 93500 series and created new CPT codes in the 93400 series and in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71846 through 71849), along with the process by which we assigned the new CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the cardiac catheterization services described by the new CPT codes. As discussed in that final rule with comment period, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2011. Specifically, to estimate the hospital costs associated with the 20 new non-congenital cardiac catheterization-related CPT codes based on their CY 2011 descriptors, we used claims and cost report data from CY 2009. Because of the substantive coding changes associated with the new non-congenital cardiac catheterization-related CPT codes for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. We stated that many of the new CPT codes were previously reported using multiple CY 2009 CPT codes, and we provided a crosswalk of the new CY 2011 cardiac catheterization CPT codes mapped to the CY 2009 cardiac catheterization CPT codes in Table 11 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71849). Table 11 showed the criteria we applied to select a claim to be used in the calculation of the cost for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71847 through 71848), we developed these criteria based on our clinicians' understanding of services that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described in the new CPT codes. We used approximately 175,000 claims for the new non-congenital catheterization-related CPT codes, together with the single and ''pseudo'' single procedure claims for the remaining non-congenital catheterization-related CPT codes in APC 0080 (Diagnostic Cardiac Catheterization), to calculate CPT level costs and the cost for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 were new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B to that final rule with comment period to identify them as subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

For CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the new cardiac catheterization CPT codes. That is, we continued to use the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes by using the existing hospital outpatient claims and the cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. Specifically, we used the CY 2010 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2012 to determine the payment rates for the cardiac catheterization CPT codes. For CY 2012, we did not make any changes to the CY 2011 APC assignments of any of the codes assigned to APC 0080 because the claims data supported continuation of these APC assignments.

Because the cardiac catheterization CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, our analysis of the CY 2011 claims data available for this proposed rule shows no violation in the 2 times rule for the cardiac catheterization CPT codes because the lowest cost of a CPT code with significant claims data in APC 0080 is approximately $1,716 (for CPT code 93451), while the highest cost of a CPT code with significant claims data is approximately $3,308 (for CPT code 93461). We believe that the cardiac catheterization CPT codes continue to be appropriately placed in APC 0080 based on clinical homogeneity and resource costs. Therefore, for CY 2013, we are proposing to continue to assign the cardiac catheterization CPT codes to APC 0080 as listed below in Table 5.

TABLE 5—PROPOSED APCS TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES WOULD BE ASSIGNED FOR CY 2013

CY 2012 HCPCS code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&I hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&I hrt art/ventricle angio	T	0080	T	0080
93461	R&I hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynamic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93565	Inject l ventr/atrial angio	N	NA	N	NA
93566	Inject r ventr/atrial angio	N	NA	N	NA
93567	Inject suprvlv aortography	N	NA	N	NA
93568	Inject pulm art hrt cath	N	NA	N	NA

(5) Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)

For CY 2011, the AMA's CPT Editorial Panel established three new codes to describe computed tomography of the abdomen and pelvis. CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material), 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) were effective January 1, 2011. As shown in Table 6, for CY 2011, these services were paid in one of two methods under the hospital OPPS. They were either paid separately through a single APC or through a composite APC. We assigned CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), CPT code 74177 to APC 0283 (Computed Tomography With Contrast), and CPT code 74178 to APC 0333 (Computed Tomography Without Contrast Followed By Contrast). We also assigned CPT code 74176 to composite APC 8005 (CT and CTA Without Contrast Composite), and CPT codes 74177 and 74178 to composite 8006 (CT and CTA With Contrast Composite). We assigned the codes to status indicator ''Q3'' to indicate that the codes were eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other computed tomography procedures to the same patient on the same day.

Consistent with our longstanding policy for new codes, we assigned these codes to interim APCs for CY 2011, with comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period denoting that the codes were new with an interim APC assignment on which comments would be accepted. In accordance with our longstanding policy to provide codes to enable payment to be made for new services as soon as the code is effective, our interim APC assignments for each code were based on our understanding of the resources required to furnish the services and their clinical characteristics as defined in the code descriptors.

TABLE 6—CY 2011 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2011 CPT Code	CY 2011 short descriptor	CY 2011 SI	CY 2011 single code APC	CY 2011 single code APC payment rate	CY 2011 composite APC	CY 2011 composite APC payment rate
74176	Ct abd & pelvis	Q3	0332	$193.85	8005	$420.85
74177	Ct abd & pelv w/contrast	Q3	0283	299.81	8006	628.61
74178	Ct abd & pelv 1/< regns	Q3	0333	334.24	8006	628.61

As we described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74259), in general, stakeholders who provided comments on the interim assignments of these codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes was to assign these procedures to APCs that recognize that each of the new codes reflects the reporting under a single code of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claims data that reflect the combined cost of the two predecessor codes. In addition, at the February 28–March 1, 2011 Panel meeting, several presenters reported their concern and disagreement with our single APC assignments for these new codes. The presenters stated that the payment rates for the single APC assignments reflected only half of the true costs of these services based on their internal calculated costs. Similar to the public commenters, the

presenters indicated that, prior to CY 2011, these services were reported using a combination of codes, and suggested that CMS revise the methodology to include these combinations of codes to determine accurate payment rates for these services. Specifically, the presenters indicated that simulating the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes would result in the best estimates of costs for these codes and, therefore, the most accurate payment rates.

After examination of our claims data for the predecessor codes, and after considering the various concerns and recommendations that we received on this issue (specifically, the views of the stakeholders who met with us to discuss this issue, the comments received in response to the CY 2011 OPPS/ASC final rule with public comment period, and input from the Panel at its February 28–March 1, 2011 meeting), we proposed to revise our payment methodology for CPT codes 74176, 74177, and 74178 for CY 2012 (76 FR 42235). That is, we proposed to simulate the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes to determine the most accurate payment rates for these codes. This new proposed payment methodology necessitated establishing two new APCs, specifically, APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) to which CPT code 74176 would be assigned, and APC 0334 (Combined Abdominal and Pelvis CT With Contrast) to which CPT codes 74177 and 74178 would be assigned. In addition, we proposed to continue to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006 for CY 2012.

Based on the feedback that we received from the Panel at its August 10–11, 2011 meeting, and the public comments received on the CY 2012 OPPS/ASC proposed rule in support of the proposed revised payment methodology for CPT codes 74176, 74177, and 74178, we finalized our proposals in the CY 2012 OPPS/ASC final rule with comment period. Specifically, we reassigned CPT code 74176 from APC 0332 to APC 0331, CPT code 74177 from APC 0283 to APC 0334, and CPT code 74178 from APC 0333 to APC 0334. (We refer readers to the CY 2012 OPPS/ASC final rule with comment period for a detailed description of the methodology we used to simulate the costs of these procedures using claims data for the predecessor CPT codes (76 FR 74259 through 74262).) We also continued with our composite APC assignments for these codes. Specifically, we continued to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006. Table 7 below shows the payment rates for these codes for the CY 2012 update.

TABLE 7—CY 2012 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2012 CPT Code	CY 2012 short descriptor	CY 2012 SI	CY 2012 single code APC	CY 2012 single code APC payment rate	CY 2012 composite APC	CY 2012 composite APC payment rate
74176	Ct abd & pelvis	Q3	0331	$405.17	8005	$431.60
74177	Ct abd & pelv w/contrast	Q3	0334	580.54	8006	721.12
74178	Ct abd & pelv 1/< regns	Q3	0334	580.54	8006	721.12

We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74262) that we would reassess whether there is a continued need for these APCs for the CY 2013 OPPS/ASC update once we have actual charges for these services. Because CPT codes 74176, 74177, and 74178 became effective on January 1, 2011, we have hospital claims data available for these codes that we can use for ratesetting for the first time. Analysis of the latest CY 2011 hospital outpatient claims data for the CY 2013 OPPS/ASC proposed rulemaking update, which is based on claims processed with dates of service from January 1, 2011 through December 31, 2011, reveals a decrease in costs for the three procedures, compared to the costs simulated using predecessor CPT codes for CY 2012. CPT code 74176 shows a cost of approximately $314 based on 312,493 single claims (out of 713,662 total claims), while CPT code 74177 reveals a cost of approximately $476 based on 367,002 single claims (out of 951,296 total claims). In addition, CPT code 74178 shows a cost of approximately $537 based on 184,580 single claims (out of 267,401 total claims). Because we used hospital claims data specific to CPT codes 74176, 74177, and 74178, we believe these costs accurately reflect the resources associated with providing computed tomography of the abdomen and pelvis as described by these CPT codes in the HOPD.

Furthermore, our analysis of the CY 2011 claims data available for this proposed rule shows no 2 times rule violation for either APC 0331 or APC 0334. Therefore, for CY 2013, we are proposing to continue to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. (Because we have claims data available for these three CPT codes, we will no longer simulate their costs using predecessor codes as we did in CY 2012.) In addition, we are proposing to continue to assign these codes to their existing composite APCs for CY 2013. Specifically, we are proposing to continue to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006. Table 8 below lists the computed tomography of the abdomen and pelvis CPT codes along with their proposed status indicators, and single and composite APC assignments for CY 2013.

TABLE 8—PROPOSED APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES FOR CY 2013

CY 2012 CPT Code	CY 2012 short descriptor	Proposed CY 2013 SI	Proposed CY 2013 single code APC	Proposed CY 2013 composite APC
74176	Ct abd & pelvis	Q3	0331	8005
74177	Ct abd & pelv w/contrast	Q3	0334	8006
74178	Ct abd & pelv 1/> regns	Q3	0334	8006

(6) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Public Law 108–173 (MMA), mandated 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 additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and include separate groups for palladium-103 and iodine-125 sources. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS proposed and final rules. As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, 75 FR 71978, and 76 FR 74160), we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons. 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 cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, would also 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.

Therefore, for CY 2013, we are proposing to use the costs from CY 2011 claims data for setting the proposed CY 2013 payment rates for brachytherapy sources, as we are proposing for most other items and services that would be paid under the CY 2013 OPPS. We based the proposed rates for brachytherapy sources using geometric mean unit costs for each source, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of this proposed rule. We are proposing to continue the other payment policies for brachytherapy sources 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 non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to 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). 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 superseded for a period of time 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.

Consistent with our policy regarding APC payments made on a prospective basis, as we did for CY 2011 and CY 2012, we are proposing to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Hospitals can receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment specified at 42 CFR 419.43(d). In addition, implementation of prospective payment for brachytherapy sources provides opportunities for eligible hospitals to receive additional payments in CY 2013 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this proposed rule.

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 2013 payment rates for brachytherapy sources, identified with status indicator ''U''. We are inviting public comment on this proposed policy and also 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 C4–05–17, 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 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 only necessary, high quality care and to provide that 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, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy 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.

For CY 2013, we are proposing to continue our composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), II.A.2.e.(5), and II.A.2.e.(6), respectively, of this proposed rule.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

We are proposing to continue to include composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS for CY 2013. Beginning in CY 2008, we created these two composite APCs to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. In the circumstances when observation care is provided in conjunction with a high level visit or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter through one of the two composite APCs as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy.

For CY 2013, we are proposing to continue the extended assessment and management composite APC payment methodology and criteria for APCs 8002 and 8003 that we finalized for CYs 2009 through 2012. We continue to believe that the composite APCs 8002 and 8003 and related policies provide the most appropriate means of paying for these services. We also are proposing to calculate the costs for APCs 8002 and 8003 using the same methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we are proposing to use all single and ''pseudo'' single procedure claims from CY 2011 that met the criteria for payment of each composite APC and apply the standard packaging and trimming rules to the claims before calculating the proposed CY 2013 costs. The proposed CY 2013 cost resulting from this methodology for composite APC 8002 is approximately $446, which was calculated from 17,072 single and ''pseudo'' single bills that met the required criteria. The proposed CY 2013 cost for composite APC 8003 is approximately $813, which was calculated from 255,231 single and ''pseudo'' single bills that met the required criteria.

At its February 2012 meeting, the Advisory Panel on Hospital Outpatient Payment (the Panel) recommended that CMS continue to report clinic/emergency department visit and observation claims data and, if CMS identifies changes in patterns of utilization or cost, that CMS bring those issues to the Visits and Observation Subcommittee. Additionally, the Panel recommended that CMS examine data for discharge status, point of entry, age, primary and secondary diagnoses, and type of hospital (teaching, nonteaching, rural, urban) for patients receiving greater than 48 hours of observation services, if available, and report the findings to the Visits and Observation Subcommittee. The Panel recommended that the Visits and Observation Subcommittee review claims data for HCPCS code G0379 (Direct referral of patient for hospital observation care), and consider the appropriate APC group for the code. The Panel also recommended that the results of CMS' study on unconditionally packaged HCPCS code G0378 (Hospital observation service, per hour) be presented to the Visits and Observation Subcommittee. The Panel recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will provide the requested data to the Panel at a future meeting.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

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 based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the 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 and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

For CY 2013, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. That is, we are proposing to use CY 2011 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2012 practice, we are proposing not to use the claims that meet these criteria in the calculation of the costs for APCs 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing that the costs for APCs 0163 and 0651 continue

to be calculated using single and ''pseudo'' single procedure claims. We believe that this composite APC 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 cost upon which to base the composite APC payment rate.

Using a partial year of CY 2011 claims data available for this CY 2013 proposed rule, we were able to use 650 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the proposed CY 2013 payment for composite APC 8001 is based. The proposed cost for composite APC 8001 for CY 2013 is approximately $3,362.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

Effective January 1, 2008, we established APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one specified electrophysiologic ablation service. Correctly coded claims for these services often include multiple codes for component services that are reported with different CPT codes and that, prior to CY 2008, were always paid separately through different APCs (specifically, APC 0085 (Level II Electrophysiologic Evaluation), APC 0086 (Ablate Heart Dysrhythm Focus), and APC 0087 (Cardiac Electrophysiologic Recording/Mapping)). Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC costs for these services, and advanced our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the cost upon which the payment rate for composite APC 8000 is based, we used multiple procedure claims that contained at least one CPT code from Group A for evaluation services and at least one CPT code from Group B for ablation services reported on the same date of service on an individual claim. Table 9 in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66656) identified the CPT codes that are assigned to Groups A and B. For a full discussion of how we identified the Group A and Group B procedures and established the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659). Where a service in Group A is furnished on a date of service that is different from the date of service for a code in Group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

For CY 2013, we are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. We continue to believe that the cost for these services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for cardiac electrophysiologic evaluation and ablation services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Consistent with our CY 2008 through CY 2012 practice, we are proposing not to use the claims that meet the composite payment criteria in the calculation of the costs for APCs 0085 and 0086, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. The costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims.

For CY 2013, using a partial year of CY 2011 claims data available for this proposed rule, we were able to use 11,358 claims containing a combination of Group A and Group B codes to calculate a proposed cost of approximately $11,458 for composite APC 8000.

Table 9 below lists the proposed groups of procedures upon which we would base composite APC 8000 for CY 2013.

TABLE 9—PROPOSED GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes used in combinations: At least one in Group A and one in Group B	CY 2012 CPT Code	Proposed single code CY 2013 APC	Proposed CY 2013 SI (composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia.	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording.	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement.	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination.	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

(4) Mental Health Services Composite APC (APC 0034)

For CY 2013, 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, which we consider to be the most resource-intensive of all outpatient mental health treatments for CY 2013. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 to 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 partial hospitalization payment, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). We are proposing to continue to set the payment rate for APC 0034 at the same rate as we are proposing to pay for APC 0176 (Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs), which is the maximum partial hospitalization per diem payment, and that the hospital would continue to be paid one unit of APC 0034. Under this proposal, the I/OCE would continue to determine whether to pay for these specified mental health services individually or make a single payment at the same rate as the APC 0176 per diem rate for partial hospitalization 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 represent the most resource-intensive of all outpatient mental health treatments. Therefore, we do not believe that we should pay more for services under the OPPS than the partial hospitalization per diem rate.

(5) 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 8 of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74171 through 74175).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement at 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 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).

For CY 2013, 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 payment methodology. We continue to believe that this policy would continue to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2013 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on costs calculated from a partial year of CY 2011 claims available for this CY 2013 OPPS/ASC 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 costs, we used the same methodology that we used to calculate the final CY 2012 costs for these composite APCs, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74169). The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC costs, pursuant to our established methodology (76 FR 74169), appear in Table 11 of this proposed rule.

We were able to identify approximately 1.0 million ''single session'' claims out of an estimated 1.5 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the proposed CY 2013 costs for the multiple imaging composite APCs.

Table 10 below lists the proposed HCPCS codes that would be subject to the multiple imaging composite policy and their respective families and approximate proposed composite APC costs for CY 2013. Table 11 below lists the OPPS imaging family services that overlap with HCPCS codes on the proposed CY 2013 bypass list.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound

Proposed CY 2013 APC 8004 (Ultrasound Composite)	Proposed CY 2013 Approximate APC Cost = $201
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA with and without Contrast

Proposed CY 2013 APC 8005 (CT and CTA without Contrast Composite)*	Proposed CY 2013 Approximate APC Cost = $412
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.

Proposed CY 2013 APC 8006 (CT and CTA with Contrast Composite)	Proposed CY 2013 Approximate APC Cost = $700
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.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

* 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 will assign APC 8006 rather than APC 8005.

Family 3—MRI and MRA with and without Contrast

Proposed CY 2013 APC 8007 (MRI and MRA without Contrast Composite)*	Proposed CY 2013 Approximate APC Cost = $725
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
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.
Proposed CY 2013 APC 8008 (MRI and MRA with Contrast Composite)	**Proposed CY 2013 Approximate APC Cost = $1,066**
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.
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.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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 will assign APC 8008 rather than APC 8007.

TABLE 11—PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2013 BYPASS LIST

Family 1—Ultrasound	
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.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA with and without Contrast	
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.

Family 3—MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint.
70544	Mri angiography head w/o dye.
70551	Mri brain w/o dye.
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.
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.

(6) Cardiac Resynchronization Therapy Composite APC (APC 0108)

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizing a pacing electrode implanted in combination with an implantable cardioverter defibrillator (ICD) is known as CRT–D. Hospitals commonly report the implantation of a CRT–D system using 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 (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)) and 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator). As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176), over the past several years, stakeholders have pointed out significant fluctuations in the payment rate for CPT code 33225 and that, because the definition of CPT code 33225 specifies that the pacing electrode is inserted at the same time as an ICD or pacemaker, CMS would not have many valid claims upon which to calculate an accurate cost. In response to these concerns, we established a policy beginning in CY 2012 to recognize CPT codes 33225 and 33249 as a single, composite service when the procedures are performed on the same day and to assign them to APC 0108 (Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes) when they appear together on a claim with the same date of service. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176 through 74182) for a full description of how we developed this policy.

As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182), hospitals continue to use the same CPT codes to report CRT–D implantation services, and the I/OCE will identify when the combination of CPT codes 33225 and 33249 on the same day qualify for composite service payment. We make a single composite payment for such cases. When not performed on the same day as the service described by CPT code 33225, the service described by CPT code 33249 is also assigned to APC 0108. When not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 is assigned to APC 0655.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176 through 74182) for a full description of how we developed this policy.

In order to ensure that hospitals correctly code for CRT services in the future, we also finalized a policy in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182) to implement claims processing edits that will return to providers incorrectly coded claims on which a pacing electrode insertion (the procedure described by CPT code 33225) is billed without one of the following procedures to insert an ICD or pacemaker, as specified by the AMA in the CPT codebook:

- 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial);
- 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular);
- 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular);
- 33212 (Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular);
- 33213 (Insertion or replacement of pacemaker pulse generator only; dual chamber, atrial or ventricular);
- 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator));
- 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator);
- 33217 (Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator);
- 33222 (Revision or relocation of skin pocket for pacemaker);
- 33233 (Removal of permanent pacemaker pulse generator);

- 33234 (Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular);
- 33235 (Removal of transvenous pacemaker electrode(s); dual lead system, atrial or ventricular);
- 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator); or
- 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).

For CY 2013, we are proposing to continue to recognize CRT–D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. By continuing to recognize these procedures as a single, composite service, we are able to use a higher volume of correctly coded claims for CPT code 33225, which, because of its add-on code status, is always performed in conjunction with another procedure and, therefore, to address the inherent ratesetting challenges associated with CPT code 33225. We also note that this policy is consistent with the principles of a prospective payment system, specifically to place similar services that utilize technologies with varying costs in the same APC in order to promote efficiency and decision making based on individual patient's clinical needs rather than financial considerations. In calculating the costs upon which the payment rate for APC 0108 is based for CY 2013, for this proposed rule, we included single procedure claims for the individual services assigned to APC 0108, as well as single procedure claims that contain the composite CRT–D service, defined as the combination of CPT codes 33225 and 33249 with the same date of service. We were able to use 9,790 single bills from the CY 2013 proposed rule claims data to calculate a proposed cost of approximately $31,491 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we are proposing to continue to assign them status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this proposed rule. The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service is also reflected in Addendum M to this proposed rule (which is available via the Internet on the CMS Web site).

We note that we have revised the claims processing edits in place for CPT code 33225 due to revised guidance from the AMA in the CPT code book specifying the codes that should be used in conjunction with CPT code 33225. Specifically, on February 27, 2012, the AMA posted a correction as errata to the CY 2012 CPT code book on the AMA web site at *http://www.ama-assn.org/resources/doc/cpt/cpt-corrections.pdf*. This correction removed CPT code 33222 (Revision or relocation of skin pocket for pacemaker) as a service that should be provided in conjunction with CPT code 33225, and added CPT codes 33228 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system), 33229 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system), 33263 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system), and 33264 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system). In accordance with this revised guidance, we deleted CPT code 33222 as a code that can satisfy the claims processing edit for CPT code 33225, and added CPT codes 33228, 33229, 33263, and 33264 as codes that can satisfy this edit beginning in CY 2012.

f. Proposed Geometric Mean-Based Relative Payment Weights

When the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a PPS under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient setting to the outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508), required that we develop a proposal to replace the hospital outpatient payment system with a PPS and submit a report to the Congress on the proposed system. The statutory framework for the OPPS was established by the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33) with section 4523 amending section 1833 of the Act by adding subsection (t), which provides for a PPS for hospital outpatient department services and the BBRA of 1999 (Pub. L. 106–113), with section 201 further amending section 1833(t) of the Act. The implementing regulations for these statutory authorities were codified at 42 CFR Part 419, effective for services furnished on or after August 1, 2000.

Section 1833 of the Act set forth the methodological requirements for developing the PPS for hospital outpatient services (the OPPS). At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services, and corresponding rapidly growing beneficiary coinsurance. Accordingly, much of the focus was on finding ways to address those issues. The OPPS statute, section 1833(t)(2)(C) of the Act, initially provided that relative payment weights for covered outpatient department services be established based on median costs under section 4523(a) of the BBA of 1997. Later, section 201(f) of the BBRA of 1999 amended section 1833(t)(2)(C) of the Act to allow the Secretary the discretion to base the establishment of relative payment weights on either median or mean hospital costs. Since the OPPS was initially implemented, we have established relative payment weights based on the median hospital costs for both statistical reasons and timely implementation concerns. The proposed

rule for the OPPS was published prior to the passage of the BBRA of 1999, which amended the Act to permit the use of mean costs. At that time, we noted that making payment for hospital outpatient services based on the median cost of each APC was a way of discouraging upcoding that occurs when individual services that are similar have disparate median costs, as well as associating services for which there are low claims volume into the appropriate classifications based on clinical patterns and their resource consumption (63 FR 47562).

As discussed in the CY 2000 OPPS final rule with comment period (65 FR 18482 through 18483), initial implementation of the payment system for hospital outpatient services was delayed due to multiple extensions of the proposed rule comment period, Year 2000 (Y2K) system concerns, and other systems challenges in developing the OPPS. Even though the BBRA of 1999 passed during that period of time, and provided the Secretary with the discretion to establish relative payment weights under the OPPS based on mean hospital costs, we determined that reconstructing the database to evaluate the impact of using mean costs would have postponed implementation of the OPPS further. There were important challenges at the time, including being responsive to stakeholder comments regarding the initial OPPS and addressing implementation issues so that the payment and claims processing systems would work correctly. To do so in a timely manner was critical; therefore, median costs were selected as an appropriate metric on which to base payment relativity, both based on the statistical reasons noted above, and practical implementation concerns.

In addition to the reasons discussed above, developing relative payment weights based on median costs was a way of attenuating the impact of cost outlier cases. In an environment where facility coding practices were still in their infancy, median costs served to minimize the impact of any coding errors. Using median costs to establish service cost relativity served the same function as any measure of central tendency (including means), ensuring that the payment weights used in the OPPS would, in general, account for the variety of costs associated with providing a service.

Since the beginning of the OPPS and throughout its development, we have striven to find ways to improve our methods for estimating the costs associated with providing services. The dialogue with the public regarding these issues, the meaningful information and recommendations that the Panel (previously the APC Panel) has provided, and the policies we have established to better derive the costs on which OPPS payment is calculated have contributed to improving cost estimation. However, challenges remain in our continuing effort to better estimate the costs associated with providing services. These challenges include our limited ability to obtain more meaningful information from the claims and cost report data available and ensuring that the approach used to calculate the payments for services accurately captures the relative costs associated with providing them. Over the years, we have implemented many changes to the OPPS cost modeling process to help address these challenges.

To obtain more information from the claims data we have available, we first began bypassing codes from the standard process to develop ''pseudo'' single claims in CY 2003 (67 FR 66746). In CY 2006, this concept later evolved into the bypass list (and its corresponding criteria for addition) which allows us to extract more cost information from claims that would otherwise be unusable for modeling service cost (70 FR 68525). In CY 2008, we examined clinical areas where packaging of services was appropriate, which allows us to use more claims in modeling the payments for primary procedures and encourage providers to make cost efficient choices where possible (72 FR 66610 through 66649). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66590), we noted that this packaging approach increased the number of ''natural'' single bills, while simultaneously reducing the universe of codes requiring single bills for ratesetting. Beginning in CY 2008, we also established composite APCs for services that are typically provided together in the same encounter, allowing us to use even more previously unusable claims (due to containing multiple separately payable major codes) for modeling service cost, as well as develop APCs that reflect the combined encounter (72 FR 66650 through 66658). We have implemented many steps to obtain more information from the claims and cost report data available to us, and continue to examine ways in which we can derive more meaningful information on service costs for use in ratesetting.

In our experience in working with the OPPS, we also have implemented many processes to ensure that the cost information we derive from cost reports and claims data is accurate. In the beginning of the OPPS, we implemented a cost trim of three standard deviations outside the geometric mean cost, similar to the cost data trim in the IPPS, because it would ensure that the most aberrant data were removed from ratesetting (65 FR 18484). We also have implemented similar trims to the hospital departmental CCR and claims based unit data related to the services (71 FR 67985 through 67987).

During the CY 2008 rulemaking cycle, we contracted with Research Triangle Institute, International (RTI) to examine possible improvements to the OPPS cost estimation process after they had investigated similar issues in the IPPS setting (72 FR 66659 through 66602). There was significant concern that charge compression, which results from the hospital practice of attaching a higher mark-up to charges for low cost supplies and a lower mark-up to charges for higher cost supplies, was influencing the cost estimates on which the OPPS relative payment weights are based. Based on RTI's recommendations, in CY 2009, we finalized modifications to the Medicare cost report form to create an ''Implantable Medical Devices Charged to Patients'' cost center to address public commenter concerns related to charge compression in the ''Medical Supplies Charged to Patients'' cost center (73 FR 48458 through 48467). These modifications helped to address potential issues related to hospital markup practices and how they are reflected in the CCRs in the Medicare cost reporting form.

In CY 2010, we incorporated a line item trim into our data process that removed lines that were eligible for OPPS payment in the claim year but received no payment, presumably because of a line item rejection or denial due to claims processing edits (74 FR 60359). This line item trim was developed with the goal of using additional lines to model prospective payment.

In addition to these process changes that were designed to include more accurate cost data in ratesetting, we have developed a number of nonstandard modeling processes to support service or APC specific changes. For example, in the device dependent APCs, we have incorporated edits into the cost estimation process to ensure that the full cost of the device is incorporated into the primary procedure.

While we have already implemented numerous changes to the data process in order to obtain accurate resource cost estimates associated with providing a procedure, we continue to examine possible areas of improvement. In the past, commenters have expressed

concern over the degree to which payment rates reflect the costs associated with providing a service, believing that, in some cases, high cost items or services that might be packaged are not accordingly reflected in the payment weights (72 FR 66629 through 66630 and 66767). As mentioned above, in the CY 2008 OPPS/ASC final rule with comment period, we developed a packaging policy that identified a number of clinical areas where services would be commonly performed in a manner that was typically ancillary and supportive to other primary procedures. Packaging for appropriate clinical areas provides an incentive for efficient and cost-effective delivery of services. In that final rule with comment period, we recognized that there were strengths and weaknesses associated with using median costs as the metric for developing the OPPS payment weights (72 FR 66615). Medians are generally more stable than means because they are less sensitive to extreme observations, but they also do not reflect subtle changes in cost distributions. As a result, the use of medians rather than means under the OPPS usually results in relative weight estimates being less sensitive to packaging decisions, as well as changes in the cost model due to factors such as the additional claims processed between the proposed rule and the final rule.

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient (73 FR 68570). Establishing the cost-based relative payment weights based on a measure of central tendency, such as means or medians, ensures that the payments for the package of services should generally account for the variety of costs associated with providing those services. Prospective payments are ultimately adjusted for budget neutrality and updated by an OPD update factor, which affects the calculated payments, but the accuracy of the cost-based weights is critical in ensuring that the relative payment weights are adjusted appropriately.

We recognize that median costs have historically served and may continue to serve as an appropriate measure on which to establish relative payments weights. However, as discussed above, the metric's resistance to outlier observations is balanced by its limited ability to be reflective of changes to the dataset used to model cost or changes beyond the center of the dataset. While there was significant concern in the initial years of the OPPS regarding outlier cost values and the possible introduction of potentially aberrant values in the cost modeling, hospital experience in coding under the system, the data modeling improvements we have made to obtain more accurate cost information while removing erroneous data, and other changes in our experience with the system have all lessened the potential impact of error values (rather than actual, accurate cost outliers). As noted above, over the history of the OPPS, we have made multiple refinements to the data process to better capture service costs, respond to commenter concerns regarding the degree to which OPPS relative payment weights accurately reflect service cost and APC payment volatility from year to year, and better capture the variety of resource cost associated with providing a service as provided under section 1833(t)(2)(C) of the Act. For CY 2013, we are proposing to shift the basis for the CY 2013 APC relative payment weights that underpin the OPPS from median costs to geometric means based costs.

Geometric means better encompass the variation in costs that occur when providing a service because, in addition to the individual cost values that are reflected by medians, geometric means reflect the magnitude of the cost measurements, and are thus more sensitive to changes in the data. We believe developing the OPPS relative payment weights based on geometric mean costs would better capture the range of costs associated with providing services, including those cases involving high cost packaged items or services, and those cases where very efficient hospitals have provided services at much lower costs. The use of geometric mean costs also would allow us to detect changes in the cost of services earlier, because changes in cost often diffuse into the industry over time as opposed to impacting all hospitals equally at the same time. Medians and geometric means both capture the impact of uniform changes, that is, those changes that influence all providers, but only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis.

An additional benefit of this proposal relates to the two times rule, described in section III.B. of this proposed rule, which is our primary tool for identifying clinically similar services that have begun to deviate in terms of their financial resource requirements. Basing HCPCS projections on geometric mean costs would increase the sensitivity of this tool as we configure the APC mappings because it would allow us to detect differences when higher costs occur in a subset of services even if the number of services does not change. This information would allow us to better ensure that the practice patterns associated with all the component codes appropriately belong in the same APC.

In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of clinical practice patterns, basing the relative payment weights on geometric mean costs may also promote better stability in the payment system. In the short term, geometric mean-based relative payment weights would make the relative payment weights more reflective of the service costs. Making this change also may promote more payment stability in the long term by including a broader range of observations in the relative payment weights, making them less susceptible to gaps in estimated cost near the median observation and also making changes in the relative payment weight a better function of changes in estimated service costs.

We note that this proposed change would bring the OPPS in line with the IPPS, which utilizes hospital costs derived from claims and cost report data to calculate prospective payments, and specifically, mean costs rather than median costs to form the basis of the relative payment weights associated with each of the payment classification groups. We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74181) our intent to explore methods to ensure our payment systems do not provide inappropriate payment incentives to provide services in one setting of care as opposed to another setting of care based on financial considerations rather than clinical needs. By adopting a means cost based approach to calculating relative payment weights under the OPPS, we expect to achieve greater consistency between the methodologies used to calculate payment rates under the IPPS and the OPPS, which would put us in a better position from an analytic perspective to make cross-system comparisons and examine issues of payment parity.

For the reasons described above, we are proposing to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. While this would involve a change to the metric used to develop the relative payment weights, the use of claims would not be affected. We are proposing to continue subsetting claims using the data processes for modeling the standard APCs and the criteria-based APCs described in section II.A.2. of this

proposed rule, where appropriate. The reasoning behind implementing modeling edits or changes in the criteria-based APCs would not be affected because the process of developing the relative payment weights based on a measure of central tendency is the last step of the modeling process, and occurs only once the set of claims used in ratesetting has been established.

One important step that occurs after the development of relative payment weights is the assignment of individual HCPCS codes (services) to APCs. In our analysis of the impacts of a process conversion to geometric means, we determined that the change to means would not significantly influence the application of the 2 times rule. Very few services would need to be shifted to new APCs because of 2 times rule violations as the use of geometric means would resolve some violations that would exist under medians even as it creates others due to new cost projections. The net impact of the proposed change results in seven more violations of the 2 times rule created by the entire rebasing process than would exist if median-based values were used.

During the development of this proposal, we also determined that the cumulative effect of data shifts over the 12 years of OPPS introduced a number of inconsistencies in the APC groupings based on clinical and resource homogeneity. We believe that a shift to payments derived from geometric means would improve our ability to identify resource distinctions between previously homogenous services, and we intend to use this information over the next year to reexamine our APC structure and assignments to consider further ways of increasing the stability of payments for individual services over time.

We note that this proposal to establish all OPPS relative payment weights using geometric mean costs would apply to all APCs that would have previously been paid based on median costs. In addition, we are proposing that the relative payment weights for line item based payments such as brachytherapy sources, which are discussed in section II.A.2.d.(6) of this proposed rule, as well as blood and blood products, which are discussed in II.A.2.d.(2) of this proposed rule, be calculated based on their geometric mean costs for the CY 2013 OPPS.

The CY 2013 proposal to base relative payment weights on geometric mean costs would specifically include the CMHC and hospital-based partial hospitalization program APCs, which were previously based on median per diem costs. Their estimated payments would continue to be included in the budget neutral weight scaling process, and their treatment is similar to other nonstandard APCs discussed in section II.A. of this proposed rule. The process for developing a set of claims that is appropriate for modeling these APCs would continue to be the same as in recent years, with the only proposed difference being that a geometric mean per diem cost would be calculated rather than a median per diem cost. The proposed CY 2013 partial hospitalization payment policies are described in section VIII. of this proposed rule.

We believe it is important to make the transition from medians to means across all APCs in order to capture the complete range of costs associated with all services, and to ensure that the relative payment weights of the various APCs are properly aligned. If some OPPS payments calculated using relative payment weights are based on means while others are based on medians, the ratio of the two payments will not accurately reflect the ratio of the relative costs reported by the hospitals. This is of particular significance in the process of establishing the budget neutral weight scaler, discussed in section II.A.4. of this proposed rule.

We note that the few proposed exceptions to the applications of the geometric mean-based relative payment weights would be the same exceptions that exist when median-based weights are applied, including codes paid under different payment systems or not paid under the OPPS, items and services not paid by Medicare, items or services paid at reasonable cost or charges reduced to cost, among others. For more information about the various proposed payment status indicators for CY 2013, we refer readers to Addendum D1 to this proposed rule (which are available via the Internet on the CMS Web site).

We are proposing for CY 2013 that payment for nonpass-through separately payable drugs and biologicals will continue to be developed through its own separate process. Payments for drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process. We note that, for CY 2013, we are proposing to pay for nonpass-through 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. Also, as is our standard methodology, for CY 2013, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, and the impact analyses. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we are proposing to use their mean unit cost derived from the CY 2011 hospital claims data to determine their per day cost. The proposed nonpass-through separately payable drug and biological payment policy for CY 2013 is described in greater detail in section V.B. of this proposed rule.

Under the revised ASC payment system that was effective January 1, 2008, we established a standard ASC ratesetting methodology that bases payment for most ASC covered surgical procedures and some covered ancillary services on the OPPS relative payment weights (72 FR 42491 through 42493). Therefore, because we are proposing to calculate CY 2013 OPPS relative payment weights using geometric mean costs, we also are proposing that CY 2013 ASC payment rates under the standard ASC ratesetting methodology would be calculated using the OPPS relative payment weights that are based on geometric mean costs. We note that proposing to base the relative payment weights on geometric mean costs rather than median costs affects the proposed CY 2013 payment rates. Differences in the proposed payment rates, as with any changes from year to year, affect other parts of the OPPS, including the proposed copayments described in section II.I. of this proposed rule as well as the proposed fixed-dollar outlier threshold described in section II.G. of this proposed rule.

Under this CY 2013 proposal to base the relative payment weights on geometric means, we also are proposing to revise the related regulations that currently reflect a median cost-based OPPS to instead reflect a geometric mean cost-based OPPS. Specifically, we are proposing to revise 42 CFR 419.31, which describes the 2 times rule discussed in section III.B. of this proposed rule and the development of weights based on the cost metrics discussed in section II.A.4 of this proposed rule.

In the Addenda to this proposed rule (which are available via Internet on the CMS Web site), we are including a comparison file that identifies differences in the proposed payments between a geometric means-based OPPS and a median-based OPPS. In section XXII. of this proposed rule, which

discusses the regulatory impact analysis, we are providing an additional column in the impact tables for the OPPS that identifies the estimated impact due to APC recalibration of a geometric means-based OPPS as well as a column that estimates the impact of recalibration based on CY 2011 claims and historical cost report data. We are including in the Addenda to this proposed rule (which is available via the Internet on the CMS Web site) data that compare the budget neutral OPPS payments based on geometric means to the budget neutral OPPS payments based on medians. As depicted in the impact tables, many provider categories would experience limited impacts under the proposal to base the OPPS relative payment weights on geometric means. We note that the impact tables only estimate the OPPS payment impact based on the most current available claims and cost report data, and that providers' actual payments may vary, depending on the mix of services provided in the actual claims year. Also, the budget neutral payment adjustments ensure that, under either a geometric mean-based system or a median cost-based system, aggregate OPPS payments would remain the same.

Section XXII. of this proposed rule contains an OPPS provider impact table that estimates the effect of proposed policy changes and budget neutrality adjustments on provider payment under the CY 2013 OPPS. Column 3 of the impact table shows the estimated impact by provider category of calculating the CY 2013 OPPS payments based on geometric mean costs rather than median cost. While the proposal to shift the basis for relative payment weights to geometric mean costs may involve some changes to the relative weights on which OPPS payments are based, providers generally experience limited impacts to payment as a result of the CY 2013 proposal. Those provider categories that improve significantly as a result of the proposal to base the CY 2013 relative payment weights on geometric mean costs generally included non-IPPS hospitals that provided psychiatric, hospital-based partial hospitalization, and other services whose relative payment weights improved based on geometric mean costs. As noted above, we recognize that there may be fluctuations in the relative payment weights based on this CY 2013 proposal, but we believe that this proposal represents an improvement that more accurately estimates the costs associated with providing services.

In our experience developing the OPPS, we have implemented many changes to obtain more cost information from the claims and cost report data available to us, in an effort to arrive at more accurate estimates of service cost. Many of those changes are described above and in prior OPPS final rules. Despite the challenges created by the complexity of the data and the diversity of facility accounting systems, we continue to examine possible process and data changes that may further improve precision, validity, and utility. Commenters have historically expressed concerns about the degree to which OPPS relative payment weights are reflective of the service costs associated with providing them, APC payment rate volatility from year to year, and other cost modeling related issues. We recognize that some of those issues will continue because they are related to naturally occurring changes in the economic environment, clinical practice, and the nature of payment systems, among other reasons. However, we believe that basing the OPPS relative payment weights on geometric means would better capture the range of costs associated with providing services, improve payment accuracy while limiting year-to-year volatility, and allow reconfigurations in the APC environment using a metric that provides greater computational depth. For these reasons, and those discussed above, we are proposing to base the CY 2013 OPPS/ASC relative payment weights on geometric mean costs.

3. Proposed Changes to Packaged Services

a. Background

Like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care. The OPPS packages payment for multiple interrelated services into a single payment to create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the least expensive item that meets the patient's needs, rather than to routinely use a more expensive item, which could result if separate payment is provided for the items. Packaging also encourages hospitals to 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. 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 also may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for items and services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000.

We use the term ''dependent service'' to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term ''independent service'' to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. In future years, as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of care, it is possible that we might propose to bundle payment for a service that we now refer to as ''independent.''

We assign status indicator ''N'' to those HCPCS codes of dependent services that we believe are always integral to the performance of the primary modality; therefore, we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned to status indicator ''N'' are unconditionally packaged.

We assign status indicator ''Q1'' (STVX-Packaged Codes), ''Q2'' (T-Packaged Codes), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An STVX-packaged code describes a HCPCS code whose payment is packaged with one or more separately paid primary services with the status indicator of ''S,'' ''T,'' ''V,'' or ''X'' furnished in the hospital outpatient encounter. A T-packaged code describes a code whose payment is only packaged

with one or more separately paid surgical procedures with the status indicator of ''T'' are provided during the hospital outpatient encounter. STVX-packaged codes and T-packaged codes are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. STVX-packaged codes and T-packaged codes are conditionally packaged. We refer readers to section XII.A.1. of this proposed rule and Addendum D1, which is available via the Internet on the CMS Web site with other Addenda, for a complete listing of status indicators and the meaning of each status indicator.

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims to establish prospective payment rates. We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides other guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

In addition to the packaged items and services listed in 42 CFR 419.2(b), in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories 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. Packaging under the OPPS also includes composite APCs, which are described in section II.A.2.e. of this proposed rule.

b. Proposed Clarification of the Regulations at 42 CFR 419.2(b)

We are proposing to clarify the regulatory language at 42 CFR 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided. This proposed clarification is consistent with our interpretation and application of § 419.2(b) since the inception of the OPPS. We invite public comments on this proposed clarification.

c. Packaging Recommendations of the HOP Panel (''The Panel'') at Its February 2012 Meeting

During its February 2012 meeting, the Panel made five recommendations related to packaging and to the function of the subcommittee. One additional recommendation that originated from the APC Groups and Status Indicator (SI) Assignment Subcommittee about observation services is discussed in section II.A.2.e. of this proposed rule. The report of the February 2012 meeting of the Panel may be found on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp*.

Below we present each of the Panel's five packaging recommendations and our responses to those recommendations.

Panel Recommendation: CMS should delete HCPCS code G0259 (Injection procedure for sacroiliac joint; arthrography) and HCPCS code G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), and instead use CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography, when performed) with a status indicator of ''T,'' and assign CPT code 27096 to APC 0207 (Level III Nerve Injections).

CMS Response: For CY 2012, we assigned CPT code 27096 to status indicator ''B,'' meaning that this code is not payable under the OPPS. In order to receive payment for procedures performed on the sacroiliac joint with or without arthrography or with image guidance under the OPPS, hospitals must use either HCPCS code G0259, which is assigned to status indicator ''N'' for CY 2012, or HCPCS code G0260, which is assigned to status indicator ''T'' for CY 2012, as appropriate. CMS created HCPCS codes G0259 and G0260 to separate and distinguish the image guidance procedure from the therapeutic injection procedure for the sacroiliac joint. As stated above, guidance procedures are packaged under the OPPS because we believe that they are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support.

We believe that the existence of HCPCS codes G0259 and G0260 is necessary to assign appropriate packaged payment for the image guidance procedure, according to our established packaging policy, and separate payment for the therapeutic injection procedure. Therefore, we are not accepting the Panel's recommendation and are proposing to follow previously established policy and to continue to assign HCPCS code G0259 to status indicator ''N,'' HCPCS code G0260 to status indicator ''T,'' and CPT code 27096 to status indicator ''B'' for CY 2013.

Panel Recommendation: CMS provide data to the APC Groups and SI Subcommittee on the following arthrography services, so that the Subcommittee can consider whether the SI for these services should be changed from ''N'' to ''S'':

- HCPCS code 21116 (Injection procedure for temporomandibular joint arthrography);
- HCPCS code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography);
- HCPCS code 24220 (Injection procedure for elbow arthrography);
- HCPCS code 25246 (Injection procedure for wrist arthrography);
- HCPCS code 27093 (Injection procedure for hip arthrography; without anesthesia);
- HCPCS code 27095 (Injection procedure for hip arthrography; with anesthesia);
- HCPSC code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid with image guidance (fluoroscopy or CT) including arthrography when performed);
- HCPCS code 27370 (Injection procedure for knee arthrography); and
- HCPCS code 27648 (Injection procedure for ankle arthrography).

CMS Response: We are accepting the Panel's recommendation that CMS provide data to the APC Groups and SI Assignment Subcommittee on HCPCS codes 21116, 23350, 24220, 25246, 27093, 27095, 27096, 27370, and 27648 at a future Panel meeting.

Panel Recommendation: CMS change the status indicator for HCPCS code 19290 (Preoperative placement of needle localization wire, breast) from ''N'' to ''Q1'' and continue to monitor the frequency of the code when used in isolation.

CMS Response: We agree with the Panel that proposing a status indicator of ''Q1'' is appropriate for HCPCS code

19290. This status indicator would allow for separate payment when this procedure is performed alone or packaged payment when this procedure is performed with an associated surgical procedure. Therefore, we are accepting the Panel's recommendation and are proposing to assign HCPCS code 19290 to APC 0340 (Minor Ancillary Procedures) and status indicator ''Q1'' for the CY 2013 OPPS. APC 0340 has a proposed cost of approximately $50.19 for CY 2013.

Panel Recommendation: Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., remain the chair of the APC Groups and SI Subcommittee.

CMS Response: We are accepting the Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and SI Assignment Subcommittee.

Panel Recommendation: The work of the APC Groups and SI Assignment Subcommittee continue.

CMS Response: We are accepting the Panel's recommendation that the work of the APC Groups and SI Assignment Subcommittee continue.

d. Proposed Packaging of Drugs, Biologicals, and Radiopharmaceuticals

(1) Existing Packaging Policies

In the OPPS, we currently package five categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) Those with per day costs at or below the packaging threshold; (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; and (5) drugs treated as surgical supplies. Anesthesia drugs are discussed further in section II.A.3.c.(2) of this proposed rule. For detailed discussions of the established packaging policies for diagnostic radiopharmaceuticals and contrast agents, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768). For further details on drugs treated as surgical supplies, we refer readers to the CY 2003 OPPS final rule (67 FR 66767) and Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual.

(2) Clarification of Packaging Policy for Anesthesia Drugs

It has been longstanding OPPS policy to package ''anesthesia'' and ''supplies and equipment for administering and monitoring anesthesia or sedation,'' as described in 42 CFR 419.2(b)(4) and (b)(5). As described above, items and services paid under the OPPS that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are considered dependent items and services are packaged into the payment of their accompanying independent primary service. In accordance with our current policy on packaging items and services, drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality, and are included in our definition of ''anesthesia'' as described in § 419.2(b)(4) and (b)(5). However, we recognize that some anesthesia drugs may qualify for transitional pass-through status under section 1833(t)(6) of the Act. Therefore, in this proposed rule, we are clarifying that our general policy is to package drugs used to produce anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status. We are inviting public comment on our clarification of the existing packaging policies for anesthesia drugs under § 419.2(b)(4) and (b)(5).

e. Proposed Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (''Policy-Packaged'' Drugs and Devices)

Prior to CY 2008, the methodology of calculating a product's estimated per day cost and comparing it to the annual OPPS drug packaging threshold was used to determine the packaging status of drugs, biologicals, and radiopharmaceuticals under the OPPS (except for the CYs 2005 through 2009 exemption for 5–HT3 antiemetics). However, as established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766 through 66768), we began packaging payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for the associated procedure, regardless of their per day costs. In addition, in CY 2009, we adopted a policy that packaged the payment for nonpass-through implantable biologicals into payment for the associated surgical procedure on the claim, regardless of their per day cost (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as ''policy-packaged'' drugs. We refer to implantable biologicals as ''devices'' because, in CY 2010, we finalized a policy to treat implantable biologicals as devices for OPPS payment purposes (74 FR 60471 through 60477).

As set forth at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate, standardized for geographical wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, and in general, these costs include, but are not limited to, implantable prosthetics, implantable durable medical equipment, and medical and surgical supplies. Packaging costs into a single aggregate payment for a service, encounter, 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 efficiency and also enables hospitals to manage their resources with maximum flexibility.

Prior to CY 2008, we noted that the proportion of drugs, biologicals, and radiopharmaceuticals that were separately paid under the OPPS had increased in recent years, a pattern that we also observed for procedural services under the OPPS. Our final CY 2008 policy that packaged payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, regardless of their per day costs, contributed significantly to expanding the size of the OPPS payment bundles and is consistent with the principles of a prospective payment system.

As discussed in more detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645 through 68649), we presented several reasons supporting our initial policy to package payment of diagnostic radiopharmaceuticals and contrast agents into their associated procedures on a claim. Specifically, we stated that we believed packaging was appropriate because: (1) The statutorily required OPPS drug packaging threshold had expired; (2) diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service, rather than serving themselves as a therapeutic modality; and (3) section 1833 (t)(14)(A)(iii) of the Act required that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost (76 FR 74307).

Therefore, we believe it is appropriate to propose to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from specified covered outpatient drugs (SCODs) for CY 2013. Therefore, we are proposing to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as ''policy-packaged'' drugs, regardless of their per

day costs, for CY 2013. We also are proposing to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment for the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

For CY 2013, we are proposing to make an additional payment of $10 for diagnostic radiopharmaceuticals that utilize the Tc-99m radioisotope produced by non-HEU methods. We are proposing to base this payment on the best available estimations of the marginal costs associated with non-HEU radioisotope production, pursuant to our authority described in section 1833(t)(2)(E) of the Act which allows us to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS. We describe this proposed policy in further detail in section III.C.3. of this proposed rule.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure because we consider these products to always be ancillary and supportive to independent services, similar to implantable nonbiological devices that are always packaged. We continued to follow this policy in CY 2012 (76 FR 74306 through 74310). Specifically, we continue to package payment for nonpass-through implantable biologicals, also known as devices that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body. For CY 2013, we are proposing to continue to apply the policies finalized in CY 2012, to package payment for nonpass-through implantable biologicals (''devices'') that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

Although our final CY 2009 policy (which we are proposing to continue for CY 2013 as discussed below) packaged payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for their associated procedures, we are proposing to continue to provide payment for these items in CY 2013 based on a proxy for average acquisition cost, as we did in CY 2009. We continue to believe that the line-item estimated cost for a diagnostic radiopharmaceutical or contrast agent in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals and contrast agents, respectively. As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), we believe that hospitals have adapted to the CY 2006 coding changes for radiopharmaceuticals and responded to our instructions to include charges for radiopharmaceutical handling in their charged for the radiopharmaceutical products. Further, because the standard OPPS packaging methodology packaged the total estimated cost of each diagnostic radiopharmaceutical and contrast agent on each claim (including the full range of costs observed on the claims) with the costs of associated procedures for ratesetting, this packaging approach is consistent with considering the average cost for diagnostic radiopharmaceuticals and contrast agents. In addition, as we noted in the CY 2009 OPPS/ASC final rule with comment period (72 FR 68646), these drugs, biologicals, or radiopharmaceuticals for which we have not established a separate APC and, therefore, for which payment would be packaged rather than separately provided under the OPPS, are considered to not be SCODs. Similarly, drugs and biologicals with per day costs of less than $80 in CY 2013, which is the proposed packaging threshold for CY 2013, that are packaged and for which a separate APC has not been established also are not SCODs. This reading is consistent with our proposed payment policy whereby we package payment for diagnostic radiopharmaceuticals and contrast agents and provide payment for these products through payment for their associated procedures.

f. Summary of Proposals

The HCPCS codes that we are proposing for unconditionally packaged (for which we are proposing to continue to assign status indicator ''N''), or conditionally packaged (for which we are proposing continue to assign status indicators ''Q1,'' ''Q2,'' or ''Q3''), are displayed in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site). The supporting documents for this CY 2013 OPPS/ASC proposed rule, including, but not limited to, Addendum B, are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To view the proposed status indicators by HCPCS code in Addendum B, select ''CMS 1589–P'' and then select the folder labeled ''2013 OPPS Proposed Rule Addenda'' from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

4. Proposed Calculation of OPPS Scaled Payment Weights

For CY 2013, we are proposing to calculate the relative payment weights for each APC for CY 2013 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. In years prior to CY 2007, we standardized all 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 the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights for 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 APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels). For CY 2013, we are proposing to base the relative payment weights on which OPPS payments will be made by using geometric mean costs, as described in section II.A.2.f. of this proposed rule. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we are proposing to continue to use the cost of the mid-level clinic visit APC (APC 0606) in calculating unscaled weights. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2013 geometric mean cost for APC 0606, for CY 2013, we are proposing to assign APC 0606 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0606 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative payment weights for all other APCs does not affect the 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 2013 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 2012 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2013 unscaled relative payment weights. For CY 2012, we multiplied the CY 2012 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2011 claims to calculate the total weight for each service. We then added together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2013, we are proposing to perform the same process using the proposed CY 2013 unscaled weights rather than scaled weights. We then calculate the proposed weight scaler by dividing the CY 2012 estimated aggregate weight by the proposed CY 2013 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. For a detailed discussion of the weight scaler 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*. We are proposing to include estimated payments to CMHCs in our comparison of estimated unscaled weights in CY 2013 to estimated total weights in CY 2012 using CY 2011 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the proposed unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2013 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.3504 to ensure that the proposed CY 2013 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states 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) was included in the proposed budget neutrality calculations for the CY 2013 OPPS.

We note that we are providing additional information, in association with this proposed rule, so that the public can provide meaningful comment on our proposal to base the CY 2013 OPPS relative payment weights on geometric mean costs. We will make available online a file that compares the calculated CY 2013 proposed OPPS payments using geometric mean costs to those that would be calculated based on median costs. The proposed scaled relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) incorporate the proposed recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine 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 2013 IPPS/LTCH PPS proposed rule (77 FR 27975), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2012 forecast of the FY 2013 market basket increase, the proposed FY 2013 IPPS market basket update is 3.0 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of Public Law 111–148 and as amended by section 10319(g) of that law and further amended by section 1105(e) of Public Law 111–152, provide adjustments to the OPD fee schedule increase factor for CY 2013.

Specifically, section 1833(t)(3)(F) requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustments described in that section. 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 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 through 27976), we discuss the calculation of the proposed MFP adjustment for FY 2013, which is 0.8 percentage point.

We are proposing that if more recent data are subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the CY 2013 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and (F) of the Act, in the CY 2013 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for, each of 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 2013, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 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)(ii) of the Act, we are proposing to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor for CY 2013.

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 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 2.1 percent for the CY 2013 OPPS (3.0 percent, which is the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8

percentage point MFP adjustment, less the 0.1 percentage point additional adjustment).

We note that hospitals that fail to meet the Hospital OQR Program reporting requirements would to be 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 made for their services, as required by section 1833(t)(17) of the Act. As a result, those hospitals failing to meet the Hospital OQR Program reporting requirements would receive an OPD fee schedule increase factor of 0.1 (3.0 percent, which is the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment, less 2.0 percentage point for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XV.F. of this proposed rule.

In this proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*4*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2013, we reduce the OPD fee schedule increase factor by the multifactor productivity adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(ii) 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 0.1 percentage point for CY 2013.

To set the OPPS conversion factor for CY 2013, we are proposing to increase the CY 2012 conversion factor of $70.016 by 2.1 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2013 to ensure that any revisions we make to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We calculated an overall proposed budget neutrality factor of 1.0003 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2013 IPPS wage indices to those payments using the current (FY 2012) IPPS wage indices, as adopted on a calendar year basis for the OPPS (77 FR 27946 through 27955).

For CY 2013, we are not proposing to make a change to our rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

For CY 2013, 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 2013 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2013 payments under section 1833(t) of the Act including the proposed CY 2013 cancer hospital payment adjustment to the estimated CY 2013 total payments using the CY 2012 final cancer hospital payment adjustment under sections 1833(t)(18)(B) and 1833(t)(2)(E) of the Act. The difference in the CY 2013 estimated payments due to applying the proposed CY 2013 cancer hospital payment adjustment relative to the CY 2012 final cancer hospital payment adjustment does not have a significant impact on the budget neutrality calculation. Therefore, we are proposing to apply a proposed budget neutrality adjustment factor of 1.0000 to the conversion factor to ensure that the cancer hospital payment adjustment is budget neutral.

For this proposed rule, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2013 would equal approximately $84 million, which represents 0.18 percent of total projected CY 2013 OPPS spending. Therefore, the proposed conversion factor would also be adjusted by the difference between the 0.22 percent estimate of pass-through spending for CY 2012 and the 0.18 percent estimate of CY 2013 pass-through spending, resulting in a proposed adjustment for CY 2013 of 0.04 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2013.

The proposed OPD fee schedule increase factor of 2.1 percent for CY 2013 (that is, the estimate of the hospital inpatient market basket percentage increase of 3.0 percent less the proposed 0.8 percentage point MFP adjustment and less the 0.1 percentage point required under section 1833(t)(3)(F) of the Act), the required proposed wage index budget neutrality adjustment of approximately 1.0003, the proposed cancer hospital payment adjustment of 1.000, and the proposed adjustment of 0.04 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2013 of $71.537.

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 adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR Program requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XV.F. of this proposed rule. To calculate the proposed CY 2013 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2013 payment update, we are proposing to make all other adjustments discussed above, but using a proposed reduced OPD fee schedule update factor of 0.1 percent (that is, the proposed OPD fee schedule increase factor of 2.1 percent further reduced by 2.0 percentage points as required by section 1833(t)(17)(A)(i) of the Act for failure to comply with the Hospital OQR requirements). This results in a proposed reduced conversion factor for CY 2013 of $70.106 for those hospitals that fail to meet the Hospital OQR requirements (a difference of -$1.431 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2013, we are proposing to use a conversion factor of $71.537 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. For further discussion on the proposal to base the CY 2013 OPPS relative payment weights using geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*4*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2013 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We are proposing to use a reduced conversion factor of $70.106 in the calculation of payments for hospitals that fail to comply with the Hospital OQR Program requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to account for geographic wage differences in a portion of the OPPS payment rate, which

includes the copayment standardized amount and is attributable to labor and labor-related costs. This portion of the OPPS payment rate is called the OPPS labor-related share. This adjustment must be made in a budget neutral manner and 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 not proposing to revise this policy for the CY 2013 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the wage index for a particular hospital is used to determine the 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 FY 2013 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 the copayment amount.

As published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18545), the OPPS has consistently adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, 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 believed 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 provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (77 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act requires a ''frontier State'' wage index floor of 1.00 in certain cases. For the CY 2013 OPPS, we are proposing to implement this provision in the same manner as we did for CY 2012. That is, frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011 and FY 2012 IPPS/LTCH PPS final rules (75 FR 50160 through 50161 and 76 FR 51586, respectively) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27951) for a detailed discussion 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.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2013 IPPS wage indices 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 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 2013 IPPS/LTCH PPS proposed rule (77 FR 27946 through 27955) for a detailed discussion of all proposed changes to the FY 2013 IPPS wage indices. 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.

Section 102 of the Medicare and Medicaid Extender Act, extended through FY 2011, section 508 reclassifications as well as certain special exceptions. The most recent extension of these special wage indices was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). These legislative provisions extended certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. We implemented this latest extension in a notice (CMS–1442–N) published in the **Federal Register** on April 20, 2012 (77 FR 23722). Therefore, the extension is no longer applicable, effective with FY 2013. As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2012 through June 30, 2012, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the end date under the OPPS for certain nonsection 508 and nonspecial exception providers to receive special wage indices was June 30, 2012, instead of March 31, 2012, so that these providers also received a full 6 months of payment under the revised wage index comparable to the IPPS.

For purposes of the OPPS, we are proposing to continue our policy in CY 2013 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2013 IPPS/LTCH PPS proposed rule (and made 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 hospitals that would receive the adjustment for FY 2013. We note that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27952) for a more detailed discussion on the Lugar redesignation waiver for the out-migration adjustment). As we have done in prior years, we are including Table 4J 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 2013 OPPS. Addendum L is available via the Internet on the CMS Web site.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies for geographic adjustment to hospital payments recently have been released. For summaries of the studies, their findings, and recommendations on reforming the wage index system, we refer readers to section IX.B. of the preamble of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28116 through 28119).

As stated earlier in this section, we continue to 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. Therefore, we are proposing to use the final FY 2013 IPPS wage indices for calculating OPPS payments in CY 2013. 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 2013 IPPS wage indices 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 2013 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. Medicare contractors 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 Medicare contractor 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 2013 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 2013, 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 2013 OPPS relative weights. Table 12 below lists the proposed CY 2013 default urban and rural CCRs by State and compares them to last year's 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 weight each hospital's CCR by the volume of separately paid line-items on hospital claims that correspond 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 this CY 2013 OPPS/ASC proposed rule, approximately 62 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2010, and approximately 38 percent were for cost reporting periods ending in CY 2009. 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 2012 and CY 2013 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 12 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2013.

TABLE 12—PROPOSED CY 2013 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2013 default CCR	Previous default CCR (CY 2012 OPPS final rule)
ALASKA	RURAL	0.489	0.487
ALASKA	URBAN	0.303	0.305
ALABAMA	RURAL	0.208	0.210
ALABAMA	URBAN	0.193	0.194
ARKANSAS	RURAL	0.219	0.221
ARKANSAS	URBAN	0.233	0.245
ARIZONA	RURAL	0.238	0.237
ARIZONA	URBAN	0.191	0.190
CALIFORNIA	RURAL	0.192	0.193
CALIFORNIA	URBAN	0.203	0.201
COLORADO	RURAL	0.331	0.342
COLORADO	URBAN	0.227	0.226
CONNECTICUT	RURAL	0.364	0.365
CONNECTICUT	URBAN	0.287	0.288
DISTRICT OF COLUMBIA	URBAN	0.300	0.302
DELAWARE	RURAL	0.280	0.280
DELAWARE	URBAN	0.349	0.347
FLORIDA	RURAL	0.182	0.182
FLORIDA	URBAN	0.166	0.164
GEORGIA	RURAL	0.237	0.238
GEORGIA	URBAN	0.213	0.214
HAWAII	RURAL	0.323	0.321
HAWAII	URBAN	0.306	0.306
IOWA	RURAL	0.297	0.296
IOWA	URBAN	0.267	0.269
IDAHO	RURAL	0.417	0.417
IDAHO	URBAN	0.357	0.353
ILLINOIS	RURAL	0.239	0.238
ILLINOIS	URBAN	0.230	0.230
INDIANA	RURAL	0.285	0.292
INDIANA	URBAN	0.256	0.262
KANSAS	RURAL	0.276	0.279
KANSAS	URBAN	0.211	0.208
KENTUCKY	RURAL	0.215	0.217
KENTUCKY	URBAN	0.241	0.239
LOUISIANA	RURAL	0.242	0.247
LOUISIANA	URBAN	0.225	0.224
MARYLAND	RURAL	0.275	0.276
MARYLAND	URBAN	0.246	0.246
MASSACHUSETTS	RURAL	0.427	0.427
MASSACHUSETTS	URBAN	0.322	0.322
MAINE	RURAL	0.445	0.438
MAINE	URBAN	0.449	0.453
MICHIGAN	RURAL	0.303	0.305
MICHIGAN	URBAN	0.302	0.305
MINNESOTA	RURAL	0.470	0.482
MINNESOTA	URBAN	0.321	0.320
MISSOURI	RURAL	0.242	0.243
MISSOURI	URBAN	0.263	0.260
MISSISSIPPI	RURAL	0.226	0.224
MISSISSIPPI	URBAN	0.183	0.189
MONTANA	RURAL	0.431	0.434
MONTANA	URBAN	0.384	0.386
NORTH CAROLINA	RURAL	0.253	0.251
NORTH CAROLINA	URBAN	0.254	0.257
NORTH DAKOTA	RURAL	0.322	0.322
NORTH DAKOTA	URBAN	0.414	0.421
NEBRASKA	RURAL	0.318	0.318
NEBRASKA	URBAN	0.254	0.252
NEW HAMPSHIRE	RURAL	0.317	0.323
NEW HAMPSHIRE	URBAN	0.292	0.291
NEW JERSEY	URBAN	0.207	0.212
NEW MEXICO	RURAL	0.256	0.264
NEW MEXICO	URBAN	0.278	0.288
NEVADA	RURAL	0.234	0.233
NEVADA	URBAN	0.162	0.167
NEW YORK	RURAL	0.420	0.419
NEW YORK	URBAN	0.367	0.356
OHIO	RURAL	0.321	0.320
OHIO	URBAN	0.237	0.234

TABLE 12—PROPOSED CY 2013 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2013 default CCR	Previous default CCR (CY 2012 OPPS final rule)
OKLAHOMA	RURAL	0.239	0.239
OKLAHOMA	URBAN	0.213	0.217
OREGON	RURAL	0.314	0.311
OREGON	URBAN	0.335	0.328
PENNSYLVANIA	RURAL	0.266	0.270
PENNSYLVANIA	URBAN	0.200	0.199
PUERTO RICO	URBAN	0.504	0.492
RHODE ISLAND	URBAN	0.264	0.270
SOUTH CAROLINA	RURAL	0.210	0.211
SOUTH CAROLINA	URBAN	0.215	0.214
SOUTH DAKOTA	RURAL	0.307	0.307
SOUTH DAKOTA	URBAN	0.252	0.252
TENNESSEE	RURAL	0.210	0.211
TENNESSEE	URBAN	0.195	0.199
TEXAS	RURAL	0.235	0.236
TEXAS	URBAN	0.205	0.196
UTAH	RURAL	0.373	0.379
UTAH	URBAN	0.359	0.359
VIRGINIA	RURAL	0.227	0.226
VIRGINIA	URBAN	0.237	0.239
VERMONT	RURAL	0.408	0.407
VERMONT	URBAN	0.384	0.384
WASHINGTON	RURAL	0.366	0.368
WASHINGTON	URBAN	0.301	0.298
WISCONSIN	RURAL	0.352	0.351
WISCONSIN	URBAN	0.310	0.311
WEST VIRGINIA	RURAL	0.281	0.280
WEST VIRGINIA	URBAN	0.341	0.337
WYOMING	RURAL	0.379	0.386
WYOMING	URBAN	0.301	0.302

E. Proposed OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (called either transitional corridor payments or transitional outpatient payments (TOPs)) if the payments it received for covered OPD services under the OPPS were less than the payments it would have received for the same services under the prior reasonable cost-based system (referred to as the pre-BBA amount). Section 1833(t)(7) of the Act provides that the TOPs were temporary payments for most providers and intended to ease their transition from the prior reasonable cost-based payment system to the OPPS system. There are two types of hospitals excepted from the policy described above, cancer hospitals and children's hospitals. Specifically, such a hospital could receive TOPs to the extent its PPS amount was less than its pre-BBA amount in the applicable year. Section 1833(t)(7)(D)(i) of the Act originally provided for TOPs to rural hospitals with 100 or fewer beds for covered OPD services furnished before January 1, 2004. However, section 411 of Public Law 108–173 (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) amended section 1833(t)(7)(D)(i) of the Act to extend these payments through December 31, 2005, for rural hospitals with 100 or fewer beds. Section 411 also extended the TOPs to sole community hospitals (SCHs) located in rural areas for services furnished during the period that began with the provider's first cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. Accordingly, the authority for making TOPs under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Public Law 108–173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Public Law 109–171 (the Deficit Reduction Act of 2005) extended the TOPs for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. Section 5105 of Public Law 109–171 also reduced the TOPs to rural hospitals from 100 percent of the difference between the provider's OPPS payments and the pre-BBA amount. This provision provided that, in cases in which the OPPS payment was less than the provider's pre-BBA amount, the amount of payment would be increased by 95 percent of the amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Public Law 109–171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs applied to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, by law, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Public Law 109–171. However, we stated they were eligible for the adjustment for rural SCHs authorized under section 411 of Public Law 108–173. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated § 419.70(d) of our regulations to reflect the requirements of Public Law 109–171.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41461), we stated that, effective for services provided on or after January 1, 2009, rural hospitals with 100 or fewer beds that are not SCHs would no longer be eligible for TOPs, in accordance with section 5105 of Public Law 109–171. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 147 of Public Law 110–275 (the Medicare Improvements for Patients and Providers Act of 2008) amended section 1833(t)(7)(D)(i) of the Act by extending the period of TOPs to rural hospitals with 100 beds or fewer for 1 year, for services provided before January 1, 2010. Section 147 of Public Law 110–275 also extended TOPs to SCHs (including EACHs) with 100 or fewer beds for covered OPD services provided on or after January 1, 2009, and before January 1, 2010. In accordance with section 147 of Public Law 110–275, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2009.

For CY 2009, we revised our regulations at §§ 419.70(d)(2) and (d)(4) and added a paragraph (d)(5) to incorporate the provisions of section 147 of Public Law 110–275. In addition, we made other technical changes to § 419.70(d)(2) to more precisely capture our existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of § 419.70.

For CY 2010, we made a technical correction to the heading of § 419.70(d)(5) to correctly identify the policy as described in the subsequent regulation text. The paragraph heading now indicates that the adjustment applies to small SCHs, rather than to rural SCHs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Public Law 110–275. However, subsequent to issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act (Pub. L. 111–148) amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act and extended the period of TOPs to SCHs (including EACHs) for 1 year, for services provided before January 1, 2011, and section 3121(b) of the Affordable Care Act removed the 100-bed limitation applicable to such SCHs for covered OPD services furnished on and after January 1, 2010, and before January 1, 2011. In accordance with section 3121 of the Affordable Care Act, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2010. Accordingly, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71882), we updated § 419.70(d) of the regulations to reflect the self-implementing TOPs extensions and amendments described in section 3121 of the Affordable Care Act.

Section 108 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) extended for 1 year the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the hospital is increased by 85 percent of the amount of the difference between the two payments. In addition, section 108 of the MMEA also extended for 1 year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) and removed the 100-bed limit applicable to such SCHs for covered OPD services furnished on or after January 1, 2010, and before January 1, 2012. Therefore, for such hospitals, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the hospital is increased by 85 percent of the amount of the difference between the two payments. Effective for services provided on or after January 1, 2012, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including EACHs) are no longer be eligible for TOPs, in accordance with section 108 of the MMEA. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74199), we revised our regulations at § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, section 308 of the Temporary Payroll Tax Cut Continuation Act of CY 2011 (Pub. L. 112–78), as amended by section 3002 of the Middle Class Tax Relief and Jobs Creation Act (Pub. L. 112–96), extended through December 31, 2012, the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments.

Section 308 of Public Law 112–78 also extended through February 29, 2012 the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, without the bed size limitation. Therefore, for such hospitals, for services furnished before March 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. However, section 3002 of Public Law 112–96 extended through December 31, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, that has no more than 100 beds. Therefore, for such hospitals, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. Accordingly, we are proposing to revise § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 308 of Public Law 112–78 and section 3002 of Public Law 112–96.

Effective for services provided on or after March 1, 2012, SCHs (including EACHs) with greater than 100 beds are no longer eligible for TOPs, in accordance with section 308 of Public Law 112–78. Effective for services provided on or after January 1, 2013, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including an EACH) are no longer eligible for TOPs, in accordance with section 3002 of Public Law 112–96.

2. 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 Public Law 108–173. Section 411 gave 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 CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, 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) to clarify that EACHs are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three 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 copayment. As we stated in the CY 2006 OPPS final rule with comment period (70 FR 68560), 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 2012. 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 2013 OPPS, we are proposing to continue our policy of a budget neutral 7.1 percent payment adjustment 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 (76 FR 46232). We intend to reassess the 7.1 percent adjustment in the future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims data, cost reports, and provider information.

F. Proposed OPPS Payments 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), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act (cancer hospitals) under the OPPS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act. These 11 cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Congress created section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to serve as a permanent payment floor by limiting cancer hospitals' potential losses under the OPPS. Through 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 TOPs to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA'' payment amount is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital. 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 and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, 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 the costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. In addition, section 3138 of the Affordable Care Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 3138 of the Affordable Care Act provides that if the Secretary determines that cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. After conducting the study required by section 3138, we determined in 2012 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 our findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPPS hospitals, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects the 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 each of the 11 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 CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91.

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2013

For CY 2013, we are proposing to continue our policy to provide additional payments to 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 this proposed rule. To calculate the proposed CY 2013 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 2013 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 2011 claims data that we used to model the impact of the proposed CY 2013 APC relative weights (3,975 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2013 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2010 to 2011. We then removed the cost report data of the 48 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 177 hospitals with 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 3,750 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 91 percent of reasonable cost (weighted average PCR of 0.91). Based on these data, we are proposing a target PCR of 0.91 that would be used to determine the CY 2013 cancer hospital payment adjustment that would be paid at cost report settlement. 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 0.91 for each cancer hospital.

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2011, the outlier threshold was determined to be met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outlier payments to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple 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 rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. However, we implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009, in our CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy for the past several years 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 2011 OPPS payment, using available CY 2011 claims and the revised OPPS expenditure estimate for the 2012 Trustee's Report, is approximately 1.06 percent of the total aggregated OPPS payments. Therefore, for CY 2011, we estimate that we paid 0.06 percent above the CY 2011 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887 through 71889), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2011. The outlier thresholds were set so that estimated CY 2011 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2011 claims data and CY 2012 payment rates, we currently estimate that the aggregate outlier payments for CY 2012 will be approximately 1.03 percent of the total CY 2012 OPPS payments. The difference between 1.0 percent and 1.03 percent is reflected in the regulatory impact analysis in section XXII. of this proposed rule. We note that we provide proposed estimated CY 2013 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 2013, 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 for outlier payments. We are proposing that a portion of that 1.0 percent, an amount equal to 0.12 percent of outlier payments (or 0.0012 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.C. 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 APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2013 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 the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,400 fixed-dollar threshold. This proposed threshold reflects the methodology discussed below in this section, as well as the

proposed APC recalibration for CY 2013.

We calculated the proposed fixed-dollar threshold for this proposed rule using largely the same methodology as we did in CYs 2011 and 2012 (75 FR 71887 through 71889 and 76 FR 74207 through 74209). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2012 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years. For this proposed rule, we used CY 2011 claims to model the CY 2013 OPPS. In order to estimate the proposed CY 2013 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2011 claims using the same inflation factor of 1.1406 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). We used an inflation factor of 1.0680 to estimate CY 2012 charges from the CY 2011 charges reported on CY 2011 claims. The methodology for determining this charge inflation factor is discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). 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, for this CY 2013 OPPS/ASC proposed rule, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the proposed FY 2013 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2013 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2013, we are proposing to apply an adjustment factor of 0.9790 to the CCRs that were in the April 2012 OPSF to trend them forward from CY 2012 to CY 2013. The methodology for calculating this proposed adjustment was discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142 through 28144). We note that due to the issue described in the IPPS proposed rule correction notice published on June 11, 2012, the operating and capital CCR inflation factors were reversed (77 FR 34326). In estimating the proposed CY 2013 OPPS fixed-dollar outlier threshold, we have applied the corrected CCR inflation factor.

Therefore, to model hospital outlier payments for this CY 2013 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2012 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9644 to approximate CY 2013 CCRs) to charges on CY 2011 claims that were adjusted (using the proposed charge inflation factor of 1.1406 to approximate CY 2013 charges). We simulated aggregated CY 2013 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 2013 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,400, 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. We are proposing to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of $2,400 are met. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 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 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 our policy that we implemented in CY 2010 that the hospitals' costs would 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 XV. of this proposed rule.

3. Proposed Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 CFR 68599), we adopted as final policy a process to reconcile hospital or CMHC outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. OPPS outlier reconciliation more fully ensures accurate outlier payments for those facilities that have CCRs that fluctuate significantly relative to the CCRs of other facilities, and that receive a significant amount of outlier payments (73 FR 68598). As under the IPPS, we do not adjust the fixed-dollar threshold or the amount of total OPPS payments set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, and as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596), we are proposing for CY 2013, to not incorporate any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold.

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 proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative 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 2013 scaled weight for the APC by the proposed CY 2013 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 XV. of this proposed rule.

We demonstrate in the steps below 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: ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' or ''X'' (as defined in Addendum D1 to this proposed rule), 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.

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 national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2013 OPPS fee schedule increase factor of 2.1 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. We confirmed that this labor-related share for hospital 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).

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. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2013 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 Public Law 98–21. We note that the reclassifications of hospitals under section 508 of Public Law 108–173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extended section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) extended section 508 and certain additional special exception hospital reclassifications from October 1, 2011 through March 31, 2012. Therefore, these reclassifications will not apply to the CY 2013 OPPS. (For further discussion of the proposed changes to the FY 2013 IPPS wage indices, as applied to the CY 2013 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.

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 associated proposed wage index increase developed for the FY 2013 IPPS and listed as Table 4J in the FY 2013 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 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, 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 proposed rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071

We have provided examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we use a provider that is located in Brooklyn, New York that is assigned to CBSA 35644. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The proposed CY 2013 full national unadjusted payment rate for APC 0019 is $337.48. The proposed reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR Program requirements is $330.73. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The proposed FY 2013 wage index for a provider located in CBSA 35644 in New York is 1.2991. The proposed labor-related portion of the full national unadjusted payment is $263.05 (.60 * $337.48 * 1.2991). The labor-related portion of the proposed reduced national unadjusted payment is $257.79 (.60 * $330.73 * 1.2991). The nonlabor-related portion of the full national unadjusted payment is $134.99 (.40 * $337.48). The nonlabor-related portion of the proposed reduced national unadjusted payment is $132.29 (.40 * $330.73). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is $398.04 ($263.05 + $134.99). The sum of the reduced national adjusted payment is $390.08 ($257.79 + $132.29).

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 to the amount of the inpatient deductible.

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 colonscopies, 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 2013, 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, 2013, 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 XV. of this proposed rule, for CY 2013, 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 APC 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. The CY 2013 proposal to base APC relative weights on geometric mean costs also affects proposed APC payment rates and, through them, the corresponding beneficiary copayments. However, as described in the CY 2004 OPPS/ASC 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). For a more detailed discussion of the proposal to base the APC relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule.

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 APC 0019, $67.50 is 20 percent of the full national unadjusted payment rate of $337.48. For APCs with only a minimum unadjusted copayment in Addenda A and B of 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 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 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, 2013, 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 2013 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

Also, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible.

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 medical services and procedures;
- 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. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS 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. In Table 13 below, we summarize our proposed process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. Because the payment rates associated with codes effective July 1 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2012 OPPS quarterly update CR could not be included in Addendum B to this proposed rule. Nevertheless, we are requesting public comments on the codes included in the July 2012 OPPS quarterly update and including these codes in the preamble to this proposed rule.

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, 2012	Level II HCPCS Codes	April 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
July 1, 2012	Level II HCPCS Codes	July 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
October 1, 2012	Level II HCPCS Codes	October 1, 2012	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.

TABLE 13—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES—Continued

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
January 1, 2013	Level II HCPCS Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we solicited public comments in this CY 2013 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2013 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, 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 2012 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, which were subject to public comment following publication of the CY 2012 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 2013 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2012 Level II HCPCS and CPT Codes Effective April 1, 2012 and July 1, 2012 for Which We Are Soliciting Public Comments in This CY 2013 Proposed Rule

Through the April 2012 OPPS quarterly update CR (Transmittal 2418, Change Request 7748, dated March 2, 2012) and the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2012, we made effective 13 new Level II HCPCS codes and 7 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2012 update and another 8 new Level II HCPCS codes were effective for the July 2012 update for a total of 13. Seven new Category III CPT codes were effective for the July 2012 update. Of the 13 new Level II HCPCS codes, we recognized for separate payment 11 of these codes, and of the 7 new Category III CPT codes, we recognized for separate payment all 7 new Category III CPT codes, for a total of 18 new Level II HCPCS and Category III CPT codes that are recognized for separate payment for CY 2013.

Through the April 2012 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 14 below, we provided separate payment for the following HCPCS codes:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial)
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.))
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg)
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial)
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography)

In this proposed rule, we are proposing to assign the Level II HCPCS codes listed in Table 14 to the specific proposed APCs and status indicators for CY 2013.

TABLE 14—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291*	Injection, aflibercept, 2 mg vial	G	9291
C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

*Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 effective July 1, 2012.

Through the July 2012 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2012, we allowed separate payment for six of the eight new Level II HCPCS codes. Specifically, as displayed in Table 15 of this proposed rule, we provided separate payment for the following HCPCS codes:

- HCPCS code C9368 (Grafix core, per square centimeter)
- HCPCS code C9369 (Grafix prime, per square centimeter)
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg)
- HCPCS code Q2046 (Injection, aflibercept, 1 mg)
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg)
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg)

We note that three of the Level II HCPCS Q-codes that were made effective July 1, 2012, were previously

described by HCPCS J-codes or C-codes that were separately payable under the hospital OPPS. First, HCPCS code Q2045 replaced HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg), beginning July 1, 2012. HCPCS code J1680 was assigned to status indicator ''K'' (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment) on January 1, 2012. However, because HCPCS code J1680 is replaced by HCPCS code Q2045 effective July 1, 2012, we changed its status indicator to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2045 describes the same drug as HCPCS code J1680, we continued its separate payment status and assigned it to status indicator ''K'' effective July 1, 2012. However, because the dosage descriptor for HCPCS code Q2045 is not the same as HCPCS code J1680, we assigned HCPCS code Q2045 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2045 is assigned to APC 1414 (Human fibrinogen conc inj) effective July 1, 2012.

Second, HCPCS code Q2046 replaced HCPCS code C9291 (Injection, aflibercept, 2 mg vial) effective July 1, 2012. HCPCS code C9291 was assigned pass-through status when it was made effective April 1, 2012. Because HCPCS code Q2046 describes the same product as HCPCS code C9291, we continued its pass-through status and assigned HCPCS code Q2046 to status indicator ''G'' as well as assigned it to the same APC, specifically APC 9291 (Injection, aflibercept), effective July 1, 2012. HCPCS code C9291 is deleted effective June 30, 2012.

Third, the HCPCS Workgroup replaced HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) with new HCPCS code Q2048, effective July 1, 2012. Consequently, the status indicator for HCPCS code J9001 is changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2048 describes the same drug as HCPCS code J9001, we continued its separate payment status and assigned HCPCS code Q2048 to status indicator ''K'' effective July 1, 2012. In addition, because, HCPCS code Q2049 is similar to HCPCS code Q2048, we assigned HCPCS code Q2049 to status indicator ''K'' effective July 1, 2012.

Of the 15 HCPCS codes that were made effective July 1, 2012, we did not recognize for separate payment two HCPCS codes because they are both paid under a payment system other than OPPS. Specifically, HCPCS code Q2047 (Injection, peginesatide, 0.1 mg (for ESRD on dialysis)) is assigned to status indicator ''A'' (Not paid under OPPS; paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS), and HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu)) is assigned to status indicator ''L'' (Not paid under OPPS; paid at reasonable cost).

Table 15 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2012, with their proposed status indicators, proposed APC assignments, and proposed payment rates for CY 2013.

TABLE 15—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC	Proposed CY 2013 payment rate
C9368	Grafix core, per square centimeter	G	9368	$7.96
C9369	Grafix prime, per square centimeter	G	9369	0.61
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A	N/A
Q2045*	Injection, human fibrinogen concentrate, 1 mg	K	1414	0.73
Q2046**	Injection, aflibercept, 1 mg	G	1420	980.50
Q2047	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)	A	N/A	N/A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046	537.21
Q2049†	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421	498.26

*HCPCS code Q2045 replaced HCPCS code J1680 effective July 1, 2012. The status indicator for HCPCS code J1680 was changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. The proposed payment rate for HCPCS code Q2045 is based on ASP+6 percent.

**HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012.

***HCPCS code Q2048 replaced HCPCS code J9001 effective July 1, 2012. The status indicator for HCPCS code J9001 was changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. The proposed payment rate for HCPCS code Q2048 is based on ASP+6 percent.

†The proposed payment rate for HCPCS code Q2049 is based on ASP+6 percent.

For CY 2013, we are proposing to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I CPT vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2012 update, there were no new Category I CPT vaccine codes. Through the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we allowed separate payment for all seven new Category III CPT codes effective July 1, 2012. Specifically, as displayed in Table 16 of this proposed rule, we allowed separate payment for the following Category III CPT codes:

- CPT code 0302T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode))
- CPT code 0303T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only)
- CPT code 0304T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only)
- CPT code 0305T (Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report)

• CPT code 0306T (Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report)

• CPT code 0307T (Removal of intracardiac ischemia monitoring device)

• CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens)

Table 16 below lists the Category III CPT codes that were implemented in July 2012, along with their proposed status indicators, proposed APC assignments, where applicable, and proposed payment rates for CY 2013.

TABLE 16—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012

CY 2012 CPT code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC	Proposed CY 2013 payment rate
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode).	T	0089	$8,275.79
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only.	T	0106	3,780.92
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only.	T	0090	6,663.83
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report.	S	0690	33.92
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report.	S	0690	33.92
0307T	Removal of intracardiac ischemia monitoring device	T	0105	1,718.55
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens.	T	0234	1,669.74

We are soliciting public comments on the CY 2013 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2012, and July 1, 2012, through the respective OPPS quarterly update CRs. These codes are listed in Tables 14, 15, and 16 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2013 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include the codes, their proposed status indicators, proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes are listed in Tables 15 and 16, respectively. We are proposing to incorporate these codes into Addendum B to the CY 2013 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2012 OPPS update CR and displayed in Table 14 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2013 payment rates are also shown.

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2012 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2013 for Which We Will Be Soliciting Public Comments in the CY 2013 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have 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 updating the OPPS for the following calendar year. For CY 2013, these codes will be flagged with comment indicator ''NI'' in Addendum B 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, the CPT and Level II HCPCS codes that will be effective January 1, 2013, will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. We are proposing to continue this process for CY 2013. Specifically, for CY 2013, we are proposing to include in Addendum B to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013 (including the Category III CPT codes that are released by the AMA in July 2012) that would be incorporated in the January 2013 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012, or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 OPPS quarterly update CRs. The October 1, 2012 and January 1, 2013 codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2013 OPPS/ASC final rule

with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2013. We are proposing that their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

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 have also developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. For example, packaged items and services include:

(a) Use of an operating, treatment, or procedure room;

(b) Use of a recovery room;

(c) Observation services;

(d) Anesthesia;

(e) Medical/surgical supplies;

(f) Pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of this proposed rule);

(g) Incidental services such as venipuncture;

(h) Guidance services, image processing services, intraoperative services, imaging, supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media.

Further discussion of packaged services is included in section II.A.3. of this proposed rule.

In CY 2008, we implemented 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 (72 FR 66650 through 66652). Under CY 2012 OPPS policy, we provide composite APC payment for certain extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, multiple imaging services, and cardiac resynchronization therapy services. Further discussion of composite APCs is included in section II.A.2.e. 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. Each APC weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 0606 (Level 3 Hospital Clinic Visits). The APC weights are scaled to APC 0606 because it is the middle level hospital clinic visit APC (the Level 3 hospital clinic visit CPT code out of five levels), and because middle level hospital clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments 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. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights recommendations for specific services for the CY 2013 OPPS and our responses to them are discussed in the relevant specific sections throughout this proposed rule).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). For CY 2013, we are proposing to use the cost of the item or service in implementing this provision, as discussed in section II.A.2.f. of this proposed 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).

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 cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. 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 cost to be significant (75 FR 71832). 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 100 million single procedure or single session claims we use for establishing 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 cost. In this proposed rule, 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 CY 2013.

We have identified APCs with 2 times violations for which we are proposing

changes to their HCPCS codes' APC assignments in Addendum B (available via the Internet on the CMS Web site) to this proposed rule. In these cases, to eliminate a 2 times violation or to improve clinical and resource homogeneity, we are proposing to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2013 included in the proposed rule are related to changes in costs of services that were observed in the CY 2011 claims data newly available for CY 2013 ratesetting. We also are proposing changes to the status indicators for some codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for some 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 2013. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. Addendum B to this CY 2013 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those HCPCS codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2012 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 Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low volume items and services. Taking into account the APC changes that we are proposing for CY 2013, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then we used the following criteria to decide 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.

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).

Table 17 of this proposed rule lists 21 APCs that we are proposing to exempt from the 2 times rule for CY 2013 based on the criteria cited above and based on claims data processed from January 1, 2011, through December 31, 2011. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2011, and December 31, 2011, that were processed on or before June 30, 2012, and updated CCRs, if available. Based on the CY 2011 claims data, we found 21 APCs with 2 times rule violations. We applied the criteria as described earlier to identify the APCs that we are proposing as exceptions to the 2 times rule for CY 2013, and identified 21 APCs that meet the criteria for exception to the 2 times rule for this proposed rule. We have not included in this count those APCs where a 2 times violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), with an APC cost set based on multiple procedure claims. Therefore, we have identified only APCs, including those with criteria-based costs, such as device-dependent APCs, with 2 times rule violations. These proposed APC exceptions are listed in Table 17 below.

TABLE 17—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0006	Level I Incision & Drainage.
0012	Level I Debridement & Destruction.
0045	Bone/Joint Manipulation Under Anesthesia.
0057	Bunion Procedures.
0060	Manipulation Therapy.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0173	Level II Partial Hospitalization (4 or more services) for CMHCs.
0230	Level I Eye Tests & Treatments.
0272	Fluoroscopy.
0325	Group Psychotherapy.
0330	Dental Procedures.
0340	Minor Ancillary Procedures.
0369	Level III Pulmonary Tests.
0403	Level I Nervous System Imaging.
0409	Red Blood Cell Tests.
0604	Level 1 Hospital Clinic Visits.
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing.
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver.
0690	Level I Electronic Analysis of Devices.

The proposed 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/index.html*.

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.

We note that the cost bands for New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500–$600)) is made at $550. Currently, there are 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level IA ($0–$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500–$10,000). In CY 2004 (68 FR 63416), we last 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'' (Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

Every year we receive many requests for higher payment amounts under our New Technology APCs for specific procedures 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 in cost-efficient settings, 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 our 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. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies.

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

2. Proposed Movement of Procedures From New Technology APCs to Clinical APCs

As we explained in the November 30, 2001 final rule (66 FR 59902), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original 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 most appropriately reflects its cost.

Consistent with our current policy, for CY 2013, we are proposing to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move 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 collected.

Currently, in CY 2012, there are three procedures described by HCPCS G-codes receiving payment through a New Technology APC. Specifically, HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21–40 specimens) is assigned to New Technology APC 1505 (New Technology—Level V ($300–$400)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens) is assigned to New Technology APC 1506 (New Technology—Level VI ($400–$500)); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens) is assigned to New Technology APC 1508 (New Technology—Level VIII ($600–$700)). These HCPCS codes have been assigned to New Technology APCs since CY 2009.

Analysis of the hospital outpatient data for claims submitted for CY 2011 indicates that prostate saturation biopsy procedures are rarely performed on Medicare beneficiaries. For OPPS claims submitted from CY 2010 through CY 2011, our claims data show no single claim submitted for HCPCS code G0417 in CY 2010 or in CY 2011. Similarly, our claims data did not show any hospital

outpatient claims for HCPCS codes G0418 and G0419 from either CY 2010 or CY 2011. Given the continued lack of cost data for these HCPCS codes, we are proposing to reassign these procedures to an APC that is appropriate from a clinical standpoint. Specifically, we are proposing to reassign HCPCS G-codes G0417, G0418, and G0419 to clinical APC 0661 (Level V Pathology), which has a proposed APC cost of approximately $160 for CY 2013. We believe that all three procedures, as described by HCPCS codes G0417, G0418, and G0419, are comparable clinically to other pathology services currently assigned to APC 0661 and likely require similar resources.

Table 18 below lists the HCPCS G-codes and associated status indicators that we are proposing to reassign from New Technology APCs 1505, 1506, and 1508 to APC 0661 for CY 2013.

TABLE 18—PROPOSED REASSIGNMENT OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCS FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
G0417	Sat biopsy prostate 21–40	S	1505	X	0661
G0418	Sat biopsy prostate 41–60	S	1506	X	0661
G0419	Sat biopsy prostate: >60	S	1508	X	0661

3. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

a. Background

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the elderly (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 Administration has established an agenda 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 5-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.

Full Cost Recovery, which is routinely considered in CMS reimbursement, is the accounting practice used by producers and suppliers to describe the recovery of all contributing costs. Unlike legacy sources that often benefit from government subsidized multi-function facilities, the cost of these alternative methods will be increased over the cost of medical radioisotopes produced using HEU because hospitals' payments to producers and suppliers will have to cover capital expense (such as, for example, the cost of building new reactors, particle accelerators, or other very long term investments), as well as all other new industry-specific ancillary costs (such as, for example, the cost of long-term storage of radioactive waste). Hospitals that use medical radioisotopes that are produced from non-HEU sources can expect producers and suppliers to pass on to them the full impact of these costs.

In the short term, some hospitals will be able to depend on low cost legacy producers using aging subsidized reactors while other hospitals will be forced to absorb the full cost of non-HEU alternative sources. Over several years, we believe that these cost differentials will promote increased regional shortages and create larger cost differentials and greater cost variations between hospitals. As a result, we believe this change in supply source will create a significant payment inequity among hospitals resulting from factors that are outside of normal market forces.

b. Proposed Payment Policy

We are proposing to exercise our authority to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS in accordance with section 1833(t)(2)(E) of the Act. We do not believe that we can ensure equitable payments to hospitals over the next 4 to 5 years in the absence of an adjustment to account for the significant payment inequities created by factors that will likely arise due to the change in supply source for the radioisotope used commonly in modern medical imaging procedures. We are proposing to provide an adjustment for the marginal cost for radioisotopes produced from non-HEU sources over the costs for radioisotopes produced by HEU sources. We believe such an adjustment would ensure equitable payments in light of the Administration's HEU agenda, market influences, cost differentials, and cost variations that will create significant payment inequities among hospitals.

For CY 2013, we are proposing to make an additional payment of $10, which is an amount based on the best available estimations of the marginal costs associated with non-HEU Tc-99m production as calculated using Full Cost Recovery. We are proposing to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per dose) to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure. Hospitals would be able to report this code once per dose along with any diagnostic scan or scans using Tc-99m as long as the Tc-99m doses used can be certified by the hospital as coming from non-HEU sources and have been priced using a Full Cost Recovery accounting methodology. The code would pay hospitals for the additional (marginal) cost of using Tc-99m from a non-HEU source.

Hospitals would not be required to make a separate certification of the non-HEU source on the claim; the inclusion of the proposed new HCPCS QXXXX code on the claim would indicate that the hospital has met the conditions of the service definition as it does for any billed service. However, in the event of an audit, hospitals would be expected to be able to produce documentation that the individual dose delivered to the patient was completely produced from a non-HEU source. We are proposing three ways in which hospitals could accomplish this.

First, the hospital could produce documentation such as invoices or patient dose labels or tracking sheets that indicated that the patient's dose was completely produced from non-HEU sources and priced based on Full Cost Recovery. In this first case, the supplier would be expected to be able to trace a specific dose to a completely

non-HEU batch. Current pharmacy recordkeeping is generally able to trace all components of radiopharmaceuticals back to their source production batches. A hospital would not be compliant with the code definition if the documentation indicated the supplier had produced a mixed batch and labeled a fraction of the doses equal to the non-HEU fraction in the batch.

Second, a hospital could produce documentation that the entire batch of Tc-99m doses derives from non-HEU sources for a specified period of time, for example, the time that a single non-HEU based generator is in use. This approach would obviate the need for specific dose tracking from a claims audit perspective, although that information is typically required for other purposes. An attestation from the generator supplier would be sufficient evidence for the hospital, as would invoices that showed that all Tc-99m during a specified period came from inherently non-HEU alternative sources.

Third, if the industry should implement labeling of generators and/or doses with labels attesting to 100 percent non-HEU sources priced at Full Cost Recovery, documentation of labeled isotope usage using either the specific dose approach or the 100 percent hospital usage approach could provide evidence of hospital compliance. The hospital would be required to retain appropriate documentation within the hospital (including pharmacy) records but would not need to keep any specific documentation within the individual medical record. Also, we would consider a dose to be priced for Full Cost Recovery when the supplier could attest that the supply chain adheres to usual industry practices to account for Full Cost Recovery, specifically including the capital cost of sustainable production and the environmental cost of waste management.

To reduce the administrative overhead for hospitals, we are proposing not to require hospitals to separately track additional costs for the non-HEU Tc-99m, but to include the cost of the radioisotope in the cost of the diagnostic radiopharmaceutical as usual, reporting only a token $1 charge for the HCPCS QXXXX code line. We would continue to calculate the total costs of radionuclide scans using claims data, and would periodically recalculate the estimated marginal cost of non-HEU Full Cost Recovery sources using models relying on the best available industry reports and projections, and would adjust the payment for HCPCS QXXXX code accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS QXXXX code payment. We believe this proposal would allow us to continuously compensate for unanticipated changes in Tc-99m cost attributable to new non-HEU supply sources.

D. Proposed OPPS APC-Specific Policies

1. Placement of Amniotic Membrane (APC 0233)

In CY 2011, the AMA CPT Editorial Panel revised the long descriptor for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to include the words ''multiple layers'' to further clarify the code descriptor. In addition, the AMA CPT Editorial Panel created two new CPT codes that describe the placement of amniotic membrane on the ocular surface without reconstruction: one describing the placement of a self-retaining (non-sutured/non-glued) device on the surface of the eye; and the other describing a single layer of amniotic membrane sutured to the surface of the eye. Specifically, the AMA CPT Editorial Panel established CPT codes 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured), effective January 1, 2011.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedures before assigning them to an APC. In determining the APC assignments for CPT codes 65778 and 65779, we took into consideration the clinical and resource characteristics involved with placement of amniotic membrane products on the eye for wound healing via a self-retaining device and a sutured, single-layer technique. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72402), we assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures), which had a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures), which had a payment rate of approximately $519.

In addition, consistent with our longstanding policy for new codes, we assigned these two new CPT codes to interim APCs for CY 2011. Specifically, we assigned CPT codes 65778 and 65779 to comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to indicate that the codes were new with an interim APC assignment that were subject to public comment. In accordance with our longstanding policy, our interim APC assignments for each code was based on our understanding of the resources required to furnish the service as defined in the code descriptor and on input from our physicians.

At the Panel's February 28–March 1, 2011 meeting, a presenter requested the reassignment of CPT codes 65778 and 65779 to APC 0244 (Corneal and Amniotic Membrane Transplant), which is the same APC to which CPT code 65780 is assigned. The presenter indicated that prior to CY 2011, the procedures described by CPT codes 65578 and 65779 were previously reported under the original version of CPT code 65780, which did not specify ''multiple layers,'' and as such these new codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the procedures described by CPT codes 65778 and 65779 are very similar to the procedure described by CPT code 65780.

The Panel recommended that CMS reassign the APC assignments for both CPT codes 65778 and 65779. Specifically, the Panel recommended the reassignment of CPT code 65778 from APC 0239 to APC 0233(Level III Anterior Segment Eye Procedures), and the reassignment of CPT code 65779 from APC 0255 to APC 0233. In addition, the Panel recommended that CMS furnish data when data become available for these two codes. We noted at that time that because these codes were effective January 1, 2011, the first available claims data for these codes would be for the CY 2013 OPPS rulemaking cycle.

We accepted the Panel's recommendations. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74247), we indicated that, while we agreed with the Panel's recommendation to reassign CPT codes 65778 and 65779 to APC 0233, we believed that CPT code 65778 should be assigned to a conditionally packaged status indicator of ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator ''T''; but in all other circumstances, the code would be paid separately. Because the procedure described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD, and because the procedure would almost exclusively be provided in addition to and following another procedure or service, we proposed to reassign CPT code 65778 to a conditionally packaged status indicator of ''Q2.'' In addition, our

medical advisors indicated that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used in the HOPD to cover the surface of the eye after a procedure that results in a corneal epithelial defect.

At the August 10–11, 2011 Panel Meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65778 for CY 2012, and instead, assign it to status indicator ''T.'' Based on information presented at the meeting, and after further discussion on the issue, the Panel recommended that CMS reassign the status indicator for CPT code 65778 from conditionally packaged ''Q2'' to status indicator ''T.'' Several commenters also urged CMS not to finalize its proposal to conditionally package CPT code 65778 by assigning it a status indicator ''Q2'' and instead adopt the Panel's recommendation to assign status indicator ''T.''

After consideration of the Panel's August 2011 recommendation and the public comments that we received to the CY 2012 OPPS/ASC proposed rule, we finalized our proposal and reassigned the status indicator for CPT code 65778 from ''T'' to ''Q2'' effective January 1, 2012 (76 FR 74246). Given the clinical characteristics of this procedure, we believed that conditionally packaging CPT code 65778 was appropriate under the OPPS.

For the CY 2013 OPPS update, we are proposing to continue to assign CPT code 65778 to its conditionally packaged status of ''Q2.'' Similarly, we believe that we should assign CPT code 65779 to a conditionally packaged status of ''Q2.'' Therefore, for CY 2013, we are proposing to revise the status indicator for CPT code 65779 from status indicator ''T'' to ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator ''T,'' but in all other circumstances, the code would be paid separately. This reassignment would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the OPPS.

As indicated at the February 28–March 1, 2011 Panel meeting, because CPT codes 65778 and 65779 were effective January 1, 2011, the first available claims data for these codes would be in CY 2012 for the CY 2013 OPPS rulemaking. We now have claims data for CPT codes 65778 and 65779, and our data show that both procedures are performed in the HOPD setting. Analysis of the CY 2011 claims data available for this proposed rule, which is based on claims processed from January 1 through December 31, 2011, reveals that the estimated cost for CPT code 65778 is approximately $1,025 based on 33 single claims (out of 130 total claims), and the estimated cost for CPT code 65779 is approximately $2,303 based on 35 single claims (out of 260 total claims). Based on the clinical similarity to other procedures currently assigned to APC 0233, and because there is no violation with the 2 times rule, we believe that we should continue to assign both CPT codes 65778 and 65779 to APC 0233, which has a proposed cost of approximately $1,150. Review of the procedures assigned to APC 0233 shows that the range of the CPT cost for the procedures with significant claims data is between approximately $859 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,397 (for CPT code 66840 (Removal of lens material)).

In summary, for CY 2013, we are proposing to continue to assign CPT code 65778 to its conditionally packaged status of ''Q2'' and to reassign the status indicator for CPT code 65779 from ''T'' to ''Q2,'' similar to CPT code 65778. In addition, we are proposing to continue to assign both CPT codes 65778 and 65779 to APC 0233, which has a proposed cost of approximately $1,150. Both procedures and their CY 2013 proposed APC assignments are displayed in Table 19 below.

TABLE 19—PROPOSED APC ASSIGNMENTS FOR CPT CODES 65778 AND 65779 FOR CY 2013

CY 2012 HCPCS code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
65778	Cover eye w/membrane	Q2	0233	Q2	0233
65779	Cover eye w/membrane suture	T	0233	Q2	0233

2. Proton Beam Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures, CPT code 77520 (Proton treatment delivery; simple, without compensation) with an estimated cost of approximately $331 (based on 185 single claims of 185 total claims submitted for CY 2011); and CPT code 77522 (Proton treatment delivery; simple, with compensation) with an estimated cost of approximately $1,191 (based on 14,279 single claims of 15,405 total claims submitted for CY 2011). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures, CPT code 77523 (Proton treatment delivery, intermediate) with an estimated cost of approximately $920 (based on 3,009 single claims of 3,202 total claims submitted for CY 2011), and CPT code 77525 (Proton treatment delivery, complex) with an estimated cost of approximately $483 (based on 1,400 single claims of 1,591 total claims submitted for CY 2011). Based on these CY 2011 claims data, the estimated cost of APC 0664 is approximately $1,171, and the estimated cost of APC 0667 is approximately $750.

Because only three providers bill Medicare for these services, their payment rates, which are set annually based on claims data according to the standard OPPS ratesetting methodology, may fluctuate significantly from year to year. For CY 2013, the estimated cost of APC 0664 is approximately the same as its CY 2012 payment rate of $1,184. However, the estimated cost of APC 0667 has decreased substantially, which is largely attributable to cost changes for CPT code 77523. For CY 2013, we are proposing to improve the resource homogeneity within the proton beam APCs by including the services requiring fewer resources in APC 0664 (Level I) and the services requiring greater resources in APC 0667 (Level II). Specifically, we are proposing to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. Under the proposed reassignment, the estimated cost of APC 0664 is $462 and the estimated cost of APC 0667 is $1,138. We are inviting public comments on this proposal.

3. Intraoperative Radiation Therapy (IORT) (APC 0412)

a. Background

The AMA CPT Editorial Panel created three new Category I CPT codes for intraoperative radiation therapy (IORT), effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session); 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session); and 77469 (Intraoperative radiation treatment management). As with all new CPT codes for CY 2012, these three codes were included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period (available via the CMS Web site), effective on January 1, 2012. In accordance with our standard practice each year, our clinicians review the many CPT code changes that will be effective in the forthcoming year and make decisions regarding status indicators and/or APC assignments based on their understanding of the nature of the services. We are unable to include proposed status indicators and/or APC assignments in the proposed rule for codes that are not announced by the AMA CPT Editorial Panel prior to the issuance of the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, interim status indicators and/or APC assignments for all new CPT codes that are announced by the AMA CPT Editorial Panel subsequent to the issuance of the OPPS/ASC proposed rule to enable payment for new services as soon as the codes are effective.

We identified the new codes for IORT for CY 2012 in Addendum B to the CY 2012 OPPS/ASC final rule with comment period as being open to public comment by showing a comment indicator of ''NI'' and made interim status indicator assignments for each of these new IORT codes, based on our understanding of the clinical nature of the services they describe. Specifically, for CY 2012, we packaged these IORT service codes with the surgical procedures with which they are billed, assigning them interim status indicators of ''N'' (Items and Services Packaged into APC Rates). We did so based on a policy that was adopted in the CY 2008 OPPS final rule with comment period (72 FR 66610 through 66659) to package services that are typically ancillary and supportive of a principal diagnostic or therapeutic procedure, which would generally include intraoperative services. Because IORT are intraoperative services furnished as a single dose during the time of the related surgical session, we packaged them into the payment for the principal surgical procedures with which they are performed based on claims data used for the CY 2012 OPPS/ASC final rule with comment period.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, stakeholders provided comments on the interim status of these IORT service codes for CY 2012, asserting that these services are not ancillary to the surgical procedures, urging us to unpackage these codes, and requesting that we assign them to an APC reflective of the resources used to provide the IORT services. The stakeholders argued that IORT services described by CPT codes 77424 and 77425 are separate, distinct, and independent radiation treatment services from the surgical services to remove a malignant growth. According to the commenters, IORT is performed separately by a radiation oncologist and a medical physicist when there is concern for residual unresected cancer because of narrow margins related to the surgical resection.

b. CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

Based on the comments and information received on the proposed IORT policies contained in the CY 2012 OPPS/ASC final rule with comment period, and after further review and consideration of those comments and the clinical nature of the IORT procedures, we agree that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. Therefore, for CY 2013, we are proposing to unpackage CPT codes 77424 and 77425, and assign them to APC 0412, currently entitled ''IMRT Treatment Delivery.'' IORT treatment services are clinically similar to other radiation treatment forms, such as IMRT treatment, which are assigned to APC 0412. Furthermore, we are proposing to change the title of APC 0412 to ''Level III Radiation Therapy'' to encompass a greater number of clinically similar radiation treatment modalities. The proposed rule cost of APC 0412 based on CY 2011 claims data is approximately $496. As is our normal procedure for new CPT codes, we will monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425.

We believe that CPT code 77469 should receive equal treatment to other radiation management codes, such as CPT code 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)), which are assigned status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPPS. Therefore, we are proposing that the appropriate status indicator code assignment for CPT code 77469 be ''B'' for nonpayable status under the OPPS for CY 2013, a change from its current CY 2012 status indicator assignment of ''N'' for packaged payment status.

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 requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. 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, which is the first date on which pass-through payment may be made for any medical device that is described by such category. 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.

There currently are four device categories eligible for pass-through payment. These device categories are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device

(implantable)), which we made effective for pass-through payment October 1, 2010; HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment January 1, 2012. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, we will package the C1749 device costs into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. Proposed CY 2013 Policy

As stated above, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Device pass-through categories C1830 and C1840 were established for pass-through payments on October 1, 2011, and will have been eligible for pass-through payments for more than 2 years but less than 3 years as of the end of CY 2013. Also, device pass-through category C1886 was established for pass-through payments on January 1, 2012, and will have been eligible for pass-through payments for at least 2 years but less than 3 years as of the end of CY 2013. Therefore, we are proposing a pass-through payment expiration date for device categories C1830, C1840, and C1886 of December 31, 2013. Under our proposal, beginning January 1, 2014, device categories C1830, C1840, and C1886 will no longer be eligible for pass-through payments, and their respective device costs would be packaged into the costs of the procedures with which the devices are reported in the claims data.

2. 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 (cost of device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (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 the device. 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 eligible device's pass-through payment amount. We have consistently employed 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.

We currently have published a list of all procedural APCs with the CY 2012 portions (both percentages and dollar amounts) 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*. 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 in CY 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).

b. Proposed CY 2013 Policy

For CY 2013, we are proposing to continue our 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. We are proposing to continue our policy, for CY 2013, that the pass-through evaluation process and pass-through 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. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). 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)).

For CY 2013, we also are proposing to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we are proposing to continue to calculate and set any device APC offset amount for a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2013 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts.

In addition, we are proposing to update, on the CMS Web site at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html, the list of all procedural APCs with the final CY 2013 portions (once available at the time of final rulemaking) of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2013 device pass-through payment applications and by CMS in reviewing those applications.

3. Proposed Clarification of Existing Device Category Criterion

a. Background

Section 1833(t)(6)(B)(ii)(IV) of the Act directs the Secretary to establish a new device category for pass-through payment for which none of the pass-through categories in effect (or that were previously in effect) is appropriate. Commenters who responded to our various proposed rules, as well as applicants for new device categories, had expressed concern that some of our existing and previously in effect device category descriptors were overly broad, and that the device category descriptors as they are currently written may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment (70 FR 68630 through 68631). As a result of these comments, we finalized a policy, effective January 1, 2006, to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where we believe that an existing or previously in effect category descriptor does not appropriately describe the new device. Accordingly, effective January 1, 2006, we revised § 419.66(c)(1) of the regulations to reflect this policy change. In order to determine if a new device is appropriately described by any existing or previously in effect category of devices, we apply two tests based upon our evaluation of information provided to us in the device category application. First, an applicant for a new device category must show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. Second, an applicant must demonstrate that utilization of its device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments, including procedures utilizing devices in any existing or previously in effect device categories. We consider a new device that meets both of these tests not to be appropriately described by any existing or previously in effect pass-through device categories (70 FR 68630 through 68631).

b. Proposed Clarification of CY 2013 Policy

For CY 2013, we are proposing to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. We are clarifying that this test includes showing that a new device is not similar to predicate devices that once belonged in any existing or previously in effect pass-through device categories. Under this test, a candidate device may not be considered to be appropriately described by any existing or previously in effect pass-through device categories if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) that belong or once belonged to an existing or any previously in effect device category, and that the candidate device is not similar to devices whose costs are reflected in the OPPS claims data in the most recent OPPS update. The substantial clinical improvement criterion, which also must be satisfied in every case, as indicated in § 419.66(c)(2) of our regulations, is separate from the criterion that a candidate device not be similar to devices in any existing or previously in effect pass-through categories. We are inviting public comments regarding this proposed clarification.

B. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

To ensure equitable payment when the 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 are instructed to report no cost/full credit cases 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, the hospital is 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, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its 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 are 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'' payment adjustment policies (72 FR 66743 through 66749).

2. Proposed APCs and Devices Subject to the Adjustment Policy

For CY 2013, we are proposing to continue the existing policy of reducing OPPS payment for specified APCs 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. (We refer readers to section II.A.2.d.(1) of this proposed rule for a description of our standard ratesetting methodology for device-dependent APCs.)

For CY 2013, 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 this policy applies (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 device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also are proposing to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an

inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We continue to believe these criteria are appropriate because free 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.

We examined the offset amounts calculated from the CY 2013 proposed rule data and the clinical characteristics of APCs to determine whether the APCs to which the no cost/full credit and partial credit device adjustment policy applied in CY 2012 continue to meet the criteria for CY 2013, and to determine whether other APCs to which the policy did not apply in CY 2012 would meet the criteria for CY 2013. Based on the CY 2011 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this policy applies.

Table 20 below lists the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013 and displays the proposed payment adjustment percentages for both no cost/full credit and partial credit circumstances. We are proposing that the no cost/full credit adjustment for each APC to which this policy would continue to apply would be the device offset percentage for the APC (the estimated percentage of the APC cost that is attributable to the device costs that are already packaged into the APC). We also are proposing that the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC.

Table 21 below lists the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013. We will update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply for CY 2013, consistent with the three criteria discussed earlier in this section, based on the final CY 2011 claims data available for the CY 2013 OPPS/ASC final rule with comment period.

We are proposing, for CY 2013, that OPPS payments for implantation procedures to which the ''FB'' modifier is appended are reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 21 below is present on the claim, and the procedure code maps to an APC listed in Table 20 below. We also are proposing that OPPS payments for implantation procedures to which the ''FC'' modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 21 is present on the claim and the procedure code maps to an APC listed in Table 20. Beneficiary copayment is based on the reduced amount when either the ''FB'' modifier or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

TABLE 20—PROPOSED APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC Title	Proposed CY 2013 device offset percentage for no cost/ full credit case	Proposed CY 2013 device offset percentage for partial credit case
0039	Level I Implantation of Neurostimulator Generator	86	43
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55	28
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	66	33
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70	35
0090	Insertion/Replacement of Pacemaker Pulse Generator	71	35
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	48	24
0107	Insertion of Cardioverter-Defibrillator	83	42
0108	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes	84	42
0227	Implantation of Drug Infusion Device	82	41
0259	Level VII ENT Procedures	84	42
0315	Level II Implantation of Neurostimulator Generator	88	44
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	87	44
0385	Level I Prosthetic Urological Procedures	63	31
0386	Level II Prosthetic Urological Procedures	70	35
0425	Level II Arthroplasty or Implantation with Prosthesis	58	29
0648	Level IV Breast Surgery	50	25
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74	37
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.	73	37
0680	Insertion of Patient Activated Event Recorders	74	37

TABLE 21—PROPOSED DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2013

Proposed CY 2013 device HCPCS Code	Proposed CY 2013 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

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 (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (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 (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. For those drugs and biologicals referred to as ''current,'' the transitional pass-through payment began 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.'' Under the 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 product's first payment as a hospital outpatient service under Medicare Part B. Proposed CY 2013 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 CAP program has been postponed since CY 2009, and such a program is not proposed to be reinstated for CY 2013.

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*.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the ''otherwise applicable Medicare OPD fee schedule'' amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. For CY 2012, we estimated the OPPS pass-through payment for drugs and biologicals to be $19 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2013 is $32 million, which is discussed in section VI.B. of this proposed rule.

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 Status in CY 2012

We are proposing that the pass-through status of 23 drugs and biologicals would expire on December 31, 2012, as listed in Table 22 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, 2012.

These drugs and biologicals were approved for pass-through status on or before January 1, 2011. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals and contrast agents, 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 $80), as discussed further in section V.B.2. of this proposed rule. If the drug's or biological's estimated per day cost 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 2013, as discussed further in section V.B.3. of this proposed rule). Section II.A.3.d. of this proposed rule discusses the packaging of all nonpass-through contrast agents and diagnostic radiopharmaceuticals.

TABLE 22—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2012

Proposed CY 2013 HCPCS Code	Proposed CY 2013 long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	N	N/A
C9279	Injection, ibuprofen, 100 mg	N	N/A
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K	9367
J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg	K	1413
J0588	Injection, incobotulinumtoxin A, 1 unit	K	9278
J0597	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	K	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	K	1340
J0840	Injection, crotalidae polyvalent immune fab (ovine), up to 1 gram	K	9274
J0897	Injection, denosumab, 1 mg	K	9272
J1290	Injection, ecallantide, 1 mg	K	9263
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	9270
J3095	Injection, telavancin, 10 mg	K	9258
J3262	Injection, tocilizumab, 1 mg	K	9264
J3357	Injection, ustekinumab, 1 mg	K	9261
J3385	Injection, velaglucerase alfa, 100 units	K	9271
J7183	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	N	N/A
J7335	Capsaicin 8% patch, per 10 square centimeters	K	9268
J8562	Fludarabine phosphate, oral, 10 mg	K	
J9043	Injection, cabazitaxel, 1 mg	K	1339
J9302	Injection, ofatumumab, 10 mg	K	9260
J9307	Injection, pralatrexate, 1 mg	K	9259
J9315	Injection, romidepsin, 1 mg	K	9265
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion.	K	9273

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2013

We are proposing to continue pass-through status in CY 2013 for 21 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, 2012. These drugs and biologicals, which were approved for pass-through status between April 1, 2011 and July 1, 2012, are listed in Table 23 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2012 are assigned status indicator ''G'' in Addenda A and B of this proposed rule and 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 rate of ASP+6 percent in CY 2013, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Thus, for CY 2013, 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 2013. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2013 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is 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 pass-through contrast agents and diagnostic radiopharmaceuticals, their pass-through payment amount would be equal to ASP+6 percent because, if not on pass-through status, payment for these products would be packaged into the associated procedure. Therefore, we are proposing that the difference between ASP+6 percent and the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized would be the CY 2013 pass-through payment amount for these policy-packaged products.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2013 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 42722 and 42723).

In CY 2013, as is consistent with our CY 2012 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through 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 status during CY 2013, 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 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 is also 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.d. of this proposed rule, over the last 5 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, is packaged into payment for the associated procedure. We are proposing to continue the packaging of these items, regardless of their per day cost, in CY 2013. 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 either a diagnostic radiopharmaceutical or a contrast agent (identified as a ''policy-packaged'' drug, first described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68639)) would otherwise be packaged if the product did not have pass-through 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 IV.A.2. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, 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 2012, we are proposing to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2013. Similarly, we are proposing that the associated copayment amount for pass-through anesthesia drugs that would otherwise be packaged if the item did not have pass-through status would be zero for CY 2013. As discussed in further detail in section II.3.c.2. of this proposed rule, we are clarifying that our general policy is to package drugs used for anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, or anesthesia drug is not subject to a copayment according to the statute. Therefore, we are proposing to not publish a copayment amount for these items in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

The 21 drugs and biologicals that we are proposing to continue on pass-through status for CY 2013 or that have been granted pass-through status as of July 2012 are displayed in Table 23.

TABLE 23—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013

Proposed CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	Injection, belatacept, 1 mg	G	9286
C9287	Injection, brentuximab vedotin, 1 mg	G	9287
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9366	EpiFix, per square centimeter	G	9366
C9368**	Grafix core, per square centimeter	G	9368
C9369**	Grafix prime, per square centimeter	G	9369
J0131	Injection, acetaminophen, 10 mg	G	9283
J0490	Injection, belimumab, 10 mg	G	1353
J0638	Injection, canakinumab, 1mg	G	1311
J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg.	G	0947
J2507	Injection, pegloticase, 1 mg	G	9281
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u	G	1416
J9179	Injection, eribulin mesylate, 0.1 mg	G	1426
J9228	Injection, ipilimumab, 10 mg	G	9284
Q2046*	Injection, aflibercept, 1 mg	G	1420

TABLE 23—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013—Continued

Proposed CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365

*HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012. Because the payment rate associated with this code effective July 1, 2012 is not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2012 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

**Because the payment rates associated with these codes effective July 1, 2012 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2012 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents 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 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 nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2013, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section II.A.3.d. of this proposed rule.

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. There is currently one radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9584 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries). This product, which is presently referred to using HCPCS code A9584, was granted pass-through status using HCPCS code C9406 beginning July 1, 2011, and we are proposing that it continue receiving pass-through status in CY 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. As described earlier in section V.A.3. of this proposed rule, we are proposing that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for 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.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, rather than drugs. 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.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. These instructions are contained within the I/OCE CMS specifications on the CMS Web site at *http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/index.html*.

For CY 2013 and future years, we are proposing to continue to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. In addition, we are proposing to continue to require that when a hospital bills with an ''FB'' modifier with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 24 of this proposed rule would be reduced by the full ''policy-packaged'' offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also are proposing to continue to require

hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

For CY 2012, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2013, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Table 24 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2013 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 24—PROPOSED APCS TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

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. There currently are no contrast agents with pass-through status under the OPPS. As described in section V.A.3. of this proposed rule, new pass-through contrast agents would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Although there are no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2013, in order to provide an appropriate transitional pass-through payment for them because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2013 to deduct from the payment for new pass-through contrast agents that are approved for pass-through status as a drug or biological during CY 2013, an amount that reflects 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). For CY 2013, as we did in CY 2012, we are proposing to continue to apply this same policy to contrast agents. Specifically, we are proposing to utilize the ''policy-packaged'' drug offset fraction for clinical APCs calculated as 1 minus (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). In CY 2010, we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents (74 FR 60495 through 60499). 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. We are proposing to continue to apply this methodology for CY 2013 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of this proposed rule, a specific offset based on the procedural APC would be applied to payments for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

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, including contrast agents, 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.

Proposed procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a ''policy-packaged'' drug amount greater than $20 that is not a nuclear medicine APC identified in Table 24 above and these APCs are displayed in Table 25 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 (70 FR 60483 through 60484). For CY 2013, 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 25, 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 25—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.

TABLE 25—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013—Continued

Proposed CY 2013 APC	Proposed CY 2013 APC title
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0093	Vascular Reconstruction/Fistula Repair without Device.
0104	Transcathether Placement of Intracoronary Stents.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2012 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: As a packaged payment included in the payment for the associated service, or 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. (Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

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 $60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at $65; for CY 2011, we set the packaging threshold at $70; and for CY 2012, we set the packaging threshold at $75.

Following the CY 2007 methodology, for this CY 2013 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 2013 and rounded the resulting dollar amount ($81.59) to the nearest $5 increment, which yielded a figure of $80. 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 note that we are not proposing a change to the PPI that is used to calculate the threshold for CY 2013; rather, this change in terminology reflects a change to the BLS naming convention for this series.) We refer below to this series generally as the PPI for Prescription Drugs.

We chose this PPI as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/

ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we are proposing a packaging threshold for CY 2013 of $80. (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, Nonimplantable Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

To determine the proposed CY 2013 packaging status for all nonpass-through drugs and biologicals that are not policy packaged for this proposed rule, we calculated on a HCPCS code-specific basis the per day cost of all drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2011 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2011 claims processed before January 1, 2012 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 diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we are proposing to continue to package in CY 2013, as discussed in section V.B.2.d. of this proposed rule.

In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2013, 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 70 FR 68638). For each drug and nonimplantable 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 nonimplantable biologicals for CY 2013, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2013 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2011 (data that were used for payment purposes in the physician's office setting, effective April 1, 2012) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2013 we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2011 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 were also the bases for drug payments in the physician's office setting, effective April 1, 2012. 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 2011 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 $80, and identify items with a per day cost greater than $80 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2011 HCPCS codes that were reported to the CY 2012 HCPCS codes that we display in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2013.

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, nonimplantable 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 will be subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and nonimplantable biologicals in the CY 2013 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2012, 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, 2012, along with updated hospital claims data from CY 2011. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2013 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and nonimplantable 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 2012. 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, 2012. These physician's office payment rates would then be updated in the January 2013 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2013. 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 2011 claims data and updated cost report information available for the CY 2013 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in this CY 2013 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the 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 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Specifically, for CY 2013, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the proposed $80 drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 proposed rule, would continue to receive separate payment in CY 2013.
- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data

used for this CY 2013 proposed rule, would remain packaged in CY 2013.

• HCPCS codes for drugs and nonimplantable biologicals for which we are proposing packaged payment in CY 2013 but then have per day costs greater than $80, based on the updated ASPs and hospital claims data used for this CY 2013 proposed rule, would receive separate payment in CY 2013.

c. 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. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPS (73 FR 68665). 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 2008 OPPS/ASC final rule with comment period (72 FR 66775), we explained that once claims data were available for these previously unrecognized HCPCS codes, we would determine the packaging status and resulting status indicator for each HCPCS code according to the general, established HCPCS code-specific methodology for determining a code's packaging status for a given update year. However, we also stated that we planned to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug or biological did not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

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. We analyzed CY 2008 claims data for the HCPCS codes describing different dosages of the same drug or biological that were newly recognized in CY 2008 and found that our claims data would result in several different packaging determinations for different codes describing the same drug or biological. Furthermore, we found that our claims data included few units and days for a number of newly recognized HCPCS codes, resulting in our concern that these data reflected claims from only a small number of hospitals, even though the drug or biological itself may be reported by many other hospitals under the most common HCPCS code. Based on these findings from our first available claims data for the newly recognized HCPCS codes, we believed that adopting our standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes instead of others, particularly because we do not currently require hospitals to report all drug and biological HCPCS codes under the OPPS in consideration of our previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment.

For CY 2013, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives 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 2013.

For CY 2013, 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 2011 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. HCPCS codes J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units), Q0171 (Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0172 (Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0175 (Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0176 (Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0177 (Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), and Q0178 (Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen) did not have pricing information available for the ASP methodology and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2011 claims data to make the packaging determinations for these drugs. For all other drugs and biologicals that have HCPCS codes describing different dosages, we then multiplied the 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 $80 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $80 (whereupon 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 is displayed in Table 26 below.

TABLE 26—PROPOSED HCPCS CODES TO WHICH THE CY 2013 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2013 HCPCS code	Proposed CY 2013 long descriptor	Proposed CY 2013 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.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0165	Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0167	Dronabinol, 2.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0168	Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0175	Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0176	Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0177	Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0178	Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	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'' is 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 ''specified covered outpatient drugs,'' known as 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) of the Act provides for an adjustment in OPPS payment rates for 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 treat all separately payable drugs and biologicals, which includes SCODs, and drugs and biological that are not SCODs, the same. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii)(I) 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 choice rather than a statutory requirement. Later in the discussion of our proposed policy for CY 2013, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals. Although we do not distinguish SCODs in that discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we are choosing to apply it to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

In the CY 2006 OPPS proposed rule (70 FR 42728 through 42731), we discussed the June 2005 report by MedPAC regarding pharmacy overhead costs in HOPDs and summarized the findings of that study. In response to the MedPAC findings, in the CY 2006 OPPS proposed rule (70 FR 42729), we discussed our belief that, because of the varied handling resources required to prepare different forms of drugs, it would be impossible to exclusively and appropriately assign a drug to a certain overhead category that would apply to all hospital outpatient uses of the drug. Therefore, our CY 2006 OPPS proposal included a proposal to establish three distinct Level II HCPCS C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). We also proposed: (1) To combine several overhead categories recommended by MedPAC; (2) to establish three drug handling categories, as we believed that larger groups would minimize the number of drugs that may fit into more than one category and would lessen any undesirable payment policy incentives to utilize particular forms of drugs or specific preparation methods; (3) to collect hospital charges for these HCPCS C-codes for 2 years; and (4) to ultimately base payment for the corresponding drug handling APCs on CY 2006 claims data available for the CY 2008 OPPS.

In the CY 2006 OPPS final rule with comment period (70 FR 68659 through 68665), we discussed the public comments we received on our proposal regarding pharmacy overhead. The overwhelming majority of commenters did not support our proposal regarding pharmacy overhead and urged us not to finalize this policy, as it would be administratively burdensome for hospitals to establish charges for HCPCS codes for pharmacy overhead and to report them. Therefore, we did not finalize this proposal for CY 2006. Instead, we established payment for separately payable drugs and biologicals at ASP+6 percent, which we 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). Hereinafter, we refer to this methodology as our standard drug payment methodology. We concluded that payment for drugs and biologicals and pharmacy overhead at a combined ASP+6 percent rate would serve as an acceptable proxy for the combined acquisition and overhead costs of each of these products.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we finalized our proposed policy to provide a single payment of ASP+6 percent for the hospital's acquisition cost for the drug or biological and all associated pharmacy overhead and handling costs. The ASP+6 percent rate that we finalized was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent according to our standard drug payment methodology, but we adopted payment at ASP+6 percent for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD and awaited the accumulation of CY 2006 data as discussed in the prior year's rule.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), in response to ongoing discussions with interested parties, we proposed to continue our methodology of providing a combined payment rate for drug and biological acquisition and pharmacy overhead costs while continuing our efforts to improve the available data. We also proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs

and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. Similar to the public response to our CY 2006 pharmacy overhead proposal, the overwhelming majority of commenters did not support our CY 2008 proposal and urged us to not finalize this policy (72 FR 66761). At its September 2007 meeting, the APC Panel recommended that hospitals not be required to separately report charges for pharmacy overhead and handling and that payment for overhead be included as part of drug payment. The APC Panel also recommended that CMS continue to evaluate alternative methods to standardize the capture of pharmacy overhead costs in a manner that is simple to implement at the organizational level (72 FR 66761). Because of concerns expressed by the APC Panel and public commenters, we did not finalize the proposal to instruct hospitals to separately report pharmacy overhead charges for CY 2008. Instead, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), we finalized a policy of providing payment for separately payable drugs and biologicals and their pharmacy overhead at ASP+5 percent as a transition from their CY 2007 payment of ASP+6 percent to payment based on the equivalent average ASP-based payment rate calculated from hospital claims according to our standard drug payment methodology, which was ASP+3 percent for the CY 2008 OPPS/ASC final rule with comment period. Hospitals continued to include charges for pharmacy overhead costs in the line-item charges for the associated drugs reported on claims.

For CY 2009, we proposed to pay separately payable drugs and biologicals at ASP+4 percent, including both SCODs and other drugs without CY 2009 OPPS pass-through status, based on our standard drug payment methodology. We also continued to explore mechanisms to improve the available data. We proposed to split the ''Drugs Charged to Patients'' cost center into two cost centers: One for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. After consideration of the public comments received and the APC Panel recommendations, we finalized a CY 2009 policy (73 FR 68659) to provide payment for separately payable nonpass-through drugs and biologicals based on costs calculated from hospital claims at a 1-year transitional rate of ASP+4 percent, in the context of an equivalent average ASP-based payment rate of ASP+2 percent calculated according to our standard drug payment methodology from the final rule claims data and cost report data. We did not finalize our proposal to split the single standard ''Drugs Charged to Patients'' cost center into two cost centers largely due to concerns raised by hospitals about the associated administrative burden. Instead, we indicated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68659) that we would continue to explore other potential approaches to improve our drug cost estimation methodology, thereby increasing payment accuracy for separately payable drugs and biologicals.

In response to the CMS proposals for the CY 2008 and CY 2009 OPPS, a group of pharmacy stakeholders (hereinafter referred to as the pharmacy stakeholders), including some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations, commented that CMS should pay an acquisition cost of ASP+6 percent for separately payable drugs, should substitute ASP+6 percent for the packaged cost of all packaged drugs and biologicals on procedure claims, and should redistribute the difference between the aggregate estimated packaged drug cost in claims and payment for all drugs, including packaged drugs at ASP+6 percent, as separate pharmacy overhead payments for separately payable drugs. They indicated that this approach would preserve the aggregate drug cost observed in the claims data, while significantly increasing payment accuracy for individual drugs and procedures by redistributing drug cost from packaged drugs. Their suggested approach would provide a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the pharmacy stakeholders' assessment of the complexity of pharmacy handling associated with each specific drug or biological (73 FR 68651 through 68652). Each separately payable drug or biological HCPCS code would be assigned to one of the three overhead categories, and the separate pharmacy overhead payment applicable to the category would be made when each of the separately payable drugs or biologicals was paid.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35332), we acknowledged the limitations of our data and our availability to find a method to improve that data in a way that did not impose unacceptable administrative burdens on providers. Accepting that charge compression was a reasonable but unverifiable supposition, we proposed to redistribute between one-third and one-half of the estimated overhead cost associated with coded packaged drugs and biologicals with an ASP, which resulted in our proposal to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that did not have pass-through payment status at ASP+4 percent. We calculated estimated overhead cost for coded packaged drugs and biologicals by determining the difference between the aggregate claims cost for coded packaged drugs and biologicals with an ASP and the ASP dollars (ASP multiplied by the drug's or biological's units in the claims data) for those same coded drugs and biologicals; this difference was our estimated overhead cost for coded packaged drugs and biologicals. In our rationale described in the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that approximately $150 million of the estimated $395 million total in pharmacy overhead cost, specifically between one-third and one-half of that cost, included in our claims data for coded packaged drugs and biologicals with reported ASP data should be attributed to separately payable drugs and biologicals and that the $150 million serves as the adjustment for the pharmacy overhead costs of separately payable drugs and biologicals. As a result, we also proposed to reduce the costs of coded drugs and biologicals that are packaged into payment for procedural APCs to offset the $150 million adjustment to payment for separately payable drugs and biologicals. In addition, we proposed that any redistribution of pharmacy overhead cost that may arise from the CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals that we calculate based on the charges and costs reported by hospitals on claims and cost reports.

As a result of this approach, no redistribution of cost would occur from other services to drugs and biologicals or vice versa.

While we had no way of assessing whether this current distribution of overhead cost to coded packaged drugs and biologicals with an ASP was appropriate, we acknowledged that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. Further, we recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products. For these reasons, we stated that we believed some portion, but not all, of the total overhead cost that is associated with coded packaged drugs and biologicals (the difference between aggregate cost for those drugs and biologicals on the claims and ASP dollars for the same drugs and biologicals), based on our standard drug payment methodology, should, at least for CY 2010, be attributed to separately payable drugs and biologicals.

We acknowledged that the observed combined payment for acquisition and pharmacy overhead costs of ASP–2 percent for separately payable drugs and biologicals may be too low and ASP+247 percent for coded packaged drugs and biologicals with reported ASP data in the CY 2010 claims data may be too high (74 FR 35327 and 35328). Therefore, we stated that a middle ground would represent the most accurate redistribution of pharmacy overhead cost. Our assumption was that approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2008 claims data offered a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals (74 FR 35328). One third of the $395 million of pharmacy overhead cost associated with packaged drugs and biologicals was $132 million, whereas one-half was $198 million.

Within the one-third to one-half parameters, we proposed reallocating $150 million in drug and biological cost observed in the claims data from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals for CY 2010 for their pharmacy overhead costs. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent.

In the CY 2010 OPPS final rule with comment period, we adopted a transitional payment rate of ASP+4 percent based on a pharmacy overhead adjustment methodology for CY 2010 that redistributed $200 million from packaged drug and biological cost to separately payable drug cost (74 FR 60499 through 60518). This $200 million included the proposed $150 million redistribution from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional $50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals (74 FR 60517). We stated that this was an intentionally conservative estimate as we could not identify definitive evidence that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to that of coded packaged drugs and biologicals with an ASP. We stated that we could not know the amount of overhead associated with these drugs without making significant assumptions about the amount of pharmacy overhead cost associated with the drugs and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513). In addition, as in prior years, we reiterated our commitment to continue in our efforts to refine our analyses.

For CY 2011, we continued the CY 2010 pharmacy overhead adjustment methodology (74 FR 60500 through 60512). Consistent with our supposition that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals, we redistributed $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and redistributed $50 million from the cost of uncoded packaged drugs and biologicals, for a total redistribution of $200 million from costs for coded and uncoded packaged drugs to separately payable drugs and biologicals, with the result that we pay separately paid drugs and biologicals at ASP+5 percent for CY 2011. The redistribution amount of $150 million in overhead cost from coded packaged drugs and biologicals with an ASP and $50 million in costs from uncoded packaged drugs and biologicals without an ASP were within the parameters established in the CY 2010 OPPS/ASC final rule. In addition, as in prior years, we described some of our work to improve our analyses during the preceding year, including an analysis of uncoded packaged drug and biological cost and our evaluation of the services with which uncoded packaged drug cost appears in the claims data. We conducted this analysis in an effort to assess how much uncoded drugs resemble coded packaged drugs (75 FR 71966). We stated that, in light of this information, we were not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded packaged drug cost, and therefore, we did not believe we could assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate the ASP for these uncoded packaged drugs and biologicals and without being able to gauge the magnitude of overhead complexity associated with these drugs and biologicals, we did not believe that we should have assumed that the same amount of proportional overhead should be redistributed between coded and uncoded packaged drugs, and therefore, we redistributed $50 million from uncoded packaged drugs and $150 million from coded packaged drugs (75 FR 71966). We reiterated our commitment to continue to refine our drug pricing methodology and noted that we would continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS and continue to evaluate the appropriateness of this methodology when we establish each year's payment for drugs and biologicals under the OPPS (75 FR 71967).

For CY 2012, we continued our overhead adjustment methodology of redistributing ⅓ to ½ of allocated overhead for coded packaged drugs or $150 million plus an additional $50 million in allocated overhead for uncoded packaged drugs. Additionally, we finalized a policy to update these amounts by the PPI for pharmaceuticals and redistributed $161 million in allocated overhead from coded packaged drugs and $54 million from uncoded packaged drugs. We further finalized a policy to hold the redistributed proportion of packaged drugs constant between the proposed

and the final rule, which increased the final redistribution amount in the CY 2012 final rule to $240.3 million ($169 million from coded packaged drugs and $71.3 million from uncoded packaged drugs). This approach resulted in a final payment rate of ASP+4 percent for separately payable drugs.

b. Proposed CY 2013 Payment Policy

In reexamining our current drug payment methodology for this CY 2013 OPPS/ASC proposed rule, we reviewed our past efforts to determine an appropriate payment methodology for drugs and biologicals, as described above. Since the inception of the OPPS, we have remained committed to establishing a drug payment methodology that is predictable, accurate, and appropriate. Pharmacy stakeholders and the hospital community have also, throughout the years, continually emphasized the importance of both predictable and accurate payment rates for drugs, noting that a payment methodology that emphasizes predictability and accuracy leads to appropriate payment rates that reflect the cost of drugs and biologicals (including overhead) in HOPDs. Pertinent stakeholders also have noted that predictable and accurate payment rates minimize the effect of anomalies in the claims data that may incorrectly influence the future payment for services. We understand that, with predictable payment rates, hospitals are better able to plan for the future.

As discussed above, 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). As we previously stated, we refer to this methodology as our standard drug payment methodology.

In CY 2010, 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'' (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 overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology by finalizing a policy to update the redistribution amount for inflation and keep the redistribution ratio constant between the proposed rule and the final rule.

Application of the standard drug payment methodology, with the overhead adjustment, has always yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent for nonpass-through separately payable drugs. We believe that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses. However, 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, we are concerned that the continued use of our current 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), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Considering stakeholder and provider feedback, continued limitations of the hospital claims and cost data on drugs and biologicals, and Panel recommendations, we are proposing 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, hereinafter referred to as the statutory default.

As noted above, 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, physician Part B drugs are paid at ASP+6 percent. We believe that proposing the statutory default of ASP+6 percent is appropriate at this time as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS. We believe that ASP+6 percent is an appropriate payment amount because it is consistent with payment amounts yielded by our drug payment methodologies over the past 7 years. 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 for CY 2013.

Our goals continue to be to develop a method that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately. If a better payment methodology is developed in the future, then the proposed policy to pay ASP+6 according to the statutory default would be an interim step in the development of this payment policy. We recognize the challenges in doing so given current data sources and the objective of maintaining the smallest administrative burden possible.

We 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.

At the February 2012 Panel meeting, the Panel made four recommendations on drugs and biologicals paid under the OPPS. First, the Panel recommended that CMS require hospitals to bill all drugs that are described by Healthcare Common Procedure Coding System (HCPCS) codes under revenue code 0636. While we agree that drugs and biologicals may be reported under revenue code 0636, we believe that drugs and biologicals may also be appropriately reported in revenue code categories other than revenue code

0636, including but not limited to, revenue codes 025x and 062x. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71966), we recognize that hospitals may carry the costs of drugs and biologicals in multiple cost centers and that it may not be appropriate to report the cost of all drugs and biologicals in one specified revenue code. Additionally, we generally require hospitals to follow National Uniform Billing Committee (NUBC) guidance for the choice of an appropriate revenue code that is also appropriate for the hospital's internal accounting processes. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636. However, we continue to believe that OPPS ratesetting is most accurate when hospitals report charges for all items and services that have HCPCS codes using those HCPCS codes, regardless of whether payment for the items and services is packaged. It is our standard ratesetting methodology to rely on hospital cost report and charge information as it is reported to us through the claims data. We continue to believe that more complete data from hospitals identifying the specific drugs that were provided during an episode of care may improve payment accuracy for drugs in the future. Therefore, we continue to encourage hospitals to change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, whether specific HCPCS codes are available for those drugs and biologicals.

Second, the Panel recommended that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs. Under the proposed statutory default payment rate of ASP+6 percent, hospitals' 340B status does not affect the drug payment rate.

Third, the Panel recommended that CMS freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. The OPPS is based on the concept of payment for groups of services that share clinical and resource characteristics. We believe that the packaging threshold is reasonable based on the initial establishment in law of a $50 threshold for the CY 2005 OPPS, that updating the $50 threshold is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, we are not accepting the Panel's recommendation to freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. Instead, as discussed in section V.B.2. of this proposed rule, we are proposing an OPPS drug packaging threshold for CY 2013 of $80. However, we do believe that we have addressed the drug payment issue by proposing to pay for separately paid drugs and biologicals at ASP+6 percent for CY 2013 based upon the statutory default.

Finally, the Panel recommended that CMS pay hospitals for separately payable drugs at a rate of average sales price (ASP) + 6 percent. This Panel recommendation is consistent with our CY 2013 proposed payment rate based upon the statutory default under section 1833(t)(14)(A)(iii)(II) of the Act, which authorizes us to pay for drugs and biologicals under the OPPS at ASP+6 percent, when hospital acquisition cost data are not available.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2012, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allow manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to properly calculate the ASP amount for a given HCPCS code. If ASP information is unavailable for a therapeutic radiopharmaceutical, then 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 2013. Therefore, we are proposing for CY 2013 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. We are proposing to continue to set payment rates for therapeutic radiopharmaceuticals based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. For a full discussion of how a ''patient ready'' dose is defined, 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 2011 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 2013 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 for Blood Clotting Factors

For CY 2012, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2012, we provided payment for blood clotting factors under the OPPS at ASP+4 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 2012 updated furnishing fee is $0.181 per unit.

For CY 2013, 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*.

6. Proposed Payment for Nonpass-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 after 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 is 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. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years.

For CY 2010, we continued to provide payment for new drugs (excluding contrast agents) and nonimplantable biologicals with HCPCS codes that do not have pass-through status and are without OPPS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and nonimplantable biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+4 percent. This policy was continued in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71970 through 71973), paying for new drugs, nonimplantable biologicals, and radiopharmaceuticals that do not crosswalk to CY 2010 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent and the CY 2012 OPPS/ASC final rule with comment period at ASP+4 percent (76 FR 74330 through 74332).

For CY 2013, we are proposing to provide payment for new CY 2013 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+6 percent, consistent with the proposed CY 2013 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. We believe this proposed policy would ensure that new nonpass-through drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS.

We also are proposing to continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals and contrast agents with HCPCS codes but without claims data (those new CY 2013 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in more detail in section II.A.3.d. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2013, we are proposing to continue the policy we implemented beginning in CY 2005 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 and are not diagnostic radiopharmaceuticals and contrast agents. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator ''K'' (for separately paid nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals 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 finalized ASP-based amount (proposed for CY 2013 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, 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, nonimplantable biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals 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 are also 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 2013 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 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 would also be changed accordingly based on later quarter ASP submissions. We note that the new CY 2013 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals are not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2013 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 is open to public comment in the CY 2013 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2011 and/or CY 2012 for which we did not have CY 2011 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. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2013, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one 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 and 68667).

We are proposing to package items for which we estimated the per day administration cost to be less than or equal to $80, which is the general packaging threshold that we are proposing for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2013. We are proposing to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals and contrast agents, which we are proposing to continue to package regardless of cost as discussed in more detail in section II.A.3.d. of this proposed rule) in CY 2013. We are proposing that the CY 2013 payment for separately payable items without CY 2011 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. However, we note that 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 27 below.

TABLE 27—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA

CY 2013 HCPCS code	CY 2013 long descriptor	Estimated average number of units per day	Proposed CY 2013 SI	Proposed CY 2013 APC
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	55	K	9367
J0630	Injection, calcitonin salmon, up to 400 units	1.5	K	1433
J2793	Injection, Rilonacept	320	K	1291
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J8562	Fludarabine phosphate, oral, 10 mg	1	K	1339
J9065	Injection, cladribine, per 1 mg	10	K	0858
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	5	K	0821
J0205	Injection, alglucerase, per 10 units	420	K	0900
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050
J2513	Injection, pentastarch, 10% solution, 100 ml	4	N	N/A
J3355	Injection, urofollitropin, 75 IU	2	K	1741
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J2265	Injection, minocycline hydrochloride, 1 mg	300	K	1423
J8650	Nabilone, oral, 1 mg	4	K	1424

Finally, there were 19 drugs and biologicals, shown in Table 28 below, that were payable in CY 2011, but for which we lacked CY 2011 claims data and any other pricing information for the ASP methodology for this CY 2013 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator ''N.''

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a

payable status indicator to 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. 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 in CY 2010 for the ASP methodology. If pricing information became available, we would assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2010. We continued this policy for CY 2011 and CY 2012 (75 FR 71973 and 76 FR 74334).

For CY 2013, we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2011 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2011 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2013 are displayed in Table 28 below. If pricing information becomes available, we are proposing to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2013.

TABLE 28—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2013 HCPCS code	CY 2013 long descriptor	Proposed CY 2013 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
90706	Rubella virus vaccine, live, for subcutaneous use	E
90725	Cholera vaccine for injectable use	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	E
J1835	Injection, itraconazole, 50 mg	E
J2670	Injection, tolazonline hcl, up to 25 mg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	E
Q4117	Hyalomatrix, per square centimeter	E
Q4120	Matristem Burn matrix, per square centimeter	E
Q4126	Memoderm, per square centimeter	E
Q4127	Talymed, per square centimeter	E

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 hospital 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 make an estimate of pass-through spending to determine not only whether payments exceed the applicable percentage, but also to determine the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year in order 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 2013 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2013. 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 contains items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of device categories would equal the total CY 2013 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 2012 OPPS/ASC final rule with comment period (76 FR 74335 through 74336). 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), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices.

For drugs and nonimplantable 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 is not proposed to be reinstated for CY 2013. Because we are proposing to pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2013 OPPS at ASP+6 percent, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and nonimplantable biologicals, and because we are proposing to pay for CY 2013 pass-through drugs and nonimplantable biologicals at ASP+6 percent, our estimate of drug and nonimplantable biological pass-through payment for CY 2013 for this group of items would be zero, 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 because these products will never be separately paid. However, all pass-through diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 would be paid at ASP+6 percent like other pass-through drugs and nonimplantable biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 is not zero. In section V.A.4. of this proposed rule, we discuss our proposed policy to determine if the cost of certain ''policy-packaged'' drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a ''policy-packaged'' drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for diagnostic radiopharmaceuticals or contrast agents. For these drugs, the APC offset amount would be the portion of the APC payment for the specific procedure performed with the pass-through radiopharmaceuticals or contrast agents, which we refer to as the ''policy-packaged'' drug APC offset amount. If we determine that an offset is appropriate for a specific diagnostic radiopharmaceutical or contrast agent receiving pass-through payment, we are proposing to reduce our estimate of pass-through payment for these drugs by this amount.

Similar to pass-through estimates for devices, the first group of drugs and nonimplantable biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment for CY 2012 and that will continue to be eligible for pass-through payment in CY 2013. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of drugs and nonimplantable biologicals would equal the total CY 2013 pass-through spending estimate for drugs and nonimplantable 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 2013, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2012 (76 FR 74336).

For the first group of devices for pass-through payment estimation purposes, there currently are three device categories eligible for pass-through payment for CY 2013: C1830 (Powered bone marrow biopsy needle); C1840 (Lens, intraocular (telescopic)); and C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). We estimate that CY 2013 pass-through expenditures related to these three eligible device categories will be approximately $42 million. In estimating our proposed CY 2013 pass-through spending for device categories in the second group we include: Device categories that we know at the time of the development of this proposed rule would be newly eligible for pass-through payment in CY 2013 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2013; and contingent projections for new device categories established in the second through fourth quarters of CY 2013. 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 2013 pass-through spending for this second group of device categories is $10 million. Using our established methodology, we are proposing that the total estimated pass-through spending for device categories for CY 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) be $52 million.

To estimate proposed CY 2013 pass-through spending for drugs and nonimplantable biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and nonimplantable biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2013, we are proposing to utilize the most recent Medicare physician's office 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 nonimplantable biologicals, to project the CY 2013 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that would be continuing on pass-through status in CY 2013, we estimate the proposed pass-through payment amount as the difference between ASP+6 percent and the proposed payment rate for nonpass-through drugs and nonimplantable biologicals that would be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for a diagnostic radiopharmaceutical or contrast agent would be packaged if the product were not paid separately due to its pass-through status, we are proposing to include in the proposed CY 2013 pass-through estimate the difference between payment for the 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 have determined that the diagnostic

radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment. For this CY 2013 proposed rule, we are proposing to continue to use the above described methodology to calculate a proposed spending estimate for this first group of drugs and nonimplantable biologicals to be approximately $13 million.

To estimate proposed CY 2013 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we know at the time of development of this proposed rule would be newly eligible for pass-through payment in CY 2013, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2013, and projections for new drugs and nonimplantable biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2013), 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 proposed CY 2013 pass-through payment estimate. We also are considering the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals to be approximately $19 million.

As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our proposed CY 2013 pass-through spending estimate for drugs and nonimplantable biologicals. Our proposed CY 2013 estimate for total pass-through spending for drugs and nonimplantable biologicals (spending for the first group of drugs and nonimplantable biologicals ($13 million) plus spending for the second group of drugs and nonimplantable biologicals ($19 million)) equals $32 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that total pass-through spending for the device categories and the drugs and nonimplantable biologicals that are continuing to receive pass-through payment in CY 2013 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2013 would be approximately $84 million (approximately $52 million for device categories and approximately $32 million for drugs and nonimplantable biologicals), which represents 0.18 percent of total projected OPPS payments for CY 2013. We estimate that pass-through spending in CY 2013 would not amount to 2.0 percent of total projected OPPS CY 2013 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report HCPCS visit codes to describe three types of OPPS services: clinic visits, emergency department visits, and critical care services, including trauma team activation. For CY 2013, we are proposing to continue to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, and critical care services, which are listed below in Table 29, for CY 2013. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our longstanding policy on OPPS payment for hospital outpatient visits.

TABLE 29—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2013 HCPCS code	CY 2013 descriptor
	Clinic Visit HCPCS Codes
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1).
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2).
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3).
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4).
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5).
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1).
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2).
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3).
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4).
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5).
	Emergency Department Visit HCPCS Codes
99281	Emergency department visit for the evaluation and management of a patient (Level 1).
99282	Emergency department visit for the evaluation and management of a patient (Level 2).
99283	Emergency department visit for the evaluation and management of a patient (Level 3).
99284	Emergency department visit for the evaluation and management of a patient (Level 4).
99285	Emergency department visit for the evaluation and management of a patient (Level 5).
G0380	Type B emergency department visit (Level 1).
G0381	Type B emergency department visit (Level 2).
G0382	Type B emergency department visit (Level 3).
G0383	Type B emergency department visit (Level 4).
G0384	Type B emergency department visit (Level 5).

TABLE 29—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES—Continued

CY 2013 HCPCS code	CY 2013 descriptor
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes.
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes.
G0390	Trauma response associated with hospital critical care service.

B. Proposed Policies for Hospital Outpatient Visits

For CY 2013, we are proposing to continue our longstanding policies related to hospital outpatient visits, which includes clinic visits, emergency department visits, and critical care services. Specifically, we are proposing to continue to recognize the definitions of a new patient and an established patient, which are based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit. We also are proposing to continue to apply our policy of calculating costs for clinic visits under the OPPS using historical hospital claims data through five levels of clinic visit APCs (APCs 0604 through 0608). In addition, we are proposing to continue to recognize Type A emergency departments and Type B emergency departments for payment purposes under the OPPS, and to pay for Type A emergency department visits based on their costs through the five levels of Type A emergency department APCs (APCs 0609 and 0613 through 0616) and to pay for Type B emergency department visits based on their costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed APC assignments and payment rates for these hospital outpatient visits. Finally, we are continuing to instruct hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. We note that our continued expectation is that hospitals' internal guidelines will comport with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66805). We encourage hospitals with specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full historical discussion of these longstanding policies.

We also are proposing to continue 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 CY 2010 and in prior years, the AMA CPT Editorial Panel defined critical care 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)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays and pulse oximetry. As we have stated in manual instruction, we expect hospitals to report in accordance with CPT guidance unless we instruct otherwise. For critical care in particular, we instructed hospitals that any services that the CPT Editorial Panel indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by the CPT Editorial Panel) should not be billed separately. Instead, hospitals were instructed to report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services, and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPPS methodology for packaging costs (Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1).

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines should report all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the CY 2011 payment rate for critical care services was based on hospital claims data from CY 2009, during which time hospitals would have reported charges for any ancillary services provided as part of the critical care services, we stated in the CY 2011 OPPS/ASC final rule with comment period that we believed it was inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services (75 FR 71988). Therefore, for CY 2011, we continued to recognize the existing CPT codes for critical care services and established a payment rate based on historical data, into which the cost of the ancillary services was intrinsically packaged. We also implemented 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. We noted in the CY 2011 OPPS/ASC final rule with comment period that the payment status of the ancillary services would not change when they are not provided in conjunction with critical care services. We assigned status indicator ''Q3'' (Codes That May Be Paid Through a Composite APC) to the ancillary services to indicate that payment for these services is packaged into a single payment for specific combinations of services and made through a separate APC payment or packaged in all other circumstances, in accordance with the OPPS payment status indicated for status indicator ''Q3'' in Addendum D1 to the CY 2011 OPPS/ASC final rule with comment period. The ancillary services that were included in the definition of critical care prior to CY 2011 and that are conditionally packaged into the payment for critical care services when provided on the same date of service as critical care services for CY 2011 were listed in Addendum M to that final rule with comment period.

Because the CY 2012 costs for critical care services were based upon CY 2010 claims data, which reflect the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74343 through 74344), we continued the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical claims data, into which the cost of the ancillary services is intrinsically packaged for CY 2012. We also continued 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.

As discussed in section II.A.2.f. of this proposed rule, we are proposing to establish the CY 2013 relative payment weights upon which OPPS payment is based using geometric mean costs. The CY 2011 hospital claims data on which the proposed CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because our proposal to establish relative payment weights based on geometric mean cost data for CY 2013 represents a change from our historical practice to base payment rates on median costs and because we now have hospital claims data for the first time reflecting the revised coding guidance for critical care, we reviewed the CY 2011 hospital claims data available for this proposed rule and determined that the data show increases in both the mean and median line item costs as well as the mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, the mean and median line item costs increased 13 percent and 16 percent, respectively, and the mean and median line item charges increased 11 percent and 14 percent, respectively. Additionally, when compared to CY 2010 hospital claims data, CY 2011 hospital claims data show no substantial change in the ancillary services that are present on the same claims as critical care services, and also show continued low volumes of many ancillary services. Had the majority of hospitals changed their billing practices to separately report and charge for the ancillary services formerly included in the definition of critical care CPT codes 99291 and 99292, we would have expected to see a decrease in the costs and charges for these CPT codes, and a significant increase in ancillary services reported on the same claims. The lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggests that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we continue to believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we are proposing to continue our CY 2011 and CY 2012 policy 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. We will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

C. Transitional Care Management

In the CY 2013 MPFS proposed rule, we discuss a multiple year strategy exploring the best means to encourage the provision of primary care and care coordination services to Medicare beneficiaries. As part of the strategy discussed in that proposed rule, we are proposing to address the non-face-to-face work involved in hospital or SNF discharge care coordination by creating a HCPCS G-code for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial hospitalization), SNF stay, or CMHC partial hospitalization program to care furnished by the beneficiary's physician or qualified nonphysician practitioner in the community. As discussed in the CY 2013 MPFS proposed rule, care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital or a SNF stay to the beneficiary's primary physician or qualified nonphysician practitioner in the community could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care coordination and care transitions could improve the quality of care while simultaneously decreasing costs.

The proposed HCPCS G-code included in the CY 2013 MPFS proposed rule, GXXX1, specifically describes post-discharge transitional care management services, which include all non-face-to-face services related to the transitional care management, furnished by the community physician or nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, LTCH, SNF, and IRF; discharge from hospital outpatient observation or partial hospitalization services; or discharge from a PHP at a CMHC, to the community-based care. The post-discharge transitional care management services include non-face-to-face care management services provided by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner.

Transitional care management services include:

1. Assuming responsibility for the beneficiary's care without a gap.

2. Establishing or adjusting a plan of care to reflect required and indicated elements, particularly in light of the services furnished during the stay at the specified facility and to reflect the result of communication with beneficiary.

3. Communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including education of the patient and/or caregiver within 2 business days of discharge based on a review of the discharge summary and other available information such as diagnostic test results.

While we do not pay for physician or nonpractitioner professional services under the OPPS (42 CFR 419.22), we recognize that certain elements of the transitional care coordination services described by proposed HCPCS code GXXX1 could be provided to a hospital outpatient as an ancillary or supportive service in conjunction with a primary diagnostic or therapeutic service that would be payable under the OPPS, such as a clinic visit. As described in section II.A.3. of this proposed rule, we package payment for services that are typically ancillary and supportive to a primary service. While we do not make separate payment for such services, their costs are included in the costs of other services furnished by the hospital to the beneficiary on the same day. Because

we believe that transitional care management services may be ancillary and supportive to a primary service provided to a hospital outpatient, for purposes of OPPS payment, we are proposing to assign HCPCS code (GXXX1), a status indicator of ''N'' (Items and Services Packaged into APC Rates) signifying that its payment is packaged. We refer readers to the CY 2013 MPFS proposed rule for a full discussion of post-discharge transitional care management services in particular and, more broadly, the multiple year strategy exploring the best means to encourage primary care and care coordination services.

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 plan 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 community mental health center.

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, at 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 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 in the CY 2008 update (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 (APC 0172 (Level I Partial Hospitalization)) and a higher amount for days with 4 or more services (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 at 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 per diem payment rates. 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 at section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 under 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). In the CY 2011 OPPS/ASC proposed rule, we proposed that CMHC APC medians would be based only on CMHC data and hospital-based PHP APC medians would be based only on hospital-based PHP data (75 FR 46300). 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 CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part because the data showed that CMHCs 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 PHP programs at a lower rate than their cost structure reflects could lead to hospital-based PHP program closures and possible access problems for Medicare beneficiaries, given that hospital-based programs offer the widest access to PHP services because they are located across the country. 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 APC Level I and Level II per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based medians and the CY 2011 final CMHC medians and then adding that number to the CY 2011 final CMHC medians. 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 may, based on these analyses, 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,* No. 10–949, 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* No. 11–50682, 2012 WL 2161137 (5th Cir. June 15, 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 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* at *6).

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 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. Similarly, we established new APCs for PHP services based exclusively on hospital data. For CY 2009, 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 [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' However, we used 1996 data (plus 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.''

B. Proposed PHP APC Update for CY 2013

As discussed in section II.A.2.g. of this proposed rule, for CY 2013, we are proposing to develop the relative payment weights that underpin the OPPS using geometric means rather than the current median-based methodology. This proposal to base the relative payment weights on geometric means would also apply to the per diem costs used to determine the relative payment weights for the four PHP APCs. For PHP APCs, as with all other OPPS APCs, the proposal to base the relative payment weights on geometric means rather than medians would not affect the general process to establish appropriate claims for modeling. As with the current median-based methodology, the PHP APC payment rates would continue to be calculated by computing a separate per diem cost for each day of PHP. When there are multiple days of PHP services entered on a claim, a unique cost would continue to be computed for each day of care. However, a geometric mean would be used to calculate the per diem costs rather than a median. The process would still be repeated separately for CMHCs and hospital-based PHPs using that provider's claims data for the two categories of days with 3 services and days with 4 or more services. The four PHP APC per diem costs would continue to be included in the scaling of all APCs in OPPS to the mid-level office visit (APC 0606). Again, for a detailed discussion of the proposed CY 2013 OPPS weight scaler, we refer readers to section II.A.4. of this proposed rule.

For CY 2013, using CY 2011 claims data, we computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) services using only CY 2011 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II services using only CY 2011 hospital-based PHP claims data. These proposed geometric mean per diem costs are shown in Table 30 below.

TABLE 30—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	182.66
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	232.74

Under the CY 2013 proposal to base the OPPS relative payment weights on geometric mean costs, the proposed geometric mean per diem costs for CMHCs would continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same units of service. For CY 2013, the proposed geometric mean per diem costs for days with 3 services (Level I) is approximately $88 for CMHCs and approximately $183 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) is approximately $112 for CMHCs and approximately $233 for hospital-based PHPs. This analysis indicates that there continues to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2013 proposed geometric mean per diems costs for CMHCs calculated under the proposed CY 2013 methodology using CY 2011 claims data also have decreased compared to the CY 2012 final median per diem costs for CMHCs established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352), with per diem costs for Level I services decreasing from approximately $98 to approximately $88, and costs for Level II services decreasing from approximately $114 to approximately $112. In contrast, the CY 2013 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2013 methodology using CY 2011 claims data have increased compared to the CY 2012 final median per diem costs for hospital-based PHPs, with per diem costs for Level I services increasing from approximately $161 to approximately $183, and per diem costs for Level II services increasing from approximately $191 to approximately $233.

To provide a comparison, we also calculated PHP median per diem costs for CY 2013 using CY 2011 claims data. We computed median per diem costs for each provider type using that provider's

claims data for Level I services and for Level II services. These comparative median per diem costs are shown in Table 31 below.

TABLE 31—COMPARATIVE PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group title	Comparative median per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.52
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	121.27
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	163.86
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	224.57

The proposed geometric mean per diem costs for hospital-based PHPs for Level I and Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be higher than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For hospital-based PHPs, the per diem costs would increase from approximately $164 under the current median-based methodology to approximately $183 under the proposed geometric mean-based methodology for Level I services, and from approximately $225 to approximately $233 for Level II services.

The proposed geometric mean per diem costs for CMHCs for Level I services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be approximately the same as the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. The proposed geometric mean per diem costs for CMHCs for Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be slightly lower than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For CMHCs, the per diem costs would be approximately $88 under both the current median-based methodology and the proposed geometric mean-based methodology for CMHC Level I services, and would decrease from approximately $121 under the current median-based methodology to approximately $112 under the proposed geometric mean-based methodology for CMHC Level II services.

The data analysis also shows that the median per diem costs for CMHCs continue to be substantially lower than the median per diem costs for hospital-based PHPs for the same units of service provided. The median per diem costs for Level I services is approximately $88 for CMHCs and approximately $164 for hospital-based PHPs. The median per diem costs for Level II services is approximately $121 for CMHCs and approximately $225 for hospital-based PHPs. The significant difference in per diem costs between CMHCs and hospital-based PHPs emphasizes the distinct cost structures between the two provider types.

Finally, the data analysis indicates that CMHC median per diem costs for Level I services would have decreased from CY 2012 final median per diem costs (using CY 2010 claims data) (established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352)) to CY 2013 (using CY 2011 claims data) from approximately $98 to approximately $88, using only CMHC claims data. The CMHC median per diem costs for Level II services would have slightly increased from CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $114 to approximately $121, using only CMHC claims data. Hospital-based PHP median per diem costs for Level I and Level II services would have increased from the CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $161 to approximately $164 for Level I services and from approximately $191 to approximately $225 for Level II services, using only hospital claims data.

In summary, while we have historically based the OPPS payments on median costs for services in the APC groups, for CY 2013, we are proposing to calculate the relative payment weights for the OPPS APCs using geometric means, including the four PHP APCs, as discussed in section II.A.2.g. of this proposed rule. The proposed CY 2013 geometric mean per diem costs for the PHP APCs are shown in Tables 32 and 33 below. We invite public comments on these proposals. We will continue our efforts to explore payment reforms that will support quality and result in greater payment accuracy and reduction of fraud and abuse within the partial hospitalization program.

TABLE 32—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group title	Proposed mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89

TABLE 33—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group title	Proposed mean per diem costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$182.66

TABLE 33—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES—Continued

APC	Group title	Proposed mean per diem costs
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$232.74

C. Proposed Separate Threshold for Outlier Payments to CMHCs

In the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we indicated that, given the difference in charges for PHP services provided between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Prior to that time, there was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Therefore, 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. In addition, further analysis indicated that using the same OPPS outlier threshold for both hospitals and CMHCs did not limit outlier payments to high-cost cases and resulted in excessive outlier payments to CMHCs. Therefore, beginning in CY 2004, we established a separate outlier threshold for CMHCs. The separate outlier threshold for CMHCs has resulted in more commensurate outlier payments.

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 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.

We are proposing to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2013. We are proposing that a portion of that 1.0 percent, an amount equal to 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. In section II.G. of this proposed rule, for hospital outpatient outlier payments 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. We are proposing to set the outlier threshold for CMHCs for CY 2013 at 3.40 times the APC payment amount and the CY 2013 outlier payment percentage applicable to costs in excess of the threshold at 50 percent. Specifically, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We invite 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 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 list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient list each year to determine whether or not any procedures should be removed from the list.

B. Proposed Changes to the Inpatient List

For the CY 2013 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 list to identify any procedures that are being performed a significant amount of the time on an outpatient basis, and appropriately 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 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 two procedures that potentially could be removed from the inpatient list for CY 2013: CPT code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical); and CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)). We then reviewed the clinical characteristics and related evidence for these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. For CY 2013, we are proposing to remove the procedures described by CPT codes 22856 and 27447 from the inpatient list because we believe that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above and should thus be paid under the OPPS.

The two procedures we are proposing to remove from the inpatient only list for CY 2013 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 34 below.

TABLE 34—PROCEDURES PROPOSED TO BE REMOVED FROM THE INPATIENT ONLY LIST AND THEIR PROPOSED APC ASSIGNMENTS FOR CY 2013

HCPCS Code	Long descriptor	Proposed CY 2013 APC assignment	Proposed CY 2013 status indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical.	0208	T
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).	0425	T

The complete list of codes that we are proposing to be paid by Medicare in CY 2013 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

X. Proposed Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Conditions of Payment for Physical Therapy, Speech-Language Pathology, and Occupational Therapy Services in Hospitals and CAHs

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74360 through 74371), we clarified that hospital outpatient therapeutic services and supplies, including those described by benefit categories other than the hospital outpatient ''incident to'' category under section 1861(s)(2)(B) of the Act, are subject to the conditions of payment in 42 CFR 410.27 when they are paid under the OPPS or paid to CAHs under section 1834(g) of the Act. We issued this clarification in response to inquiries regarding the application of these conditions of payment to radiation therapy services that are described under section 1861(s)(4) of the Act when these services are furnished to hospital outpatients.

In the CY 2012 OPPS/ASC final rule with comment period, in our response to public comments (76 FR 74369), we indicated that the supervision and other requirements of § 410.27 do not apply to professional services or to services that are paid under other fee schedules such as the Clinical Laboratory Fee Schedule (CLFS). After the publication of the final rule with comment period, we continued to receive questions about the applicability of the regulations to physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) services furnished in CAHs. Several stakeholders expressed concern that the rules could be applied differently in CAHs than in OPPS hospitals. The stakeholders were concerned that OPPS hospitals, which are paid for outpatient therapy services at the applicable amount based on the Medicare Physician Fee Schedule (MPFS), would not be subject to the regulations, but that CAHs, which are paid for outpatient therapy services on a reasonable cost basis, would be subject to them.

In this proposed rule, we are clarifying that it was not our intent in the CY 2012 OPPS/ASC final rule with comment period to establish different requirements for CAHs and for OPPS hospitals for the same services. The supervision and other requirements of § 410.27 apply to facility services that are paid to hospitals under the OPPS and to these same services when they are furnished in CAHs and paid on a reasonable cost basis. In OPPS hospitals, these requirements do not apply to professional services that are separately billed under the MPFS or to PT, SLP, and OT services that are billed by the hospital as therapy services and are paid at the applicable amount based on the MPFS. The payment rules under § 410.27 also do not apply to these same services when they are furnished in CAHs.

In OPPS hospitals, a small subset of ''sometimes therapy'' PT, SLP, or OT services are paid under the OPPS when they are not furnished as therapy, meaning not under a certified therapy plan of care. Because the supervision and other conditions of payment under § 410.27 apply to this subset of ''sometimes therapy'' services when they are furnished in OPPS hospitals as nontherapy services (because they are paid under the OPPS and not based on the MPFS), those conditions of payment also apply to this subset of ''sometimes therapy'' services when they are furnished as nontherapy in CAHs. When OPPS hospitals and CAHs furnish these services as therapy services (under a therapy plan of care by a qualified therapist), the conditions of payment under § 410.27 do not apply because OPPS hospitals are paid for these services based on the MPFS and not under the OPPS. We are providing a list of the ''sometimes therapy'' services that may be paid under the OPPS in Table 35 below.

TABLE 35—''SOMETIMES THERAPY'' SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES

HCPCS Code	Descriptor
97597	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less.
97598	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure).
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session.

TABLE 35—"SOMETIMES THERAPY" SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES—Continued

HCPCS Code	Descriptor
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
97606	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.
0183T	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.

B. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Small Rural Hospitals

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74371), we extended through CY 2012 the notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds (available on the CMS Web Site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp*). We extended this enforcement instruction to our contractors for another year, through CY 2012, to allow time for the initiation of supervision reviews by the Advisory Panel on Hospital Outpatient Payment (the Panel), which began in early 2012 and are continuing in accordance with the provisions of the CY 2012 OPPS/ASC final rule with comment period. The Panel will meet again this summer to consider requests that are referred by CMS for a change in the minimum required supervision level for individual hospital outpatient therapeutic services for the CY 2013 payment year. In this proposed rule, we are requesting that CAHs and small rural hospitals submit to CMS for potential evaluation by the Panel at the summer meeting any services for which they anticipate difficulty complying with the direct supervision standard in CY 2013. In developing evaluation requests, hospitals should refer to the evaluation criteria that we finalized in the CY 2012 OPPS/ASC final rule with comment period. We recognize that hospitals have had little experience in submitting evaluation requests to CMS for consideration by the Panel. In order to give hospitals additional opportunity this year to become familiar with the submission and review process at the summer Panel meeting, and to allow hospitals time to meet the required supervision levels for services that may be considered for CY 2013, we anticipate extending the nonenforcement instruction one additional year through CY 2013. We expect that this will be the final year for the instruction, regardless of the services reviewed by the Panel during its summer meeting.

XI. Outpatient Status: Solicitation of Public Comments

Under section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90–248), the Secretary is permitted to engage in demonstration projects to determine whether changes in methods of payment for health care and services under the Medicare program would increase the efficiency and economy of those services through the creation of incentives to those ends without adversely affecting the quality of such services. Under this statutory authority, CMS has implemented the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which allows participating hospitals to receive 90 percent of the allowable Part B payment for Part A short-stay claims that are denied on the basis that the inpatient admission was not reasonable and necessary. Participating hospitals can rebill these denied Part A claims under Part B and be paid for additional Part B services than would usually be payable when an inpatient admission is deemed not reasonable and necessary. This demonstration is slated to last for 3 years, from CY 2012 through CY 2014. In this proposed rule, we are providing an update of the status of the demonstration. In addition, we are soliciting public comments on a related issue: Potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.

When a Medicare beneficiary presents to a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment. In these cases, under Medicare's longstanding policy, hospitals may rebill a separate inpatient claim for only a limited set of Part B services, referred to as ''Inpatient Part B'' or ''Part B Only'' services (Section 10, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)). The hospital also may bill Medicare Part B for any outpatient services that were provided in the 3-day payment window prior to the admission (Section 10.12, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04)). These claims are subject to the timely filing restrictions.

Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's patient status to outpatient and submit an outpatient claim because of the potentially significant impact on beneficiary liability. As we discuss below, hospital inpatients have significantly different Medicare benefits and liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital for 3 or more consecutive calendar days, coverage of postacute SNF care (to the extent all other SNF coverage requirements are met). To enable beneficiaries to make informed financial and other decisions, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on an outpatient claim) and bill all medically necessary services that it provided to Part B as outpatient

services, but only if the change in patient status is made prior to discharge, the hospital has not submitted a Medicare claim for the admission, and both the practitioner responsible for the care of the patient and the utilization review committee concur in the decision (Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100–04); MLN Matters article SE0622, ''Clarification of Medicare Payment Policy When Inpatient Admission Is Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: 'Inpatient Admission Changed to Outpatient,' '' September 2004). Medicare beneficiaries are provided with similar protections that are outlined in the Hospital Conditions of Participation. For example, in accordance with 42 CFR 482.13(b), Medicare beneficiaries have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and physician is important for patient autonomy and for achieving efficient outcomes.

While the limited scope of allowed rebilling for ''Part B Only'' services protects Medicare beneficiaries and provides disincentives for hospitals to admit patients inappropriately, hospitals have expressed concern that this policy provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the level of inpatient care. A significant proportion of the Medicare CERT error rate consists of short (1- or 2-day) stays where the beneficiary received medically necessary services that the CERT contractor determined should have been provided as outpatient services and not as inpatient services. Hospitals have indicated that often they do not have the necessary staff (for example, utilization review staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short stay, the hospital may be unable to review and change a beneficiary's patient status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

We have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admit them. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 7.5 percent in 2010. This trend is concerning because of its effect on Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, of which CMS has informed beneficiaries.[1] For instance, if a beneficiary is admitted as an inpatient, the beneficiary pays a one-time deductible for all hospital services provided during the first 60 days in the hospital. As a hospital inpatient, the beneficiary would not pay for self-administered drugs or have any copayments for the first 60 days; whereas if the beneficiary is treated as an outpatient, the beneficiary has a copayment for each individual outpatient hospital service. While the Medicare copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible, the beneficiary's total copayment for all outpatient services may be more than the inpatient hospital deductible. In addition, usually self-administered drugs provided in an outpatient setting are not covered by Medicare Part B and hospitals may charge the beneficiary for them. Also, the time spent in the hospital as an outpatient is not counted towards the 3-day qualifying inpatient stay that the law requires for Medicare Part A coverage of postacute care in a SNF (section 1861(i) of the Act).

As a result of these concerns related to the impact of extended time as an outpatient on Medicare beneficiaries, the CERT error rate, and the impact on hospitals of a later inpatient denial, CMS initiated the 3-year AB Rebilling Demonstration for voluntary hospital participants. This demonstration allows the participants to rebill outside of the usual timely filing requirements for services relating to all inpatient short-stay claims that are denied for lack of medical necessity because, despite the provision of reasonable and necessary hospital care, the inpatient admission itself was denied as not medically necessary. Under the demonstration, hospitals may receive 90 percent of the allowable payment for all Part B services that would have been medically necessary had the beneficiaries originally been treated as outpatients and not admitted as inpatients. (We note that hospitals cannot rebill for observation services, which, by definition, must be ordered prospectively to determine whether an inpatient admission is necessary). Hospitals that participate in the AB Rebilling Demonstration will waive any appeal rights associated with the denied inpatient claims eligible for rebilling. Under the demonstration, Medicare beneficiaries are protected from any adverse impacts of expanded rebilling. For example, hospitals cannot bill them for self-administered drugs or additional cost-sharing. The demonstration will provide information on the impact that expanded rebilling may have on the Medicare Trust Funds, beneficiaries, hospitals, and the CERT error rate should CMS change its policy regarding the services that can be rebilled to Medicare Part B. The demonstration is designed to evaluate potential impacts of expanded rebilling on admission and utilization patterns, including whether expanded rebilling would reduce hospitals' incentive to make appropriate initial admission decisions.

Hospitals expressed significant interest in the AB Rebilling Demonstration which began on January 1, 2012. The demonstration was approved to accept up to 380 participants. In order to participate in the demonstration, a facility must not be receiving periodic interim payments from CMS, and must be a Medicare-participating hospital as defined by section 1886(d) of the Act, a category that includes all hospitals paid under the Medicare IPPS, but excludes hospitals paid under the Inpatient Psychiatric Facilities (IPF) PPS, the IRF PPS, and the LTCH PPS, cancer hospitals, CAHs, and children's hospitals.

The hospitals that volunteered to participate and were accepted in the demonstration began rebilling in the early spring of 2012. We are currently accepting applications to participate in the ongoing AB Rebilling Demonstration, and more information about the demonstration is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Part_A_to_Part_B_Rebilling_Demonstration.html*. We plan to conduct an evaluation of the demonstration during and after its completion. While we are monitoring progress and evaluating the demonstration, we also are soliciting public comments on other actions we

[1] CMS Pamphlets: ''Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!'', CMS Product No. 11435, Revised, February 2011; ''How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings,'' CMS Product No. 11333, Revised, February 2011.

could potentially undertake to address concerns about this issue. For example, we have heard from some stakeholders who have suggested a need for us to clarify our current instruction regarding the circumstances under which Medicare will pay for an admission in order to improve hospitals' ability to make appropriate admission decisions. We have issued instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital (Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). We are interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions and clarify the application of Medicare payment policies for both hospitals and physicians, keeping in mind the challenges of implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity.

Some stakeholders also have suggested that CMS has authority to define whether a patient is an inpatient or an outpatient. They believe that it may be permissible and appropriate for us to redefine ''inpatient'' using parameters in addition to medical necessity and a physician order that we currently use, such as length of stay or other variables. For example, currently a beneficiary's anticipated length of stay at the hospital may be a factor in determining whether a beneficiary should be admitted to the hospital, but is not the only factor. We have issued instructions that state that, typically, the decision to admit should be made within 24 to 48 hours, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). However, we are interested in hearing from stakeholders regarding whether it may be appropriate and useful to establish a point in time after which the encounter becomes an inpatient stay if the beneficiary is still receiving medically necessary care to treat or evaluate his or her condition. Such a policy could potentially limit the amount of time that a beneficiary is treated as an outpatient receiving observation services before the hospital encounter becomes inpatient, provided the additional time in the hospital is medically necessary. Currently, we do not specify a limit on the time a beneficiary may be an outpatient receiving observation services, although, in the past, we have limited payment of observation services to a specific timeframe, such as 24 or 48 hours. Some in the hospital community have indicated that it may be helpful for the agency to establish more specific criteria for patient status in terms of how many hours the beneficiary is in the hospital, or to provide a limit on how long a beneficiary receives observation services as an outpatient. We are inviting public comments regarding whether there would be more clarity regarding patient status under such alternative approaches to defining inpatient status. We also note that it is important for CMS to maintain its ability to audit and otherwise carry out its statutory obligation to ensure that the Medicare program pays only for reasonable and necessary care. We are asking that commenters consider opportunities for inappropriately taking advantage of the Medicare system that time-based and other changes in criteria for patient status may create.

Another option stakeholders have suggested is the establishment of more specific clinical criteria for admission and payment, such as adopting specific clinical measures or requiring prior authorization for payment of an admission. We are inviting public comments on this approach. In addition, we are asking commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit. Finally, we are asking commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We believe this is important because some hospitals have indicated that simply having case management and utilization review staff available to assist in decisionmaking outside of regular business hours may improve the accuracy of admission decisions.

In summary, there may be several ways of approaching the multifaceted issues that have been raised in recent months around a beneficiary's patient status and Medicare hospital payment. Given the complexity of this topic, we are providing an update on the rebilling demonstration and are seeking public perspectives on potential options the agency might adopt to provide more clarity and consensus regarding patient status for purposes of Medicare payment. We are inviting commenters to draw on their knowledge of these issues to offer any suggestions that they believe would be most helpful to them in addressing the current challenges, while keeping in mind the various impacts in terms of recently observed increases in the length of time for which patients receive observation services, beneficiary liability, Medicare spending, and the feasibility of implementation of any suggested changes for both the Medicare program and hospitals.

XII. Proposed CY 2013 OPPS Payment Status and Comment Indicators

A. Proposed CY 2013 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs play 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 proposed CY 2013 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. We note that, in the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 proposed rule, the Addenda will no longer appear in the printed version of the OPPS/ASC rules that are found in the **Federal Register**. Instead, these Addenda will be published and available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2013, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2012 OPPS/ASC final rule with comment period. We continue to believe that these definitions of the OPPS status indicators continue to be appropriate for our CY 2013 proposal.

The complete list of the proposed CY 2013 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. Proposed CY 2013 Comment Indicator Definitions

For the CY 2013 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2012 OPPS.

- ''CH''—Active HCPCS codes 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.

We are proposing to use the ''CH'' comment indicator in this CY 2013 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2013 compared to their assignment as of June 30, 2012. We believe that using the ''CH'' indicator in this CY 2013 OPPS/ASC proposed rule will facilitate the public's review of the changes that we are proposing for CY 2013. The use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is proposed to be changed in this CY 2013 OPPS/ASC proposed rule.

We are proposing to use the ''CH'' comment indicator in the CY 2013 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2013 compared to their assignment as of December 31, 2012.

In addition, any existing HCPCS code numbers with substantial revisions to the code descriptors for CY 2013 compared to the CY 2012 descriptors are labeled with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC proposed rule. However, in order to receive the comment indicator ''NI,'' the CY 2013 revision to the code descriptor (compared to the CY 2012 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes are open to comment as part of this CY 2013 OPPS/ASC proposed rule. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2014 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS code numbers that are new for CY 2013 are also labeled with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC proposed rule.

Only HCPCS codes with comment indicator ''NI'' in this CY 2013 OPPS/ASC proposed rule are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2013 OPPS/ASC proposed rule are not open to public comment, unless we specifically request additional comments elsewhere in this proposed rule. The CY 2013 treatment of HCPCS codes that appear in this CY 2013 OPPS/ASC proposed rule to which comment indicator ''NI'' is not appended will be open for public comment during the comment period for the proposed rule, and we will respond to those comments in the CY 2013 OPPS/ASC final rule with comment period. We believe that the CY 2012 definitions of the OPPS status indicators continue to be appropriate for CY 2013, and therefore, we are proposing to continue to use those definitions without modification for CY 2013. Their proposed definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XIII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

MedPAC was established under section 1805 of the Act to advise the Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress no later than March and June of each year that contain its Medicare payment policy recommendations. In this section of our proposed rule, we note several recommendations regarding the Hospital outpatient prospective payment system in the March 2012 report (''Report to the Congress: Medicare Payment Policy,'' available on MedPAC's Web site at: *http://www.medpac.gov/documents/Mar12_EntireReport.pdf*).

MedPAC recommended that Congress increase payment rates for the outpatient prospective payment system in 2013 by 1.0 percent. We discuss our proposal to follow the statutory requirements for the CY 2013 OPD fee schedule increase factor in section II.B of this proposed rule.

In addition, MedPAC recommended that Congress enact legislation to reduce payment rates for evaluation and management office visits provided in hospital outpatient departments to the rates paid for these services in physician offices. MedPAC recommended that the change be phased in over 3 years. During the phase-in, MedPAC stated that the associated payment reductions to hospitals with a disproportionate share patient percentage at or above the median should be limited to 2 percent of overall Medicare payments. MedPAC also recommended that the Secretary of Health and Human Services conduct a study by January 2015 to examine whether this policy change would reduce access by low-income patients to ambulatory physician and other services. Congress has yet to accept this recommendation and enact such legislation.

B. GAO Recommendations

Congress established the U.S. Government Accountability Office (GAO) under the Budget and Accounting Act of 1921 (Pub. L. 67–13) as an independent agency that advises Congress and the heads of Executive agencies regarding Federal program expenditures. The GAO conducts audits and other analyses to ensure that Federal funds are being spent efficiently and effectively. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the GAO has not released any reports regarding the Hospital OPPS.

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG) as mandated by Public Law 95–452 (as amended) is to protect the integrity of the Department of Health and Human Services programs and the health and welfare of program beneficiaries. The OIG conducts independent audits, inspections, and investigations to improve the efficiency of these programs and to identify and prevent fraud, waste and abuse. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the OIG has not made any recommendations regarding the Hospital OPPS.

XIV. 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 ASCs, 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).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures 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 that would not 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 for 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, 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 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. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). 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 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 XIV.B. 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, we also provide quarterly update change requests (CRs) for ASC services throughout the year (January, April, July, and October). CMS releases new Level II codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via these ASC quarterly update CRs. Thus, the updates are to implement newly created 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 Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the 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 procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of 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 Codes

1. Proposed Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

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; (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 products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new 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 they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we are proposing to solicit public comments in this CY 2013 OPPS/ASC proposed rule (and respond to those comments in the CY 2013 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2013 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2014 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2012 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 2012 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the ASC treatment of these codes in the CY 2013 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which We Are Soliciting Public Comments in This CY 2013 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1, 2012 or July 1, 2012, respectively, a total of 12 new Level II HCPCS codes and 5 new Category III CPT codes that were not addressed in the CY 2012 OPPS/ASC final rule with comment period. The 12 new Level II HCPCS codes describe covered ancillary services.

In the April 2012 ASC quarterly update (Transmittal 2425, CR 7754, dated March 16, 2012), we added one new radiology Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 36 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial);
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.));
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg);
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial); and
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography).

In the July 2012 quarterly update (Transmittal 2479, Change Request 7854, dated May 25, 2012), we added seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 37 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9368 (Grafix core, per square centimeter);
- HCPCS code C9369 (Grafix prime, per square centimeter);
- HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu));
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg);
- HCPCS code Q2046 (Injection, aflibercept, 1 mg);
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg); and
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg).

We note that HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to the 10 new Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator ''L1'' (Influenza vaccine; pneumococcal vaccine; packaged item/service; no separate payment made) or payment indicator ''N1'' (Packaged service/item; no separate payment made) to the two new Level II HCPCS codes that are packaged when provided in ASCs. We are soliciting public comment on the proposed CY 2012 ASC payment indicators and payment rates for the covered ancillary services listed in Tables 36 and 37 below. Those HCPCS codes became payable in ASCs, beginning in April or July 2012, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.*

The HCPCS codes listed in Table 36 are included in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We note that all ASC addenda are only available via the Internet on the CMS Web site. Because the payment rates associated with the new Level II HCPCS codes that became effective for July 2012 (listed in Table 37) are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2013 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2012 ASC quarterly update CR and their proposed CY 2013 payment rates (based on July 2012 ASP data) that are displayed in Table 37 are not included in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2013 OPPS/ASC final rule with comment period, consistent with our annual update policy. We are soliciting public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered ancillary services in April and July 2012 through the quarterly update CRs, as listed in Tables 36 and 37 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 36—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 payment indicator
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	K2
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	K2
C9290	Injection, bupivacaine liposome, 1 mg	K2
C9291	Injection, aflibercept, 2 mg vial	K2
C9733	Non-ophthalmic fluorescent vascular angiography	N1

TABLE 37—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 payment indicator	Proposed CY 2013 payment rate
C9368	Grafix core, per square centimeter	K2	$7.96
C9369	Grafix prime, per square centimeter	K2	0.61
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L1	N/A
Q2045	Injection, human fibrinogen concentrate, 1 mg*	K2	0.73
Q2046	Injection, aflibercept, 1 mg*	K2	980.50
Q2048	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg*	K2	537.21
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K2	498.26

*HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

Through the July 2012 quarterly update CR, we also implemented ASC payment for five new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2012. These codes are listed in Table 38 below, along with their proposed payment indicators and proposed payment rates for CY 2013. Because the payment rates associated with the new Category III CPT codes that became effective for July are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The codes listed in Table 38 and their final payment indicators and rates will be included in Addendum AA to the CY 2013 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to three of the five new Category III CPT codes implemented in July 2012 and to assign payment indicator ''J8'' (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to the remaining two new Category III CPT codes implemented in July 2012. We believe that these procedures would not be expected to pose a significant safety risk to Medicare beneficiaries or would not be expected to require an overnight stay if performed in ASCs. We are soliciting public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered surgical procedures in July 2012 through the quarterly update CR, as listed in Table 38 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 38—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012 AS ASC COVERED SURGICAL PROCEDURES

CY 2012 CPT code	CY 2012 long descriptor	Proposed CY 2013 payment indicator	Proposed CY 2013 payment rate
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode).	J8	$7,181.95
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only.	G2	2,129.99
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only.	J8	5,816.80
0307T	Removal of intracardiac ischemia monitoring device	G2	968.15
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens*	G2	940.65

*CPT code 0308T replaced HCPCS code C9732 beginning July 1, 2012.

3. Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2013 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system 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 2013. Specifically, for CY

2013, we are proposing to include in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013, that would be incorporated in the January 2013 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2013 OPPS/ASC final rule with comment period and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all 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 changed the clinical appropriateness of these procedures for the ASC setting. We are proposing to update the list of ASC covered surgical procedures by adding 16 procedures to the list. We determined that these 16 procedures would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

The 16 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2013 payment indicators, are displayed in Table 39 below. We invite public comment on this proposal.

TABLE 39—PROPOSED NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2013

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 ASC payment indicator**
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel.	G2
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure).	G2
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty.	G2
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed.	G2
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	G2
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	J8
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty.	G2
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed.	G2
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	G2
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	J8
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (list separately in addition to code for primary procedure).	G2
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care.	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. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

b. 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 it 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 surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2013 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the 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 2011 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' in CY 2012, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74400 through 74408).

Our review of the CY 2011 volume and utilization data resulted in our identification of six covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices, and that our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The six CPT codes we are proposing to permanently designate as office-based are listed in Table 40 below. We invite public comment on this proposal.

TABLE 40—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2013

CY 2012 CPT code	CY 2012 long descriptor	CY 2012 ASC payment indicator	Proposed CY 2013 ASC payment indicator *
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa.	G2	P2
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	G2	P2
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	G2	P2
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence.	G2	P2
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	G2	P3
G0365	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow).	G2	P2

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

We also reviewed CY 2011 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74404 through 74408). Among these eight procedures, there were very few claims data for six procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); 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); 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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2013.

The volume and utilization data for the remaining two procedures that have temporary office-based designations for CY 2012 are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2013. Consequently, we are proposing to assign payment indicator ''G2'' to the following two covered surgical procedure codes in CY 2013:

- CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

The proposed CY 2013 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2012 are displayed in Table 41 below. The procedures for which the proposed office-based designations for CY 2013 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 invite public comment on this proposal.

TABLE 41—PROPOSED CY 2013 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2012 CPT code	CY 2012 long descriptor	CY 2012 ASC payment indicator	Proposed CY 2013 ASC payment indicator **
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg.	R2 *	G2
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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 *
0099T	Implantation of intrastromal corneal ring segments	R2 *	R2 *
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication).	R2 *	R2 *
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2 *	R2 *
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies).	R2 *	R2 *
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed.	R2 *	G2
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 *

* 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. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(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.

(2) Proposed Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2013

For CY 2013, 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 the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as device-dependent, and APC device offset percentages based on the CY 2011 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this 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 2013 are listed in Table 42 below. The CPT code, the CPT code short descriptor, the proposed CY 2013 ASC payment indicator (PI), the proposed CY 2013 OPPS APC assignment, the proposed CY 2013 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 42 below. A review of the FB/FC device adjustment policy is also found 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 invite public comment on this proposal.

d. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

We generally discuss the no cost/full credit and partial credit devices under the heading entitled ''Proposed ASC Payment for Covered Surgical Procedure.'' However, because the no cost/full credit and partial credit device policy applies to a subset of device-intensive procedures, we believe it would be clearer to discuss the device-intensive procedure policy and the no cost/full credit and partial credit device policy consecutively and to consolidate the tables that we usually publish separately. 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. The proposed CY 2013 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this

proposed rule. The established ASC policy adopts the OPPS policy and 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 68745).

Consistent with the OPPS, we are proposing to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2013. Table 42 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 2013. Specifically, when a procedure that is listed in Table 42 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is listed in Table 43 below, where that device 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 would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. 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 42 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 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 42 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 of the cost of a device listed in Table 43 below. In order to report that they received a partial credit of 50 percent or more 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 of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

We invite public comments on these proposals.

TABLE 42—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2013, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT code	Short descriptor	Proposed CY 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 device-dependent APC offset percent	Proposing that the FB/FC policy would apply
0282T	Periph field stimul trial	J8	0040	55	Yes.
0283T	Periph field stimul perm	J8	0318	87	Yes.
0302T	Icar ischm mntrng sys compl	J8	0089	70	Yes.
0304T	Icar isch mntrng sys device	J8	0090	71	Yes.
19296	Place po breast cath for rad	J8	0648	50	Yes.
19297	Place breast cath for rad	J8	0648	50	Yes.
19298	Place breast rad tube/caths	J8	0648	50	Yes.
19325	Enlarge breast with implant	J8	0648	50	Yes.
19342	Delayed breast prosthesis	J8	0648	50	Yes.
19357	Breast reconstruction	J8	0648	50	Yes.
24361	Reconstruct elbow joint	J8	0425	58	Yes.
24363	Replace elbow joint	J8	0425	58	Yes.
24366	Reconstruct head of radius	J8	0425	58	Yes.
25441	Reconstruct wrist joint	J8	0425	58	Yes.
25442	Reconstruct wrist joint	J8	0425	58	Yes.
25446	Wrist replacement	J8	0425	58	Yes.
27446	Revision of knee joint	J8	0425	58	Yes.
33206	Insertion of heart pacemaker	J8	0089	70	Yes.
33207	Insertion of heart pacemaker	J8	0089	70	Yes.
33208	Insertion of heart pacemaker	J8	0655	73	Yes.
33212	Insertion of pulse generator	J8	0090	71	Yes.
33213	Insertion of pulse generator	J8	0654	74	Yes.
33214	Upgrade of pacemaker system	J8	0655	73	Yes.
33221	Insert pulse gen mult leads	J8	0654	74	Yes.
33224	Insert pacing lead & connect	J8	0655	73	Yes.
33225	Lventric pacing lead add-on	J8	0655	73	Yes.
33227	Remove&replace pm gen singl	J8	0090	71	Yes.
33228	Remv&replc pm gen dual lead	J8	0654	74	Yes.
33229	Remv&replc pm gen mult leads	J8	0654	74	Yes.

TABLE 42—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2013, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

CPT code	Short descriptor	Proposed CY 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 device-dependent APC offset percent	Proposing that the FB/FC policy would apply
33230	Insrt pulse gen w/dual leads	J8	0107	83	Yes.
33231	Insrt pulse gen w/dual leads	J8	0107	83	Yes.
33240	Insert pulse generator	J8	0107	83	Yes.
33249	Eltrd/insert pace-defib	J8	0108	84	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	83	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	83	Yes.
33264	Remv&replc cvd gen mult lead	J8	0107	83	Yes.
33282	Implant pat-active ht record	J8	0680	74	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	53	No.
37231	Tib/per revasc stent & ather	J8	0319	53	No.
53440	Male sling procedure	J8	0385	63	Yes.
53444	Insert tandem cuff	J8	0385	63	Yes.
53445	Insert uro/ves nck sphincter	J8	0386	70	Yes.
53447	Remove/replace ur sphincter	J8	0386	70	Yes.
54400	Insert semi-rigid prosthesis	J8	0385	63	Yes.
54401	Insert self-contd prosthesis	J8	0386	70	Yes.
54405	Insert multi-comp penis pros	J8	0386	70	Yes.
54410	Remove/replace penis prosth	J8	0386	70	Yes.
54416	Remv/repl penis contain pros	J8	0386	70	Yes.
55873	Cryoablate prostate	J8	0674	54	No.
61885	Insrt/redo neurostim 1 array	J8	0039	86	Yes.
61886	Implant neurostim arrays	J8	0315	88	Yes.
62361	Implant spine infusion pump	J8	0227	82	Yes.
62362	Implant spine infusion pump	J8	0227	82	Yes.
63650	Implant neuroelectrodes	J8	0040	55	Yes.
63655	Implant neuro-electrodes	J8	0061	66	Yes.
63663	Revise spine eltrd perq aray	J8	0040	55	Yes.
63664	Revise spine eltrd plate	J8	0040	55	Yes.
63685	Insrt/redo spine n generator	J8	0039	86	Yes.
64553	Implant neuro-electrodes	J8	0040	55	Yes.
64555	Implant neuro-electrodes	J8	0040	55	Yes.
64561	Implant neuro-electrodes	J8	0040	55	Yes.
64565	Implant neuro-electrodes	J8	0040	55	Yes.
64568	Implant neuro-electrodes	J8	0318	87	Yes.
64575	Implant neuro-electrodes	J8	0061	66	Yes.
64580	Implant neuro-electrodes	J8	0061	66	Yes.
64581	Implant neuro-electrodes	J8	0061	66	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	86	Yes.
65770	Revise cornea with implant	J8	0293	65	No.
69714	Implant temple bone w/stimul	J8	0425	60	Yes.
69715	Temple bne implnt w/stimulat	J8	0425	60	Yes.
69717	Temple bone implant revision	J8	0425	60	Yes.
69718	Revise temple bone implant	J8	0425	60	Yes.
69930	Implant cochlear device	J8	0259	84	Yes.
G0448	Place perm pacing cardiovert	J8	0108	84	Yes.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1762	Conn tiss, human (inc fascia).
C1763	Conn tiss, non-human.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1776	Joint device (implantable).
C1777	Stent, non-coat/cov w/o del.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1781	Mesh (implantable).
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1900	Lead coronary venous.
C2618	Probe, cryoablation.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

e. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2013

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 two procedures we are proposing to remove from the OPPS inpatient list for CY 2013 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these two procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 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 two procedures and their long descriptors are listed in Table 44 below.

TABLE 44—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2013 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2013 OPPS INPATIENT LIST

CPT code	Long descriptor
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical.
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).

We invite public comments on this proposal.

2. 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 2013 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2013. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2012 may be proposed for packaged status under the CY 2013 OPPS and, therefore, also under the ASC payment system for CY 2013. Comment indicator "CH," discussed in section XII.B. 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 2013.

Except for the Level II HCPCS codes listed in Table 37 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2013 are included in Addendum BB to this proposed rule.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed 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, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used 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 were, therefore, 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 2012 OPPS/ASC final rule with comment period (76

FR 74377 through 74451), we updated the CY 2011 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2010 data, consistent with the CY 2012 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2012 OPPS device offset percentages.

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 2013 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2012 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 2012 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 2012 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2013

We are proposing to update ASC payment rates for CY 2013 using the established rate calculation methodologies under § 416.171. We note that, as discussed in section II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting 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, incorporating the device-intensive procedure methodology as appropriate. Thus, we are proposing to update the payment amounts for device-intensive procedures based on the CY 2013 OPPS proposal that reflects updated proposed OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2013 MPFS nonfacility PE RVU-based amount or the proposed CY 2013 ASC payment amount calculated according to the standard ratesetting methodology.

We invite 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 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 identified 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 list of services. We identify these services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Payment for the Cardiac Resynchronization Therapy Composite

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 and 33249 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428). We are not proposing any changes to our current policy regarding ASC payment for CRT–D services for CY 2013.

e. Proposed 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 our 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 services to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

As detailed in section II.A.2.e.(2) of this proposed rule, beginning in CY 2008 under the OPPS, 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 based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the 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 implemented this policy in the OPPS because reliance on single procedure claims to set payment rates for these services resulted in the use of mainly incorrectly coded claims for LDR prostate brachytherapy because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and

radiation therapy planning services (72 FR 66652 through 66655).

Currently under the ASC payment system, ASCs receive separate payment for the component services that comprise the LDR Prostate Brachytherapy Composite when the two services are provided on the same date of service. Specifically, ASCs that report CPT codes 55875 and 77778 on the same date of service receive a payment for CPT code 55875 where the payment rate is based on the OPPS relative payment weight for single procedure claims, and a separate payment for CPT code 77778 where payment is the lower of the rate based on the OPPS relative payment weight for single procedure claims or the MPFS non-facility PE–RVU based amount.

A commenter to the CY 2012 OPPS/ASC proposed rule (76 FR 74429 through 74430) requested that CMS pay for LDR prostate brachytherapy services under the ASC payment system based on the composite OPPS payment rate rather than making two separate payments for the service reported by CPT codes 55875 and 77778. The commenter asserted that basing ASC payments for the services on the composite APC methodology in which one payment is made for the combination of the two services would result in a more accurate payment than is currently being made to ASCs because ASC payment is based on costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims. We responded that we would take the commenter's request into consideration in future rulemaking, recognizing the lead time that is necessary for the creation of the associated G-code that would be used to identify when the procedures in the LDR prostate brachytherapy composite are performed on the same date of service in an ASC.

Because we agree that data from OPPS claims reporting both services required for LDR prostate brachytherapy provide the most accurate relative payment weight upon which to base ASC payment for the component services, we are proposing to establish an ASC payment rate that is 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. We also are proposing to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service to receive the appropriate LDR Prostate Brachytherapy Composite payment. The payment rate associated with the LDR Prostate Brachytherapy Composite will be temporarily identified by G-code ''GXXX1'' in Addendum AA of this proposed rule. The permanent G-code that will identify the LDR Prostate Brahytherapy Composite for ASCs will appear in the CY 2013 OPPS/ASC final rule with comment period. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. We invite public comment on this proposal.

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. We want to further clarify 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, we established a final policy to align 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, while 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. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS. We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) 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 will, therefore, include the cost for the contrast agent.

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.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the four devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)), HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1749, C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, the HCPCS code C1749 device costs will 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 2013.

b. Proposed Payment for Covered Ancillary Services for CY 2013

For CY 2013, we are proposing to update the ASC payment rates and 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 2013 OPPS and ASC payment rates. The proposed CY 2013 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2013 ASC payment rates for those services equal to the proposed CY 2013 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2013 payment for separately payable covered radiology services is based on a comparison of the CY 2013 proposed MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2013 MPFS proposed rule) and the proposed CY 2013 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). Alternatively, payment for a radiology service may 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 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 are assigned payment indicator ''Z2'' (Radiology 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 are assigned payment indicator ''Z3'' (Radiology 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 is made based on the OPPS relative payment weights rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower. We are proposing to continue this modification to the payment methodology and, therefore, set the payment indicator to ''Z2'' for these nuclear medicine procedures in CY 2013. As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), we are proposing that payment indicators for radiology services that use contrast agents will be set to ''Z2'' in CY 2013 so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on these proposals.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- 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 Public Law 103–432 and our regulations at § 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; and
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following major criteria set out at 42 CFR 416.195:

- 42 CFR 416.195(a)(1): The IOL is approved by the FDA;
- 42 CFR 416.195(a)(2): Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising;
- 42 CFR 416.195(a)(3): The IOL is not described by an active or expired

NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and

- 42 CFR 416.195(a)(4): Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following improved outcomes:
  - Reduced risk of intraoperative or postoperative complication or trauma;
  - Accelerated postoperative recovery;
  - Reduced induced astigmatism;
  - Improved postoperative visual acuity;
  - More stable postoperative vision; or
  - Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table with the associated qualifying IOL models, at the link entitled ''NTOL Application Determination Reference document Updated 01/06/2012,'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

2. NTIOL Application Process for Payment Adjustment

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 Lens (NTIOL)'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. When a new NTIOL class is created, we 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. The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

3. Requests To Establish New NTIOL Classes for CY 2013 and Deadline for Public Comments

We received no requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date (76 FR 74443).

4. 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 2013.

5. Proposed Revisions to the Major NTIOL Criteria Described in 42 CFR 416.195

The last significant revisions to the regulations containing the substantive NTIOL evaluation criteria under 42 CFR 416.195 occurred in 2007. We are proposing significant revisions to § 416.195(a)(2) and § 416.195(a)(4). We believe that revising § 416.195 is necessary in order to improve the quality of the NTIOL applications. In recent years, we have received low quality NTIOL applications that may have been due in part to overly-broad evaluation criteria.

We are proposing to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contains a claim of a specific clinical benefit imparted by a new lens characteristic. The IOL shall have a new lens characteristic in comparison to currently available IOLs. We also are proposing to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

The proposed revision to § 416.195(a)(2) is necessary because recent NTIOL applications have not included FDA labeling claims of clinical benefit. Instead, the candidate IOLs have, in most cases, had some characteristic for which the applicant has tried to prove clinical relevance through various kinds of evidence that have not been evaluated by the FDA because the evidence is not associated with a labeling claim. The result has been the submission of low quality evidence that has been insufficient for NTIOL status. We believe that the quality of the evidence would improve if applicants were required to obtain a labeling claim for the NTIOL benefit and therefore have the evidence for such benefit evaluated by FDA. We believe that this proposed approach would better serve CMS, FDA, and the applicants because any ultimate grant of NTIOL status would be supported by a labeling claim. The manufacturer could then advertise the NTIOL benefit without running afoul of FDA advertising limitations. We would have the benefit of an FDA review of the relevant evidence, which would be particularly valuable because the FDA has a dedicated team of scientists, physicians, and engineers who are experts in evaluating IOLs.

The proposed revision to § 416.195(a)(4) is necessary to insure that the claim is clinically relevant and represents an improved outcome for Medicare beneficiaries. We request public comments on these proposed revisions to the NTIOL regulations.

6. Request for Public Comment on the ''Other Comparable Clinical Advantages'' Improved Outcome

Section 416.195(a)(4)), discussed above, lists the following improved outcomes: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

This list is from the original 1994 NTIOL statutory provision. Because this provision is almost 20 years old, outcomes (i) through (v) have only limited relevance to modern cataract surgery. For example, regarding outcome (i), it is unclear what, if any, type of IOL could reduce the risk of complication or trauma associated with cataract surgery, or what, if any, contemporary cataract surgery complication could be affected by a new type of IOL. As for outcome (ii), postoperative recovery is already rapid in uncomplicated cataract surgery; therefore, it is difficult to see how it

could be significantly accelerated. Also, regarding outcome (iii), clinically significant induced astigmatism would be reflective of poor surgical technique and would not depend upon IOL design. Regarding outcome (iv), currently available IOLs provide such high quality postoperative visual acuity that it would be difficult to measure clinically significant improved postoperative visual acuity due to a new type of IOL. Finally, for outcome (v), postoperative vision is typically stable after uncomplicated cataract surgery, so again it would be difficult to improve upon this outcome.

The last of the listed improved outcomes is the nonspecific category described as ''other comparable clinical advantages.'' Given that present-day cataract surgery is such a successful procedure that results in significantly improved vision for almost all patients who undergo the procedure and who are appropriate candidates for cataract surgery, we are soliciting comments on what potential benefits associated with a new IOL could be considered to be a ''comparable clinical advantage'' as compared to the list of the five improved outcomes from the statute and regulation described above.

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'' is also 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 2013 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 2012 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled ''January 2012 ASC Approved HCPCS Code and Payment Rates'' in the ASC Addenda Update section of the CMS Web site.

The ''CH'' comment indicator is used in Addenda AA and BB to this CY 2013 OPPS/ASC 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; 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

We are not proposing any changes to the definitions of the ASC payment and comment indicators for CY 2013. 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 2013 update.

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (C) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 15 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2012 MedPAC ''Report to the Congress: Medicare Payment Policy'' included the following recommendations relating specifically to the ASC payment system for CY 2013:

Recommendation 5–1: ''The Congress should update the payment rates for ambulatory surgical centers by 0.5 percent for calendar year 2013. The Congress should also require ambulatory surgical centers to submit cost data.''

Regarding the ASC payment update for CY 2013, MedPAC further stated that: ''On the basis of our payment adequacy indicators, the lack of ASC cost data, and our concerns about the potential effect of ASC growth on overall program spending, we believe a moderate update of 0.5 percent is warranted for CY 2013.'' With regard to the collection of cost data, MedPAC indicated that cost data are needed to fully assess ASC payment adequacy under the revised ASC payment system and to examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed to annually update ASC payment rates.

CMS Response: We note that MedPAC's recommendation is for the Congress to increase ASC payment rates by 0.5 percent in CY 2013 and require ASCs to submit cost data. Congress has not acted on these recommendations. We are proposing to continue our current policy to update the ASC conversion factor using the CPI–U, and we are not proposing to require ASC to submit cost data in this proposed rule. However, as discussed in section XIV.H.2.b. of this proposed rule, the CPI–U may not be the best measure of inflation for the goods and services provided by ASCs and, therefore, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs that would assist us in determining possible alternatives to using the CPI–U to update ASC payment rates for inflation.

H. 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 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).

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 and 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 XIV.D.2.b. of this proposed rule) the established policy is to set the payment rate at the lower of the MPFS unadjusted non-facility 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 hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount. 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, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices 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). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 Hinesville-Fort Stewart, GA, and CBSA 22 Rural Massachusetts.

In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however, in this situation, all of the areas contiguous to CBSA 11340 Anderson, SC are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2013 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). We note that, as discussed in section II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. Consistent with our established policy, we are proposing to scale the CY 2013 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2011, we are proposing to compare the total payment using the CY 2012 ASC relative payment weights with the total payment

using the CY 2013 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2012 and CY 2013. We would use the ratio of CY 2012 to CY 2013 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2013. The proposed CY 2013 ASC scaler is 0.9331 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology 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. We currently have available 98 percent of CY 2011 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 2011 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2011 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.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 2013 ASC payment system, 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 2013, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2011 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2011 ASC utilization and service-mix and the proposed CY 2013 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2012 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. 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 2012 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0002 (the proposed CY 2013 ASC wage index budget neutrality adjustment) to the CY 2012 ASC conversion factor to calculate the proposed CY 2013 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.'' The statute, therefore, 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).

ASC stakeholders, as well as MedPAC, have commented throughout the years that the CPI–U may not adequately measure inflation for the goods and services provided by ASCs (see, for example, 76 FR 74444, 74448 through 74450; 73 FR 68757; and 72 FR 66859). While we believe the CPI–U is appropriate to apply to update the ASC payment system, the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. In developing this proposed rule, we considered possible alternatives to using the CPI–U to update ASC payment rates for inflation.

ASC stakeholders have urged us to adopt the hospital market basket to update ASC payment rates for inflation when commenting on each proposed rule since the beginning of the revised ASC payment system (72 FR 66859; 73 FR 68757; 74 FR 60628 through 60629; 75 FR 72063; 76 FR 74449). We considered the hospital market basket as an alternative to the CPI–U and, while the items included in the hospital market basket seem reflective of the kinds of costs incurred by ASCs, as stated in the CY 2012 OPPS/ASC final rule with comment period, we believe that the hospital market basket does not align with the cost structures of ASCs. A much wider range of services, such as room and board and emergency services, are provided by hospitals but are not costs associated with providing services in ASCs (76 FR 74450). As other possible alternatives to the CPI–U update, we considered using the physician's practice expense (PE) component of the Medicare Economic Index (MEI) update, as well as using an average of the hospital market basket update and the PE component of the MEI update. However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of these alternatives are a better proxy for ASC costs than the CPI–U. Therefore, we are proposing a continuation of the established policy of basing the ASC update on the CPI–U. In addition, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs in the future in order to determine if one of these alternative updates or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI–U.

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) authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) 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. Section XVI.D. of this proposed rule provides a discussion of the proposed payment reduction to the annual update for ASCs that fail to meet the ASCQR Program requirements. In summary, we are proposing 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. The reduced rates would apply beginning in CY 2014. We are proposing that 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 are proposing changes to §§ 416.160(a)(1) and 416.171 to reflect this proposal.

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 number. 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 payment determination 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 may reduce this percentage change below zero. 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. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, for the 12-month period ending with the midpoint of CY 2013, the CPI–U update is projected to be 2.2 percent. Because the ASCQR Program does not affect payment rates until CY 2014, there would be no quality reporting reduction to the CPI–U for CY 2013. The MFP adjustment for the period ending with the midpoint of CY 2013 is projected to be 0.9 percent based on the methodology for calculating the MFP adjustment finalized 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). We are proposing to reduce the CPI–U update of 2.2 percent by the MFP adjustment of 0.9 percent, resulting in an MFP-adjusted CPI–U update factor of 1.3 percent. Therefore, we are proposing to apply a 1.3 percent MFP-adjusted CPI–U update factor to the CY 2012 ASC conversion factor.

For CY 2013, we also are proposing to adjust the CY 2012 ASC conversion factor ($42.627) by the wage adjustment for budget neutrality of 1.0002 in addition to the MFP-adjusted update factor of 1.3 percent discussed above, which results in a proposed CY 2013 ASC conversion factor of $43.190.

We invite public comment on these proposals.

3. Display of Proposed CY 2013 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 2013 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2013 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will 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 2012. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment on the final rule with comment period.

The values displayed in the column titled ''CY 2013 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2013. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Thus, 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 2013 payment rate displayed in the ''CY 2013 Payment'' column, each ASC payment weight in the ''CY 2013 Payment Weight'' column was multiplied by the proposed CY 2013 conversion factor of $43.190. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by

the productivity adjustment (as discussed in section XV.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2013 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2013 Payment'' column displays the proposed CY 2013 national unadjusted ASC payment rates for all items and services. The proposed CY 2013 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 2012.

XV. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality reporting programs for long term care hospitals, inpatient rehabilitation hospitals, the hospice program, ambulatory surgical centers (the Ambulatory Surgical Center Quality Reporting (ASCQR) Program), as well as a program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)). CMS has recently proposed to implement quality reporting programs for inpatient psychiatric facilities and PPS-exempt cancer hospitals.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) 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, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. Our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between electronic health records (EHRs), and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we generally applied the same principles for the development and the use of measures, with some differences:

- Our overarching goal is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The Hospital OQR Program will help achieve the three-part aim by creating transparency around the quality of care at hospital outpatient departments to support patient decision-making and quality improvement. Given the availability of well-validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: *http://www.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting should rely on a mix of standards, processes, outcomes, efficiency, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. The measure sets should evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.
- We weigh the relevance and the utility of measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. The collection of information burden on providers should be minimized to the extent possible. To this end, we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.
- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization. We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views

patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

• Measures should be developed with the input of providers, purchasers/payers, consumers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

• HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are to: Transform Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce HAIs in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74452), we responded to public comment on many of these principles. In this proposed rulemaking, we generally applied the same principals for our considerations for future measures, with some differences.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Measure Updates and Data Publication

a. Process for Updating Quality Measures

Technical specifications for the Hospital OQR Program measures are listed in the Hospital OQR Specifications Manual, which is posted on the CMS QualityNet Web site at: *http://www.QualityNet.org*. We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We provide notice of the updates via the QualityNet Web site, *http://www.QualityNet.org*, and in the Hospital OQR Specifications Manual.

We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for non-substantive changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically provided to hospitals for a preview period via QualityNet, and then displayed on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov* following the preview period. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. This information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thus providing additional incentives to hospitals to improve the quality of care that they furnish.

Under our current policy, we publish quality data by the corresponding hospital CCN, and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the *Hospital Compare* Web site. Consistent with our current policy, we make Hospital IQR and Hospital OQR data publicly available whether or not the data have been validated for payment purposes. The *Hospital Compare* Web site currently displays information covering process of care, structural, ED throughput timing, health IT, and imaging efficiency measure data under the Hospital OQR Program.

In general, we strive to display hospital quality measures on the *Hospital Compare* Web site as soon as possible, after they have been adopted and have been reported to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the interactive *Hospital Compare* Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on

non-interactive CMS Web sites, affected parties will be notified via CMS listservs, CMS email blasts, memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

We also require hospitals to complete and submit a registration form (''participation form'') in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims.

B. Proposed Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comments on the proposal to retain such measures for all future payment determinations unless otherwise specified. For the purpose of streamlining the rulemaking process, beginning with this rulemaking, we are proposing that when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace the measures. We invite public comment on this proposal.

C. Removal or Suspension of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS rulemaking, we finalized a process for immediate retirement of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 43864 through 43865). We adopted this same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634). At this time, we have not proposed to retire any measures from the Hospital OQR Program.

In previous Hospital IQR Program rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, we stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28034) that we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program. We are proposing to adopt the same terminology of ''removal'' in the Hospital OQR Program to indicate future action of discontinuing a measure in the Hospital OQR Program.

In the future, we are proposing to apply the same Hospital IQR Program measure removal criteria that we finalized, based on comments suggested during rulemaking, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), when determining whether to remove Hospital OQR Program measures. These criteria are: (1) Measure performance among hospitals 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 such as patient harm. These criteria were suggested by commenters during Hospital IQR Program rulemaking, and we agreed that these criteria are also applicable in evaluating Hospital OQR Program quality measures for removal. We are proposing to adopt these measure retirement criteria for the Hospital OQR Program as well, and we invite public comments on these proposals.

In addition, in the evaluation of measure removal, we take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for certain quality reporting programs and pay for performance programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

2. Suspension of One Chart-Abstracted Measure for the CY 2014 and Subsequent Years Payment Determinations

In the 2012 IPPS/LTCH PPS final rule (76 FR 51611), we adopted a policy to immediately suspend collection of a measure when there is a reason to believe that continued collection of the measure raises patient safety concerns.

For CY 2014 and subsequent year payment determination, we are confirming that we have suspended the collection of OP–19: Transition Record with Specified Elements Received by Discharged Patients measure. We adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. Since data collection for this measure began, concerns have been raised about the current measure specifications, including potential privacy concerns which may lead to potential patient harm in the form of family violence.

After consideration of these issues and internal review of the measure specifications, we decided to suspend data collection for OP–19 effective with January 1, 2012 encounters until further notice. On April 2, 2012 we released a Memorandum ''Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients.'' This memo notified the Hospital OQR Program stakeholder community that we had suspended data collection for the OP–19 measure effective with January 1, 2012 encounters and until further notice.

On April 12, 2012, we released a Memorandum, ''Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients'' to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or in validation.

The updated memorandum is available for review at the QualityNet Web site (*http://www.qualitynet.org*)

under the option ''Email Notifications'' within the ''Hospitals—Outpatient'' drop down menu found at the top of the page.

When NQF completes its maintenance review on this measure, and we have incorporated the necessary changes to the measure specifications in our measure manual, we anticipate being able to resume data collection, and will notify hospitals of changes in the suspension status of the measure for Hospital OQR via email blast.

Because CMS system constraints prevent immediate cessation of data collection, hospitals must continue to submit information for this measure during this temporary suspension. The data collection system currently requires a populated value for OP–19. During the period of time that the measure is suspended, hospitals may choose to populate their OP–19 submission field with a value that is not meaningful. Hospitals should not submit a null value because the lack of data for OP–19 will cause the submitted case to be rejected entirely from the data warehouse. In other words, failure to populate the OP–19 field could compromise reporting data for other measures for that same case because more than one measure can be reported within a single case.

Some vendors may have the capability to provide a default value for this measure to reduce data abstraction. Hospitals are encouraged to work with their vendors to determine options to reduce abstraction burden.

If a case is rejected from the data warehouse on the basis of a system error due to the current system's inability to accept a case without OP–19 data populated, in the event that the rejected case would have also fulfilled reporting requirements for one or more other measures, this rejection would create an unwanted consequence for a hospital participating in the Hospital OQR Program. Data rejection due to a system constraint could impact a hospital's ability to meet Hospital OQR Program requirements for receiving a full outpatient hospital annual payment update.

Therefore, we recommend continuing to submit a value for OP–19, although we will not use data submitted on OP–19 for payment determinations, will not publicly report these data, and will not validate these data until all concerns are resolved and measure specifications refined as necessary.

Because the developer is working to revise the measure specifications to address the concerns raised by affected parties, and the measure is undergoing NQF maintenance review this year, we are not proposing to remove the measure from the program at this time. After completion of the NQF maintenance process, we anticipate that normal program operations for this measure could resume once we have updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. However, should we determine that these concerns cannot be addressed, we would propose to remove this measure in a future OPPS/ASC rule. We invite public comment on the suspension of OP–19 until further notice. We also invite public comment on whether the measure should be removed from the program at this time.

3. Deferred Data Collection of OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period, we finalized OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting for CY 2014 payment determination and indicated that the applicable quarters for data collection for this measure would be 1st quarter CY 2013 and 2nd quarter CY 2013 (76 FR 74464, 74481). In order for us to adhere to this data collection schedule, we would need to publish the measure specifications in the July 2012 release of the Hospital OQR Specifications Manual. While there are NQF-endorsed specifications for this measure, in order to implement standardized data collection on a national scale, we must include detailed abstraction instructions for chart-based measures in our Specifications Manual. These instructions will not be completed and tested in time to include in the July 2012 release of the Specifications Manual, which includes collection instructions for measures beginning January 1, 2013. This is an unanticipated delay in implementation that we do not expect to be a regularly occurring issue for the Hospital OQR program.

Therefore, we are proposing to defer the data collection for this measure to January 1, 2014 encounters. We are also proposing that the measure would no longer be used for the CY 2014 payment determination, and that its first application would be for the CY 2015 payment determination. The data collection deferral for this measure is detailed in the ''Form, Manner, and Timing'' section of this proposed rule. We invite public comments on these proposals.

D. Quality Measures for CY 2015 Payment Determination

We previously finalized 26 measures for the CY 2015 Hospital OQR Program measure set in the 2012 OPPS/ASC rulemaking (76 FR 74472 through 74474).

Taking into consideration the time and effort for CMS to develop, align, and implement the infrastructure necessary to collect data on the Hospital OQR Program measures and make payment determinations, as well as the time and effort on the part of hospital outpatient departments to plan and prepare for reporting additional measures, we are not proposing any additional quality measures for CY 2015 and subsequent years payment determination in this rulemaking. As discussed above, we have suspended measure OP–19 and deferred data collection for OP–24 until the measure specifications can be further refined. We also are clarifying that the public reporting of the claims-based imaging efficiency measure OP–15 has been deferred until July 2013 at the earliest, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456).

In summary, we are proposing no additional measures for the CY 2015 payment determination, and we are proposing to retain the 25 measures previously adopted for the CY 2014 payment determination for CY 2015 and subsequent year payment determinations. We are confirming the suspension of data collection for the OP–19 measure, and consequently its use in the Hospital OQR Program, until further notice. We also are proposing to defer data collection on OP–24, and to first apply this measure toward the CY 2015 payment determination rather than to the CY 2014 payment determination as originally finalized. Set out below are the previously adopted measures which we are proposing to retain for the CY 2014, CY 2015, and subsequent years payment determinations under the Hospital OQR Program.

HOSPITAL OQR PROGRAM MEASURES ADOPTED FOR THE CY 2014, CY 2015 AND SUBSEQUENT YEAR PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival.
OP–17: Tracking Clinical Results between Visits.
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
OP–21: ED- Median Time to Pain Management for Long Bone Fracture.
OP–22: ED Patient Left Without Being Seen.
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.
OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.***
OP–25: Safe Surgery Checklist Use.
OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

Procedure category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.
Cardiovascular	33000 through 37999.
Respiratory	30000 through 32999.

* Information for OP–15 will not be reported in Hospital Compare in 2012. Public Reporting for this measure would occur in July 2013 at the earliest.
** Data collection for OP–19 was suspended effective with January 1, 2012 encounters until further notice.
*** Data collection for OP–24 would be postponed from January 1, 2013 to January 1 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

We invite public comments on these proposals.

E. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

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 HIT care coordination, patient safety, and volume. We anticipate that as EHR technology evolves, and more infrastructure are put in place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We work diligently toward this goal. We believe that this future progress at a future date, such as FY 2015, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for e-specifications. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems.

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings. In addition, we are considering initiating a call for input to assess the following measure domains: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR and ASCQR Programs.

We invite public comment on this approach and suggestions and rationale for possible quality measures for future inclusion in the Hospital OQR Program.

F. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2013 Payment Update

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, required by the Secretary will incur a 2.0 percentage point reduction to their 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.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772), we discussed how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program affected the CY 2009 payment update applicable to OPPS payments for HOPD services furnished by the hospitals defined under section 1886(d)(1)(B) of the Act to which the program applies. 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 requirements. All other hospitals paid under the OPPS that meet the reporting requirement receive the full OPPS payment update without the reduction.

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative 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): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' or ''X.'' In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770), we adopted a policy that payment for all services assigned these status indicators would be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T,'' and brachytherapy sources with assigned status indicator ''U,'' which were paid at charges adjusted to cost in CY 2009. We excluded services assigned to New Technology APCs from the list of services subject to the reduced national unadjusted payment rates because the OPD fee schedule increase factor is not used to update the payment rates for these APCs.

In addition, section 1833(t)(16)(C) of the Act, as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), specifically required that brachytherapy sources be paid during CY 2009 on the basis of charges adjusted to cost, rather than under the standard OPPS methodology. Therefore, the reduced conversion factor also was not applicable to CY 2009 payment for brachytherapy sources because payment would not be based on the OPPS conversion factor and, consequently, the payment rates for these services were not updated by the OPD fee schedule increase factor. However, in accordance with section 1833(t)(16)(C) of the Act, as amended by section 142 of the MIPPA, payment for brachytherapy sources at charges adjusted to cost expired on January 1, 2010. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60641), we finalized our CY 2010 proposal, without modification, to apply the reduction to payment for brachytherapy sources to hospitals that fail to meet the quality data reporting requirements of the Hospital OQR Program for brachytherapy services furnished on and after January 1, 2010.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement 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 weights by the reduced conversion factor. 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 multiply the final full national unadjusted payment rate in Addendum B to 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 those 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 in those cases 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. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, outlier payments will continue to be made when the 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. This policy conforms to current practice under the IPPS. We continued this policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099), and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478). 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 2013

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 2013 annual payment update factor. For the CY 2013 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $70.106 by the proposed full conversion factor of $71.537. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2013 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' and ''X'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). 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 invite public comments on these proposals.

G. Proposed Requirements for Reporting of Hospital OQR Data for the CY 2014 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2014 Payment Determination and Subsequent Years

In order to participate in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the program and hospitals that withdraw from the program, will not receive the full OPPS payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year.

We established administrative requirements for the payment determination requirements for the CY 2013 and subsequent years' payment updates in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487).

With respect to the payment determinations for CY 2014 and subsequent years, we are proposing one modification to these requirements. Under current requirements, CMS deadlines for hospitals to submit notice of participation forms are based on the date identified as a hospital's Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Deadlines are based on whether a hospital's Medicare acceptance date falls before January 1 of the year prior to the annual payment update, or on or after January 1 of the year prior to the annual payment update (for example, 2013 would be the year prior to the affected CY 2014 annual payment update). Currently, for a hospital whose Medicare acceptance date is before January 1 of the year prior to the affected payment update affected, the notice of participation form is due by March 31 of the year prior to the affected annual payment update (76 FR 74479 through 74480). We are proposing to extend this deadline for hospitals, as described below.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2014 and subsequent years payment update, we are proposing that any hospital that has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update (for example, 2013 would be the year prior to the affected CY 2014 annual payment update) that is not currently participating in Hospital OQR and wishes to participate in the Hospital OQR Program must submit a participation form by July 31, rather than March 31, of the year prior to the affected annual payment update. We are proposing a deadline of July 31 to give hospitals the maximum amount of time to decide whether they wish to participate in the Hospital OQR Program, as well as put into place the necessary staff and resources to timely report chart-abstracted data for first quarter of the year's services which are due August 1.

We invite public comment on this proposed modification to Hospital OQR Program administrative requirements for the CY 2014 and subsequent years' payment determinations.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program for the CY 2014 Payment Determination and Subsequent Years

a. Background

We are not proposing any additional measures for the CY 2014 payment determination year. We refer readers to the following OPPS/ASC final rules with comment periods for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination (74 FR 60637); 15 measures finalized for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination (75 FR 72090); and 26 measures finalized for the CY 2014 and CY 2015 payment determinations (76 FR 74469 and 74473).

We refer readers to section XV.D. of this proposed rule for a discussion of the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure. Because of the clarification that public reporting is not planned until July 2013 at the earliest, we confirm this measure will not be used in the CY 2014 payment determination. We will confirm our intent to include or exclude this measure in the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.2. of this proposed rule for a discussion of the OP–19: Transition Record with Specified Elements Received by Discharged ED Patients measure. Because the data collection for this measure is currently suspended, this measure will not be used in the CY 2014 payment determination. We will

indicate whether data collection for this measure will resume in time for the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.3. of this proposed rule for a discussion of the OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting measure. We are proposing not to use this measure in the CY 2014 payment determination and to use this measure in the CY 2015 payment determination.

b. General Requirements

We are proposing to continue the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and structural quality measure data, including all-patient volume data. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482) for a discussion of these requirements.

c. Proposed Chart-Abstracted Measure Requirements for CY 2014 and Subsequent Payment Determination Years

The table in section XV.D. of this proposed rule includes measures that are collected by abstracting the information from the patient chart. The full list of these chart abstracted measures is set out below:

- OP–1: Median Time to Fibrinolysis
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
- OP–4: Aspirin at Arrival
- OP–5: Median Time to ECG
- OP–6: Timing of Antibiotic Prophylaxis
- OP–7: Prophylactic Antibiotic Selection for Surgical Patients
- OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest pain) Received Within 30 minutes of Arrival
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP–19: Transition Record with Specified Elements Received by Discharged Patients
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture
- OP–22: ED Patient Left Without Being Seen
- 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
- OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting

We have suspended OP–19 from the CY 2014 payment determination and are proposing to defer data collection for OP–24 for the CY 2014 payment year. We invite public comment on our proposal to collect data for only those measures that are finalized to be included in the CY 2014 payment determination.

Of those measures for which we are proposing to collect data for in CY 2014, the form and manner for submission of one of these measures, OP–22: ED Patient Left Without Being Seen, is unique, and the form and manner for this measure is detailed in section XV.G.2.f. of this proposed rule.

For the remaining chart-abstracted measures for which we are proposing to collect data for the CY 2014 payment determination, we are proposing that the applicable quarters for data collection would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013 for hospitals that are continuing participants; newly participating hospitals would follow reporting requirements as outlined in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480) and in section XV.G.1. of this proposed rule.

Submission deadlines would be, in general, approximately 4 months after the last day of each calendar quarter. Thus, for example, the proposed submission deadline for data for services furnished during the first quarter of CY 2013 (January—March, 2013) would be on or around August 1, 2013. The actual submission deadlines would be posted on the *http://www.QualityNet.org* Web site.

Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using this CY 2013 measure set that was finalized in the CY 2012 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2013, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2015 payment determination, we are proposing that the applicable quarters for previously finalized chart-abstracted measures would be as follows: 3rd quarter CY 2013, 4th quarter CY 2013, 1st quarter CY 2014, and 2nd quarter CY 2014.

Hospitals that did not participate in the CY 2014 Hospital OQR Program, but would like to participate in the CY 2015 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2014, would begin data submission with respect to 1st quarter CY 2014 encounters using the CY 2015 measure set that we finalized in the CY 2012 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2014, data submission must begin with the first full quarter following the submission of a completed online participation form. We invite public comments on these proposals.

d. Proposed Claims-Based Measure Data Requirements for the CY 2014 and CY 2015 Payment Determinations

The table in section XV.D. of this proposed rule includes measures that the Hospital OQR Program collects by accessing electronic claims data submitted by hospitals for reimbursement. The full list of these claims-based measures is set out below:

- OP–8: MRI Lumbar Spine for Low Back Pain
- OP–9: Mammography Follow-up Rates
- OP–10: Abdomen CT—Use of Contrast Material
- OP–11: Thorax CT—Use of Contrast Material
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
- OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache

OP–15 has not been implemented for public reporting through rulemaking, and it is not required for the CY 2014 payment determination.

Therefore, for the CY 2014 payment determination, the 6 remaining claims-based measures (OP–8 to OP–11, OP–13 and OP–14) from the list above will be used (76 FR 74469).

We will continue our policy of calculating the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; no additional

data submission is required for hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2013 and CY 2014 payment updates, we will use paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

For the CY 2015 Hospital OQR payment determination, we are proposing to use Medicare FFS claims for services from a 12-month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. While this would be a departure from the traditional 12 month calendar year period we have used for these measures, we are proposing this period in order to align the data period for inpatient and outpatient claims based measures reported on the Hospital Compare Web site, and also to be able to post more recent data for the outpatient imaging efficiency on the Web site. We invite public comment on this proposal.

e. Proposed Structural Measure Data Requirements for the CY 2014 Payment Determination and Subsequent Years

A summary of the previously finalized structural measures that we require for the CY 2014 and subsequent years payment determinations is set out below:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
- OP–17: Tracking Clinical Results Between Visits
- OP 25—Safe Surgical Check List Use
- OP 26—Hospital Outpatient Volume for Selected Outpatient Surgical Procedures

We previously finalized that for the CY 2014 payment determination, hospitals will be required to submit data on all structural measures between July 1, 2013 and August 15, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. We are proposing to extend this submission deadline. Under this proposed change, for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. In section XV.G.2.f. of this proposed rule, we describe how this proposal would likewise extend the deadline to submit data for OP–22: ED Patient Left without Being Seen. We are proposing to continue this schedule so that, for the FY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013. We invite public comments on these proposals.

f. Proposed Data Submission Requirements for OP–22: ED–Patient Left Without Being Seen for the CY 2015 Payment Determination

OP–22: ED–Patient Left Without Being Seen is a chart-abstracted measure for which aggregate data is collected via a Web-based tool, as previously finalized. In other words, for purposes of data collection, this measure is treated like a structural measure. For this reason, it is collected on the same schedule as the structural measures described above, and we are proposing to extend the submission window for all structural measures, including OP–22. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), with respect to OP–22, we stated that hospitals would be required to submit data once for the CY 2014 payment determinations via a Web-based tool located on the QualityNet Web site. For the CY 2014 payment determination, we are proposing that hospitals would be required to submit data, including numerator and denominator counts, between July 1, 2013 and November 1, 2013 (comparable to the submission window that we are proposing for the structural measures data collection in the section above) with respect to the time period of January 1, 2012 to December 31, 2012.

For the CY 2015 payment determination, we are proposing to continue this policy. Hospitals would be required to submit data between July 1, 2014 and November 1, 2014 with respect to the time period of January 1, 2013 to December 31, 2013. We invite public comment on these proposals.

g. Proposed Population and Sampling Data Requirements for the CY 2014 Payment Determination and Subsequent Years

For the CY 2014 payment determination and subsequent years, we are proposing to continue our policy that hospitals may submit voluntarily on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies. We invite public comments on these proposals.

3. Proposed Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2014 Payment Determination and Subsequent Years

a. Random Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we adopted a policy to validate chart-abstracted patient-level data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination.

For the CY 2013 payment determination, we reduced the number of randomly selected hospitals from 800 to 450.

We are proposing to continue this policy for the CY 2014 payment determination and for subsequent years. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (FR 76 74484) for a discussion of sample size, eligibility for validation selection, and encounter minimums for chart abstracted data submitted directly to CMS from randomly selected hospitals. We invite public comment on this proposal.

b. Targeting and Proposed Targeting Criteria for Data Validation Selection for the CY 2014 Payment Determination and Subsequent Years

In the CY 2011 OPPS/ASC proposed rule (75 FR 46380) we discussed applying, to CY 2013 and subsequent year's data submission, criteria to determine whether a hospital would be included in our validation selection based on abnormal data patterns or a specific situation. At that time we provided, for public comment, specific examples of what we thought could be appropriate criteria.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we stated our belief that the targeting

criteria we shared for comment were reasonable. We considered one commenter's concern that we should use targeting criteria to ensure we do not over-select a hospital for validation. We reiterated our intent to propose the specific targeting criteria in the upcoming CY 2012 OPPS/ASC proposed rule (76 FR 42332), in order to finalize and apply it to 2012 encounter data collected for the CY 2013 validation process year. We did so, and finalized our proposal without modification in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In summary, we finalized our intent to select a random sample of hospitals for validation purposes, and to select an additional 50 hospitals selected based on specific criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy.

For the CY 2014 payment determination and subsequent years, we are proposing to continue these policies and to continue to use the targeting criteria finalized previously. Specifically, a hospital will be preliminarily selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the CY 2012 payment determination; or
- Has an outlier value for a measure based on the data it submits.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333) and CY 2012 OPPS/ASC final rule with comment period (76 FR 74486) we describe additional data validation conditions under consideration for the CY 2014 payment determination and subsequent years. We thank those who commented on the CY 2012 proposed additional data validation targeting conditions and will take their views under consideration as we develop any future proposals on these issues. At this time, we are not proposing any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for CY 2014 payment determination or in subsequent years. We invite public comment on this proposal.

c. Proposed Methodology for Encounter Selection for the CY 2014 Payment Determination and Subsequent Years

For each selected hospital (random or targeted), we are proposing to continue the approach we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, for each selected hospital (random or targeted), we would continue to validate up to 48 randomly selected patient encounters (12 per quarter; 48 per year) from the total number of encounters that the hospital successfully submitted to the OPPS Clinical Warehouse. If a selected hospital has submitted less than 12 encounters in one or more quarters, only those encounters available would be validated. For each selected encounter, a designated CMS contractor would request that the hospital submit the complete supporting medical record documentation that corresponds to the encounter. We refer readers to 42 CFR 482.24(c) for a definition of what is expected in a medical record submitted for validation. The validation process requires full supporting medical documentation, including ECG tapes and/or other pieces of a medical record that may not be stored in a single location. The hospital must ensure a full medical record goes to the contractor for accurate validation.

We continue to believe that validating a larger number of encounters per hospital for fewer hospitals at the measure level has several benefits. We believe that this approach is suitable for the Hospital OQR Program because it will: (1) produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; (2) provide more statistically reliable estimates of the quality of care delivered in each measured hospital as well as at a national level; and (3) reduce overall burden, for example, in submitting validation documentation, because hospitals most likely will not be selected to undergo validation each year, and a smaller number of hospitals per year will be selected.

For all selected hospitals, we would not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by measure or topic. We would be validating data from April 1 to March 31 of the year preceding the payment determination year. This provides validation results data in time to use to make the payment determination. For example, encounter data from April 1, 2012 to March 31, 2013 provides a full year of the most recent data possible to validate in time to make the CY 2014 payment determination. We invite public comment on our proposal to continue to use our established methodology for encounter selection and our proposed annual schedule for encounters to be validated and used in payment determinations.

d. Validation Score Calculation for the CY 2014 Payment Determination and Subsequent Years

We are proposing to retain the medical record return policy that we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, we are proposing to continue the validation score policies we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74486), for the CY 2013 payment determination. We are proposing to use the validation calculation approach finalized for the CY 2012 and CY 2013 payment determinations with validation being done for each selected hospital. Specifically, we are proposing to conduct a measures level validation by calculating each measure within a submitted record using the independently abstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. We would also compare the measure category for quality measures with continuous units of measurement, such as time, so that for these measures, both the category and the measure would need to match.

For the CY 2014 payment determination and subsequent years, we are proposing to use the medical record validation procedure we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105). A designated CMS contractor would, for each quarter that applies to the validation, ask each of the selected hospitals to submit medical documentation for up to 12 randomly selected cases submitted to and accepted by the OPPS Clinical Warehouse. The CMS contractor would request paper copies of medical documentation corresponding to selected cases from each hospital via certified mail or another trackable method that requires a hospital representative to sign for the request letter. A trackable method would be used so that we would be assured that the hospital received the request. The hospital would have 45 calendar days from the date of the request as documented in the request letter to submit the requested documentation and have the documentation received by the CMS contractor. If the hospital does not comply within 30 calendar days of receipt of the initial medical documentation request, the CMS contractor would send a second letter by

certified mail or other trackable method to the hospital, reminding the hospital that paper copies of the requested documentation must be submitted and received within 45 calendar days following the date of the initial CMS contractor request. If the hospital does not submit the requested documentation and the documentation is not received by the CMS contractor within the 45 calendar days, then the CMS contractor would assign a ''zero'' score to each data element for each selected case and the case would fail for all measures in the same topic (for example, OP–6 and OP–7 measures for a Surgical Care case).

We are proposing that the letter from the designated CMS contractor would be addressed to the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to its State QIO). If CMS has evidence that the hospital received both letters requesting medical records, the hospital would be deemed responsible for not returning the requested medical record documentation and the hospital would not be allowed to submit such medical documentation as part of its reconsideration request so that information not utilized in making a payment determination is not included in any reconsideration request.

Once the CMS contractor receives the requested medical documentation, the contractor would independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted, and the CMS contractor would then compare the two sets of data to determine whether the two sets of data match. Specifically, the CMS contractor would conduct a measures level validation by calculating each measure within a submitted case using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. The validation score for a hospital would equal the total number of measure matches divided by the total number of measures multiplied by 100 percent.

We invite public comment on our proposals regarding the medical record request policy for CY 2014 payment determination and subsequent payment determination years.

To receive the full OPPS OPD fee schedule increase factor for CY 2014, we are proposing that hospitals must attain at least a 75 percent reliability score, based upon the proposed validation process. We are proposing to use the upper bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 75 percent reliability threshold, we would consider a hospital's data to be ''validated'' for payment purposes. Because we are more interested in whether the measure has been accurately reported, we would continue to focus on whether the measure data reported by the hospital matches the data documented in the medical record as determined by our reabstraction.

We are proposing to calculate the validation score using the same methodology we finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72105 and 76 FR 74486). We also are proposing to use the same medical record documentation submission procedures that we also finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72104 and 76 FR 74486). We invite public comments on these proposals.

H. Proposed Hospital OQR Reconsideration and Appeals Procedures for the CY 2014 Payment Determination and Subsequent Years

When the Hospital IQR Program was initially implemented, it did not include a reconsideration process for hospitals. Subsequently, we received many requests for reconsideration of those payment decisions and, as a result, established a process by which participating hospitals would submit requests for reconsideration. We anticipated similar concerns with the Hospital OQR Program and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the Hospital OQR Program a reconsideration process modeled after the reconsideration process we implemented for the Hospital IQR Program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. This process required that a hospital's CEO sign any request for a reconsideration.

In the CY 2011 and CY 2012 OPPS/ASC final rules with comment periods (75 FR 72106 through 72108 and 76 FR 74486 through 75587), we continued this process for the CY 2012 and CY 2013 payment updates with some modification. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72107), we finalized that the CEO was not required to sign the reconsideration request form.

We are proposing to continue this process, with additional modifications, for the CY 2014 payment determination and subsequent years payment determinations. We have now realized that, in eliminating the requirement that a CEO sign a request form, we did not include any requirement for a signature on the reconsideration request form. To increase accountability, we are proposing for the CY 2014 payment determination and subsequent years payment determinations, that the hospital designate a contact on its reconsideration request form, who may or may not be the CEO. We would communicate with this designee. We also are proposing the hospital's designee must sign its reconsideration request form. This process is consistent with our recent proposals for reconsideration requests under the ASCQR Program (77 FR 28105).

Under this process, a hospital seeking reconsideration must—

- Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site; this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by February 3, 2014) and must contain the following information:
  - Hospital CCN.
  - Hospital Name.
  - CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital.
  - Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the affected year's Hospital OQR Program requirements and should receive the full OPD fee schedule increase factor.
  - Designated hospital personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box). We are proposing that the designee, who may or may not be the hospital's CEO, must sign the form submitted to request reconsideration.
  - A copy of all materials that the hospital submitted to comply with the requirements of the affected year's Hospital OQR Program. Such material might include, but does not need to be limited to, the applicable Notice of Participation form or completed online registration form, and measure data that the hospital submitted via QualityNet.

• Paper copies of all the medical record documentation that it submitted for the initial validation (if applicable). Hospitals submit this documentation to a designated CMS contractor which has authority to review patient level information. We post the address where hospitals are to send this documentation on the QualityNet Web site.

• To the extent that the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected year's validation requirement, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score would be eligible to be reconsidered. We review the data elements that were labeled as mismatched as well as the written justifications provided by the hospital, and make a decision on the reconsideration request.

We are proposing these requirements for the CY 2014 payment determination year program and for subsequent years. We invite public comment on these proposed changes.

Following receipt of a request for reconsideration, CMS—

• Provides an email acknowledgement, using the contact information provided in the reconsideration request, to the designated hospital personnel notifying them that the hospital's request has been received.

• Provides a formal response to the hospital-designated personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

• Applies policies that we finalized for the CY 2012 and CY 2013 payment determinations regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirement.

These policies are as follows:

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we only consider the hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more of the complete medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more of the complete medical records submitted by the hospital did not match what was requested, thus resulting in a zero validation score for the encounter(s), our review is initially limited to determining whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit the correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct and complete medical record documentation, we do not further consider the hospital's request.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 45 calendar day timeframe, our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received paper copies of the requested medical record documentation, we abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 45 calendar day period, we do not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital is able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invite public comment on the modifications we have proposed to the Hospital OQR Program reconsideration and appeals procedures.

I. Proposed Extraordinary Circumstances Extension or Waiver for the CY 2013 Payment Determination and Subsequent Years

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 60047), we adopted a process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with a modification to eliminate redundancy in the information a hospital must provide in the request. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478 through 74479), for CY 2012 and subsequent years, we retained these procedures with one modification. The CY 2012 modification allowed that the original procedures for requesting an extension or waiver of quality data submission would thereafter also extend to include medical record documentation submission for purposes of complying with our validation requirement for the Hospital OQR Program. We are proposing to retain these procedures with a modification for CY 2013 and subsequent years.

We are proposing to modify one element of the information required on the CMS request form. Under the procedures set out in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), hospitals were required to submit ''CEO *and* any other designated personnel contact information'' (emphasis added), the CEO was required to sign the form, and CMS was required to respond to the CEO and additional designated hospital personnel. The information required in CY 2013 and subsequent years would include ''CEO *or* other hospital-designated personnel contact information'' (emphasis added). This proposed change would allow the hospital to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form. Therefore, the hospital's designated-contact may or may not hold the title of CEO. We invite public comment on this proposed modification to the process for granting extraordinary circumstances extensions or waivers for the Hospital OQR Program.

Thus, we are proposing that, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would submit to CMS a

request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO or other hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address; a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form would be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide a written acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(2) Provide a formal response to the hospital's designated contact using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2013 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to emails and notices on the QualityNet Web site. We invite public comments on these proposals.

J. Electronic Health Records (EHRs)

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from EHRs to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program. Through the Medicare and Medicaid EHR Incentive Programs, we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for Hospital IQR Program and Hospital OQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of certified EHR technology, for measures that otherwise require information from the clinical record. This would allow us to collect data for measures without the need for manual chart abstraction.

In the FY 2012 IPPS/LTCH PPS proposed rule (75 FR 25894), we identified FY 2015 as a potential transition date to move to EHR-based submission and phase out manual chart abstraction for the Hospital IQR Program. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is because we hope to first align the clinical quality measures in the Medicare EHR Incentive Program with the Hospital IQR Program measures. Our goals are to align the hospital quality reporting programs, to seek to avoid redundant and duplicative reporting of quality measures for hospitals, and to rely largely on EHR submission for many measures based on clinical record data.

As noted below, the Stage 2 Medicare EHR Incentive Program proposed rule would require electronic reporting of clinical quality measures beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use. Under our timeline for EHR-based submission under the Hospital OQR Program, some eligible hospitals would be in their second year of Stage 2 reporting and these eligible hospitals could be using two methods to report similar information for the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program. We considered allowing, but not requiring, EHR-based submission at the earliest possible date, so as to reduce the burden of hospitals. We are not proposing this approach because we believe that it would not be consistent with our goal that measure results that must be publicly reported should be based on consistent, comparable results among reporting hospitals and because our first priority is to align EHR-based submissions under the Hospital IQR Program. We invite public comment on this issue.

K. Proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

In the 2012 OPPS/ASC final rule with comment period we finalized the voluntary 2012 Electronic Reporting Pilot for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program for the 2012 payment year and also revised our regulations at § 495.8(b)(2) accordingly. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74489 through 74492) for detailed discussion of the Electronic Reporting Pilot.

We are proposing to continue the Electronic Reporting Pilot for the 2013 payment year as finalized for the 2012 payment year. We are proposing to revise our regulations at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for 2013, and also to remove the reference to § 495.6(f)(9) in order to conform with the proposed changes to § 495.6(f) that were included in the EHR Incentive Program—Stage 2 proposed rule (77 FR 13817). We invite public comments on these proposals.

We note that we finalized reporting clinical quality measures for the Medicare EHR Incentive Program by attestation of clinical quality measure results in the CY 2012 OPPS/ASC final rule with comment period for 2012 and subsequent years, such as 2013 (76 FR 74489). Thus, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation for 2013, as they did for 2011 and 2012. We also note the intent of CMS to move to electronic reporting. In the Stage 2 Medicare EHR Incentive Program proposed rule, we proposed that the Medicare EHR Incentive Program would require electronic reporting of clinical quality measures beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use (77 FR 13764).

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XV.A.1. of this proposed rule for a general

overview of our quality reporting programs.

2. Statutory History of the ASC 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 74493) for a detailed discussion of the statutory history of the ASCQR Program.

3. History of the ASCQR Program

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new quality reporting requirements. However, in these rules, we indicated that we intended to implement a quality reporting program for ASCs in the future.

In preparation for proposing a quality reporting program for ASCs, in the CY 2011 OPPS/ASC proposed rule (75 FR 46383), we solicited public comments on 10 measures. In addition to preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under title XVIII of the Act for ASCs as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also submitted a report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that details this plan. This report is found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC-2011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP program. If and when legislation is enacted that authorizes CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. We adopted quality measures for the CY 2014, CY 2015, and CY 2016 payment determination years and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, data collection and submission requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPS/ASC proposed rule, because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we issued proposals for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these proposals, we refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105).

Because we have included proposals in the FY 2013 IPPS/LTCH PPS proposed rule for the ASCQR Program, we are limiting the number of proposals in this proposed rule. In addition, in an effort to prevent confusion regarding what we are proposing in this proposed rule and what we have proposed in the FY 2013 IPPS/LTCH PPS proposed rule, in this proposed rule, we are limiting our discussion of the proposals contained in the FY 2013 IPPS/LTCH PPS proposed rule primarily to background related to the proposals being made in this proposed rule.

B. ASCQR Program Quality Measures

1. Proposed Considerations in the Selection of ASCQR Program Quality Measures

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, ''except as the Secretary may otherwise provide.'' The requirements under section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In addition to following the statutory requirements, in selecting measures for the ASCQR Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency, and satisfaction for patients. Our goal for the future is to expand any measure set adopted for the ASCQR Program to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, so that the burden for reporting will be reduced.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as discussed above, the Hospital OQR Program statute only requires that we adopt measures that are appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, reflect consensus among affected parties, and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. Further, the Secretary has broader authority under the ASCQR Program statute, as discussed above, to adopt nonendorsed measures or measures that do not reflect consensus for the ASCQR Program because, under the ASCQR Program statute, these Hospital OQR Program provisions apply ''except as the Secretary may otherwise provide.''

In developing the ASCQR Program, we applied the principles set forth in the CY 2011 OPPS/ASC proposed rule

and final rule with comment period (76 FR 42337 through 42338 and 74494 through 74495, respectively). Although we are not proposing any new measures for the ASCQR Program in this proposed rule as discussed below, we plan to apply the following principles in future measure selection and development for the ASCQR Program. These principles were applied in developing other quality reporting programs and many are the same principles applied in developing the ASCQR Program last year.

- Our overarching goal is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The ASCQR Program will help achieve this three-part aim by creating transparency around the quality of care at ASCs to support patient decisionmaking and quality improvement. More information regarding the National Quality Strategy can be found at: *http://www.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting programs should rely on a mix of standards, process, outcomes, and patient experience of care measures. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.
- We weigh the relevance and the utility of measures compared to the burden on ASCs in submitting data under the ASCQR Program. The collection of information burden on providers and suppliers should be minimized to the extent possible. To this end, we continuously seek to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that use data already being reported by ASCs.
- We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (we refer readers to the Web sites at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*, and *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*).
- Measures should be developed with the input of providers/suppliers, purchasers/payers and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.
- HHS Strategic Plan and Initiatives. HHS is the U.S. Government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The current goals of the HHS Strategic Plan can be located at *http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*.
- CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

We believe that ASCs are similar to HOPDs, insofar as the delivery of surgical and related nonsurgical services. Similar standards and guidelines can be applied between HOPDs and ASCs with respect to surgical care improvement, because many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in these settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided.

We invite public comment on this approach in future measure selection and development for the ASCQR Program.

2. ASCQR Program Quality Measures

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. We also finalized our policy to retain measures from one calendar year payment determination to the next so that measures adopted for a previous payment determination year would be retained for subsequent payment determination years (76 FR 74504, 74509, and 74510).

We adopted the following five claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012: (1) Patient Burns (NQF #0263); (2) Patient Fall (NQF #0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) Hospital Transfer/Admission (NQF #0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264).

For the CY 2015 payment determination, we retained the five claims-based measures we adopted for the CY 2014 payment determination and adopted the following two structural measures: (1) Safe Surgery Checklist Use; and (2) ASC Facility Volume Data on Selected ASC Surgical Procedures. We specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013, for services furnished between January 1, 2012 and December 31, 2012, using an online measure submission Web page available at: *https://www.QualityNet.org*. We did not specify the data collection period for the five claims-based measures for the CY 2015 payment determination.

For the CY 2016 payment determination, we finalized the retention of the seven measures from the CY 2015 payment determination (five claims-based measures and two structural measures) and adopted Influenza Vaccination Coverage Among

Healthcare Personnel (NQF #0431), a process of care, healthcare-associated infection measure. We specified that data collection for the influenza vaccination measure would be via the National Healthcare Safety Network from October 1, 2014 through March 31, 2015. We did not specify the data collection period for the claims-based or structural measures.

We stated that, to the extent we finalize some or all of the measures for future payment determination years, we would not be precluded from adopting additional measures or changing the list of measures for future payment determination years through annual rulemaking cycles so that we may address changes in program needs arising from new legislation or from changes in HHS and CMS priorities.

Considering the time and effort required for us to develop, align, and implement the infrastructure necessary to collect data on the ASCQR Program measures and make payment determinations, and likewise the time and effort required on the part of ASCs to plan and prepare for quality reporting, at this time we are not proposing to delete or add any quality measures for the ASCQR Program for the CY 2014, CY 2015, and CY 2016 payment determination years or to adopt quality measures for subsequent payment determination years. For readers' reference, the following table lists the ASCQR Program quality measures we previously finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74511).

ASC PROGRAM MEASUREMENT SET ADOPTED IN PREVIOUS RULEMAKING

ASC–1: Patient Burn.*
ASC–2: Patient Fall.*
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.*
ASC–4: Hospital Transfer/Admission.*
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6: Safe Surgery Checklist Use.**
ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures.**

Procedure category	Corresponding HCPCS Codes.
Gastrointestinal.	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T.
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T.
Nervous System.	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T.
Musculoskeletal.	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727.
Genitourinary	50000 through 58999, 0193T, and 58805.
ASC–8: Influenza Vaccination Coverage among Healthcare Personnel.***	

*New measure for the CY 2014 payment determination.
**New measure for the CY 2015 payment determination.
***New measure for the CY 2016 payment determination.

3. ASC Measure Topics for Future Consideration

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. Therefore, through future rulemaking, we intend to propose new measures consistent with the principles discussed in section XVI.B.1. of this proposed rule, in order to select measures that address clinical quality of care, patient safety, and patient and caregiver experience of care. We invite public comment specifically on the inclusion of procedure-specific measures for cataract surgery, colonoscopy, endoscopy, and for anesthesia-related complications in the ASCQR Program measure set.

4. Clarification Regarding the Process for Updating ASCQR Program Quality Measures

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514). This process includes the same subregulatory process for the ASCQR Program as used for the Hospital OQR Program for updating measures, including issuing regular manual releases at 6-month intervals, providing addenda as necessary, and providing at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–9–CM, CPT, NUBC, and HCPCS codes, and at least 6 months' notice for substantive changes to data elements that would require significant systems changes. We provided a citation to the CY 2009 OPPS/ASC final rule with comment period where the final Hospital OQR Program policies are discussed (73 FR 68766 through 68767).

In examining last year's finalized policy for the ASCQR Program, we recognize that we may need to provide additional clarification of the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). Therefore, in this proposed rule, we seek to more clearly articulate the policy that we adopted for the ASCQR Program, which is the same policy that has been adopted for the Hospital OQR Program.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific evidence and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly and provide notice as described above and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514). An example of such an entity is the NQF. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We invite public comment on this clarification of the finalized ASCQR Program policy of using a subregulatory process to update measures.

C. Proposed Requirements for Reporting of ASC Quality Data

1. Form, Manner, and Timing for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

a. Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determination years (76 FR 74504 through 74511). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based

reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claims forms, the Form CMS–1500s submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754 released March 16, 2012 (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html*). Details on how to use these codes for submitting numerators and denominator information are available in the ASCQR Program Specifications Manual located on the QualityNet Web site (*https://www.QualityNet.org*). We also finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for the CY 2014 payment determination.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed that claims for services furnished between October 1, 2012 and December 31, 2012, would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors. We did not finalize a data collection and processing period for the CY 2015 payment determination, but stated our intention to do so in this proposed rule (77 FR 28104).

b. Proposals Regarding Form, Manner, and Timing for Claims-Based Measures for the CY 2015 Payment Determination and Subsequent Payment Determination Years

We are proposing that, for the CY 2015 payment determination and subsequent payment determination years, an ASC must submit complete data on individual quality claims-based measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. We are proposing that the data collection period for such claims-based measures will be for the calendar year 2 years prior to a payment determination. We also are proposing that the claims for services furnished in each calendar year would have to be paid by the administrative contractor 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. Thus, for example, for the CY 2015 payment determination, we are proposing the data collection period to be claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the administrative contractor by April 30, 2014. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors. We invite public comment on these proposals.

2. Data Completeness and Minimum Threshold for Claims-Based Measures Using QDCs

a. Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal that data completeness for claims-based measures for the CY 2014 payment determination be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications but did not have the appropriate QDCs on the submitted claims. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed, for the CY 2014 and CY 2015 payment determination years, that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASCQR Program. We stated in the proposed rule that we intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for this quality data reporting program.

b. Proposed Data Completeness Requirements for the CY 2015 Payment Determination and Subsequent Payment Determination Years

After publication of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we realized that we did not propose a methodology for determining data completeness for the CY 2015 payment determination and subsequent payment determination years. Therefore, we are proposing that data completeness for claims-based measures for the CY 2015 payment determination and subsequent payment determination years be 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 (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent payment determination years. This is the same method for determining data completeness for claims-based measures that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516) for the CY 2014 payment determination. We note that the claims we use include claims where Medicare is either the primary or secondary payor. We invite public comment on this proposal.

D. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year. Subparagraph (B) of paragraph (7) makes many of the

provisions of the Hospital OQR Program applicable to the ASCQR Program ''[e]xcept as the Secretary may otherwise provide.'' Finally, section 1833(i)(2)(D)(v) of the Act states that, in implementing the revised ASC payment system for 2011 and each subsequent year, ''any annual update under such system for the year, after application of clause (iv) [regarding the reduction in the annual update for failure to report on quality measures] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).'' Section 1833(i)(2)(D)(v) of the Act also states that the ''application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the [revised ASC payment system] for a year being less than such payment rates for the preceding year.''

2. Proposed Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for the CY 2014 Payment Determination and Subsequent Payment Determination Years

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 would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XIV.H. of this proposed rule.

To implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we are proposing that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We are proposing 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 are proposing 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 are proposing 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 and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also are proposing 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, as discussed in section XIV.D.2.b. of this proposed rule) are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We are proposing that the standard ASC ratesetting methodology for this 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 an office-based or radiology procedure 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, we are proposing that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would be based on the reduced national unadjusted payment rate.

We are proposing 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. 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.

We invite public comment on these proposals.

XVII. Proposed Inpatient Rehabilitation Facility (IRF) Quality Reporting Program Updates

A. Overview

In accordance with section 1886(j)(7) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established a quality reporting program (QRP) for Inpatient Rehabilitation Facilities (IRFs). The IRF Quality Reporting Program (IRF QRP) was implemented in the FY 2012 IRF PPS final rule (76 FR 47836). We refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47883) for a detailed discussion on the background and statutory authority for the IRF QRP.

In this proposed rule, we are proposing to: (1) Adopt updates on a previously adopted measure for the IRF QRP that will affect annual prospective

payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (3) adopt policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

While we generally would expect to publish IRF QRP proposals in the annual IRF Prospective Payment System (PPS) rule, there are no proposals for substantive changes to the IRF PPS this year, so we are only publishing an update notice. Because full notice-and-comment rulemaking is required for what we are proposing for the IRF QRP, we needed to identify an appropriate rulemaking process in which we could insert our IRF QRP proposals. As this proposed rule was already scheduled to include additional pay-for-reporting proposals for the Hospital OQR Program and quality reporting requirements for the ASCQR Program, it offered an opportunity to allow the public to review all three quality programs' proposals in concert with one another in a timeframe that would be appropriate for implementing these IRF QRP proposals in time for the FY 2014 IRF PPS payment cycle. Therefore, we elected to include the IRF QRP proposals in this CY 2013 OPPS/ASC proposed rule.

B. Updates to IRF QRP Measures Which Are Made as a Result of Review by the NQF Process

Section 1886(j)(7) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[2]

The NQF undertakes to: (1) Review new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) provide for annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) provide for measure maintenance endorsement on a 3-year cycle;(4) conduct a required follow-up review of measures with time limited endorsement for consideration of full endorsement; and (5) conduct ad hoc review of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review.[3] In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis.[4] As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We are proposing that, if the NQF updates an endorsed measure that we have adopted for the IRF QRP in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the information that is posted on the CMS IRF QRP Web site at: *http://www.cms.gov/IRF-Quality-Reporting/* so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would refer IRFs to the NQF Web site for the most up-to-date information about the quality measures (*http://www.qualityforum.org/*). We would provide sufficient lead time for IRFs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that our proposal adequately balances our need to incorporate NQF updates to NQF-endorsed IRF QRP measures in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We note that, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27870), we proposed a similar policy for the Hospital IQR Program, the PPS Cancer Exempt Hospital (PCH) Quality Reporting Program; the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

C. Proposed Process for Retention of IRF Quality Measures Adopted in Previous Fiscal Year Rulemaking Cycles

We expect that the measures that we adopt for purposes of the IRF QRP will remain current and useful for a number of years after their initial adoption. While we could elect to adopt measures for each fiscal year's payment determinations, we believe that it would be easier for all concerned if we adopt the measures in perpetuity with an expectation that we will propose to remove, suspend or replace them through future rulemaking if necessary. Therefore, for the purpose of streamlining the rulemaking process, we are proposing that when we initially adopt a measure for the IRF QRP for a payment determination, this measure will be automatically adopted for all subsequent fiscal year payment determinations or until such time as we might propose and finalize its removal, suspension, or replacement.

Quality measures may be considered for removal by CMS if: (1) Measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not

[2] For more information about the NQF Consensus Development Process, we refer readers to the Web site at: *http://www.qualityforum.org/Measuring_Performance/Maintenance_of_NQF-Endorsed%C2%AE_Performance_Measures.aspx*).

[3] For more information about the NFQ Ad Hoc Review process, we refer readers to the Web site at: *http://www.qualityforum.org/Projects/ab/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx*).

[4] For more information about the NQF Measure Maintenance process, we refer readers to the NQF Web site at: *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Process_Assessment_Measure_Maintenance.aspx.*

result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) if a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences.

For any such removal, the public will generally be given an opportunity to comment through the annual rulemaking process. However, if there is reason to believe continued data collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from IRF QRP and not wait for the annual rulemaking cycle. Such measures will be promptly removed with IRFs and the public being immediately notified of such a decision through the usual IRF QRP communication channels, including listening session, memos, email notification, and Web postings. In such instances, the removal of a measure will also be formally announced in the next annual rulemaking cycle. We are inviting public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year payment determinations unless otherwise stated.

We are proposing to apply this principle to the two measures that were selected for use in the IRF QRP beginning on October 1, 2012. These adopted measures are: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138),[5] and (2) Percent of Residents with Pressure Ulcers that Are New or Worsened (NQF #0678).

We invite public comment on our proposal to apply the principle of retention of the two above-stated quality measures that were adopted for use in the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878). Likewise, we invite public comment on our proposed use of the process, as stated above, for retention of future IRF QRP quality measures after adoption into the IRF QRP.

D. Adopted Measures for the FY 2014 Payment Determination

We have previously identified the measurement of pressure ulcers and the prevalence of urinary tract infections (UTI) as two critical areas for quality measurement under the IRF QRP. While section 1886(j)(7) of the Act generally requires the adoption of endorsed measures, there were no NQF-endorsed measures for the two desired areas in the IRF context at the time CMS was conducting its rulemaking. As section 1886(j)(7)(D)(ii) of the Act authorizes the use of measures that are not endorsed when there are no feasible and practicable endorsed options, in the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we adopted applications of an NQF-endorsed pressure ulcer measure that had been endorsed for use in skilled nursing facilities (NQF #678) and a CDC measure, the CDC's Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients (NQF #0138), that had NQF endorsement for use in intensive care settings of hospitals.

1. Clarification Regarding Existing IRF Quality Measures That Have Undergone Changes During NQF Measure Maintenance Processes

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act. This authority permitted us to adopt the Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients measure (NQF #0138). We chose to adopt this measure because there was no NQF-endorsed CAUTI measure available to assess the prevalence of urinary catheter-associated urinary tract infection [CAUTI] rates in the IRF setting.

As stated in section XVII.C. of this proposed rule, the CAUTI measure steward, the CDC, submitted the CAUTI Measure to NQF for a scheduled measure maintenance review in late 2011. At that time the CDC also filed a request to expand the CAUTI measure to non-ICU settings, including IRFs. The NQF granted the CDC's request for an expansion of the scope of endorsement of the CAUTI measure to additional non-ICU care settings, including ''rehabilitation hospitals.'' The NQF defined the term ''rehabilitation hospitals'' as including both freestanding IRFs as well as IRF units that are located within an acute care facility. Despite the expansion in the scope of endorsement of the CAUTI measure, the original NQF endorsement number was retained. However, the measure was re-titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.'' [6]

As amended, the expanded CAUTI measure also uses a different data calculation method, which is referred to as the standardized infection ratio (SIR).[7] [8] [9] [10] The change in the data calculation method does not, however, change the way in which IRFs will submit CAUTI data to the CDC. IRFs will still be required to submit their CAUTI data to the CDC via the National Healthcare Safety Network (NHSN) online system.

Under the originally endorsed version of the CAUTI measure the CDC calculated an infection rate per 1,000 urinary catheter days. Under the new method, CDC will use a SIR calculation method, which is comprised of the actual rate of infection over the expected rate of infection.[11] We believe that the SIR calculation method is a more accurate way to calculate the CAUTI measure results for comparative

[5] The CAUTI measure that was adopted in the FY 2012 IRF PPS final rule dated August 5, 2011 was titled ''Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients.'' However, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review. As part of their NQF submission, the CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU settings, including IRFs. The NQF approved the CDC's request on January 12, 2012. Due to the changes that were made to the measure, the CDC believed that it was appropriate that the measure title be changed. This measure is now titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.''

[6] *http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1121#k=0138&e=0&st=&sd=&s=n&so=a&p=1&mt=&cs=&ss=.*

[7] Centers for Disease Control and Prevention (2012, January), Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[8] National Quality Forum (2012), National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[9] Centers for Disease Control and Prevention (2012, January), Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[10] National Quality Forum (2012), National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

[11] The SIR calculation requires the establishment of ''expected'' rates of infection. We understand that CDC will need to collect the CAUTI data that will be submitted under the IRF QRP for a period of time (at least 12 months) in order to establish an ''expected'' rate for each IRF location type prior to being able to calculate a SIR. As required by Section 3004 of the Affordable Care Act, we will, at a later date, establish public reporting policies in a separate rulemaking. However, we do not intend to publicly report IRF QRP CAUTI measure data until sometime after CDC has established the expected rate and is capable of generating SIR values.

purposes because it takes into account an IRF's case mix. In addition, use of the SIR calculation does not require any change to the type of data required to be submitted by IRFs or method of data submission that IRFs must use in order to comply with the CAUTI measure reporting requirements.

We are making the following proposals in regards to the CAUTI measure: (1) We are proposing to adopt changes made to the NQF #0138 CAUTI measure which will apply to the FY 2014 annual payment update determination; (2) we are proposing to adopt the CAUTI measure, as revised by the NQF on January 12, 2012, for the FY 2015 payment determination and all subsequent fiscal year payment determinations; and (3) we are proposing to incorporate, for use in the IRF QRP, any future changes to the CAUTI measure to the extent these changes are consistent with our proposal in section XVII.B. of this proposed rule to update measures. We welcome comments on these proposals.

2. Proposed Updates to the ''Percent of Residents Who Have Pressure Ulcers That Are New or Worsened'' Measure

In the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), we again used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act to adopt an application of the ''Percent of Residents with Pressure Ulcers that Are New or Worsened'' measure (NQF #0678). We selected this measure because there was no other NQF-endorsed measure available to assess the percentage of patients with pressure ulcers that are new or worsened in the IRF setting at that time. We recognized that the NQF endorsement of this measure was, at that time, limited to short-stay nursing home patients, but we noted our belief that this measure was highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue in the care of IRF patients. Therefore, in the FY 2012 IRF PPS final rule, we finalized the adoption of an application of the NQF-endorsed #0678 pressure ulcer measure. We also said that we would request that the NQF extend its endorsement of this short-stay nursing home pressure ulcer measure to the IRF setting (76 FR 47876 through 47878).

In April 2012, CMS filed an ad hoc request for review of the NQF #0678 short-stay pressure ulcer measure with the NQF. In addition, we also requested an expansion of this measure to other care settings. As noted in the FY 2012 IRF PPS final rule discussion of our adoption of an application of this measure in the IRF context, we believe this measure is highly applicable to all post acute care settings, including IRFs (76 FR 47876). If the pressure ulcer measure is revised by the NQF, we anticipate that it will be re-titled ''Percent of Patients or Residents with Pressure Ulcers That Are New Or Worsened'' (NQF #0678) so as to reflect the expansion in the scope of the applicable patient population.

As of the publication of this proposed rule, the NQF review process for the NQF #0678 pressure ulcer measure expansion request is still in progress. If the NQF expands the scope of endorsement for this measure to the IRF setting, without any substantive changes, we are proposing to adopt and use the revised pressure ulcer measure in the IRF QRP, in accordance with the policy set forth above in XVII.B. of this proposed rule. We believe that, in this anticipated scenario, the pressure ulcer measure, as revised, will be substantively the same measure, although broader in scope, as the current NQF-endorsed #0678 pressure ulcer measure. We invite public comments on our proposed use of this policy.

In the meantime, we are proposing to proceed with our plan, as finalized in the FY 2012 IRF PPS final rule, to use an application of the Percent of Residents With Pressure Ulcers that Are New or Worsened (NQF #0678) measure for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

XVIII. Proposed Revisions to the Quality Improvement Organization (QIO) Regulations (42 CFR Parts 476, 478, and 480)

A. Summary of Proposed Changes

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248). The name of the individual organizations covered under the program was previously changed from ''Peer Review Organizations'' to ''Quality Improvement Organizations'' through rulemaking (67 FR 36539). We have identified several changes that we are proposing because they are essential to remedying longstanding problematic aspects of the QIOs' review activities. These proposed changes would enable us to improve the QIO program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries.

Several of the proposed changes are specific to the QIOs' processing of quality of care reviews, which includes beneficiary complaint reviews. Although references are made to QIO sanction activities, the proposed changes do not impact QIO sanction activities or the regulations located in 42 CFR Part 1004.

In addition, as part of our review of our regulations in light of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011), we have identified several technical corrections that would improve the readability and use of the QIO regulations.

Below, in this proposed rule, we are setting forth our proposals for revising our regulations under 42 CFR Parts 476, 478, and 480 relating to the QIO Program.

B. Quality of Care Reviews

Section 9353(c) of Public Law 99–509 amended section 1154(a) of the Act (adding a new paragraph (14)) to require QIOs (then PROs), effective August 1, 1987, to conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services (for which payment may otherwise be made under Medicare) not meeting professionally recognized standards of health care. This authority was in addition to the QIOs' already existing authority under section 1154(a)(1)(B) of the Act to perform quality of care reviews. In order to provide more clarity regarding the QIOs' roles, in this proposed rule, we are proposing to add a definition of ''quality of care review'' under § 476.1 to make clear that this review type refers to both beneficiary complaint reviews (written or oral) and general quality of care reviews. We also are proposing to add under § 476.1 definitions for ''beneficiary complaint'' to mean a complaint by a beneficiary or a beneficiary's representative alleging that the quality of services received by the beneficiary did not meet professionally recognized standards of care and may consist of one or more quality of care concerns; ''beneficiary complaint review'' to mean a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care; and ''general quality of care review'' to mean a review conducted by a QIO to determine whether the quality of services provided to a beneficiary(s) was consistent with professionally recognized standards of health care. We are proposing that a general quality of care review may be carried out as a

result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data. In addition, we are proposing to revise the language under § 476.71(a)(2) to make clear that the scope of a QIO's review includes the right to conduct quality of care reviews, including beneficiary complaint reviews and general quality of care reviews, as well as a new review process that QIOs can offer Medicare beneficiaries called ''immediate advocacy,'' which is described more fully in section XVIII.B.1. of this proposed rule.

We are proposing additional changes to the QIO regulations related to the following issues:

1. Beneficiary Complaint Reviews

At the time QIOs assumed the authority under section 9353(c) of Public Law 99–509 to conduct reviews of written beneficiary complaints, we made a decision to rely upon the existing regulations for certain requirements (for example, the timeframes for requesting medical records and the practitioner's right to consent to the release of specific findings to beneficiaries), and to subsequently establish other remaining procedural requirements through manual instructions. While this approach has provided QIOs with a basic framework for completing the reviews, we have become aware of other issues that need to be addressed through the promulgation of new regulations as well as revisions to existing regulations. In 2003, the United States Court of Appeals for the District of Columbia Circuit issued a decision in the case of *Public Citizen, Inc.* v. *U.S. Department of Health and Human Services* (332 F.3d 654, June 20, 2003) (referred to below as Public Citizen) in which the court determined that QIOs must, at a minimum, notify a complainant of the results of its review. We recently completed a comprehensive revision to the manual instructions governing both beneficiary complaints and quality of care reviews, which, in part, was designed to ensure compliance with this court decision (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100–10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf*). These new instructions were effective May 7, 2012. While these manual revisions were necessary, we believe that additional regulatory changes are needed in order to improve QIO operations. In order to subject these additional changes to the processing of beneficiary complaint reviews and general quality of care reviews to notice-and-comment rulemaking, in this proposed rule, we are proposing to add new §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, and 476.170 as described below in this section. We also are proposing to add new definitions of ''authorized representative'', ''appointed representative; ''beneficiary representative'' and ''quality improvement initiative,'' and revise the definition of ''preadmission certification'' in § 476.1. In addition, to ensure consistency with the proposed revisions to or additional sections under Part 476, we are proposing to revise §§ 480.107, 480.132, and 480.133, as discussed more fully below.

The proposed revisions to the regulations under Part 476 include several changes that would improve the beneficiary's experience when contacting a QIO about the quality of health care he or she has received and also shorten key timeframes so that beneficiaries can achieve resolution of their health care concerns in less time. We are proposing regulations under new proposed § 476.110 regarding a new alternative dispute resolution process called ''immediate advocacy.'' We are proposing to add a definition of ''immediate advocacy'' under § 476.1, and to make clear that this process is specific to oral complaints. We are proposing to define ''immediate advocacy'' as an informal alternative dispute resolution process used to quickly resolve an oral complaint that a beneficiary or his or her representative has regarding the quality of health care received, and that this process involves a QIO representative's direct contact with the provider and/or practitioner. Historically, the only option available to beneficiaries, regardless of the severity or type of issue, is the right to file a written complaint. Once a written complaint is received, the QIO is then obligated to conduct a formal peer review of the complaint, which includes a review of the beneficiary's medical information. Although this peer review process is effective, it can be quite lengthy and burdensome on providers and practitioners, given the various steps that must be completed by the QIO prior to the QIO rendering its final decision, with providers and practitioners cooperating with the QIO throughout this process. These steps include the time needed by the QIO to follow up with beneficiaries to ensure receipt of the complaint in writing, request and receive the medical information from the provider and/or practitioner, discuss the QIO's interim decision with the practitioner and/or provider, respond to a practitioner's and/or provider's request that a QIO conduct a re-review of the initial peer reviewer's decision, and obtain the practitioner's consent to the release of specific findings in the final letter to the beneficiary. By regulation, QIOs must disclose to patients or their representatives information they have requested within 30 calendar days (42 CFR 480.132); it is possible that obtaining a practitioner's consent alone could take 30 calendar days. Even if there are no delays at any point in the current peer review process, it can take over 150 calendar days for a QIO to complete its review of a beneficiary's written complaint.

At times, the length of the current peer review process can render the beneficiary's original concern moot, particularly where the beneficiary's concern relates to a communication issue between his or her providers and/or practitioners, the prescribing of medications, or the failure to receive a necessary medical item, such as a wheelchair. For these types of concerns, we believe that requiring a beneficiary to submit the complaint in writing and waiting more than 150 calendar days so that the QIO can complete its review does not provide prompt and customer friendly service to Medicare beneficiaries. Moreover, at times, certain issues raised by a Medicare beneficiary in a complaint may not even be documented in the beneficiary's medical information. This is particularly true for complaints related to communication or coordination issues surrounding the beneficiary's care. Thus, a QIO may actually know at the outset of a review that the peer review process will not divulge any information related to the beneficiary's complaint.

We believe that, by proposing to establish an informal process such as ''immediate advocacy,'' the QIO would be able to offer an alternative to a Medicare beneficiary in those situations where a resolution is needed more quickly than the current traditional peer review process. We believe that this proposed new informal process would also be beneficial in those instances where information relevant to a complaint would most likely not be contained in the medical information or where the Medicare beneficiary may simply be put off by the formality of the traditional peer review process. In proposing this new informal process, we are specifying in proposed § 476.110(a) that the process is available for oral

complaints so that there is a clear distinction from the process requiring a written complaint under section 1154(a)(14) of the Act. Again, the proposed definition of ''immediate advocacy'' under § 476.1 also would make this clear.

We also are proposing that the use of ''immediate advocacy'' would not be available if the QIO makes a preliminary determination that the complaint includes concerns that could be deemed significant, substantial, or gross and flagrant violations of the standard of care to which a beneficiary is entitled (proposed § 476.110(a)(2)(ii)). In addition, we are proposing to add definitions of ''quality of care concern'' and ''significant quality of care concern'' under § 476.1, and to incorporate the definitions of ''gross and flagrant violation'' and ''substantial violation in a substantial number of cases'' as these two terms are used in 42 CFR 1004.1. We are proposing to define ''quality of care concern'' to mean a concern that care provided did not meet a professionally recognized standard of health care, and that a general quality of care review or a beneficiary complaint review may cover a single concern or multiple concerns. ''Significant quality of care concern'' would mean a determination by the QIO that the quality of care provided to a beneficiary(s) did not meet the standard of care and while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary. ''Gross and flagrant violation'' would mean that a violation of an obligation specified in section 1156(a) of the Act has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations (as specified in 42 CFR 1004.1). ''Substantial violation in a substantial number of cases'' would mean a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO (as specified in 42 CFR 1004.1). We believe that the proposed definitions would give improved clarity to the distinctions made among concerns that do not meet the standard of care and demonstrate that QIOs are responsible for identifying all instances where care could have been improved and not just the most significant or flagrant failures to meet a standard of care. With regard to ''immediate advocacy,'' we believe that this informal process is not appropriate for those situations where a QIO preliminarily determines that a complaint could involve a ''gross and flagrant'' or ''substantial'' concern. In these circumstances, the QIO would not offer the immediate advocacy process, but instead would inform the beneficiary of the right to file a written complaint. Moreover, while we are proposing to exclude the use of the immediate advocacy process for those instances where ''significant quality of care concerns'' might be present, we are requesting public comments regarding whether the immediate advocacy process should be made available for these concerns as well. In addition, while we are proposing to restrict the use of the immediate advocacy process to a period of 6 months after a beneficiary has received the care at issue (proposed § 476.110(a)(1)), we also are requesting public comments on whether this time period should be extended beyond 6 months, whether based on the proposed structure or in order to accommodate the potential broadening of its use for ''significant quality of care concerns.''

In proposed § 476.110(a)(2), we are specifying that the immediate advocacy process can be used for issues that are not directly related to the clinical quality of health care itself or that accompany or are incidental to the medical care received. This includes, but is not limited to, issues such as delays in obtaining much needed medical items (for example, wheelchairs). In addition, in § 476.110(a)(3), we are proposing that the Medicare beneficiary must agree to the disclosure of his or her name in order for the immediate advocacy process to be used. We believe that it is important for the Medicare beneficiary to disclose his or her name because the immediate advocacy process is based on the need for open discussions to quickly resolve a beneficiary's concerns. Moreover, we also are proposing that all parties orally consent to the use of immediate advocacy (proposed § 476.110(a)(4)). Because our goal is to work with the providers and practitioners to resolve a beneficiary's concerns, we believe that consent is necessary. The use of oral consent, and not written consent, is in keeping with the cost-saving attributes of alternative dispute resolution processes.

Although we believe that the immediate advocacy process will be of great value to Medicare beneficiaries, providers, practitioners, and the QIOs, we recognize that, for some, the process may not provide the desired resolution. In addition, there could be situations where a QIO determines, after the immediate advocacy process has begun, that more serious concerns are evident. Therefore, we are proposing under § 476.110(b) that the QIO and either party can discontinue participation in immediate advocacy at any time and the steps a QIO will take when this occurs. This includes informing the beneficiary of his or her right to submit a written complaint.

In proposed § 476.110(c), we are conveying the need to maintain the confidentiality of the immediate advocacy proceedings by specifically referencing the redisclosure restrictions under § 480.107. We are proposing to make a corresponding change to § 480.107 by adding new paragraph (l), which will specify that the redisclosure of confidential information related to immediate advocacy proceedings can occur when there is consent of all parties. In proposed § 476.110(d), we are proposing to include procedures that QIOs would follow in those instances where a party fails to participate or otherwise comply with the immediate advocacy procedures. This includes making a beneficiary aware of his or her right to submit a written complaint.

We believe that the use of the immediate advocacy process will greatly reduce the burden on practitioners and providers by avoiding the formality of the traditional peer review process in appropriate situations and quickly identifying resolutions and improvements in the provision of health care. In fact, the immediate advocacy process has already been introduced through the recently completed manual instructions, and preliminary feedback indicates that it is being received positively by providers, practitioners, and Medicare beneficiaries. Medicare beneficiaries have indicated their appreciation of the quicker and more appropriate resolution of their concerns. Many times, Medicare beneficiaries would wait months for the resolution of a formal written complaint, only to be disappointed in what the QIO actually found or frustrated that the concern initially raised was rendered obsolete by more recent events. Under the immediate advocacy process, the QIO has a mechanism to resolve beneficiaries' concerns, sometimes the same day the beneficiary calls. Moreover, providers and practitioners have responded positively to being given the opportunity to immediately address beneficiary's concerns and improve care, particularly where communication is one of the

beneficiary's primary concerns. In addition, the provider's or practitioner's ability to avoid receiving and processing a formal complaint letter from the QIO and the related time and costs related to forwarding of medical records and engaging in the lengthy review process also have been positively received. The decreased burden on Medicare beneficiaries, providers, and practitioners and the time and cost savings are cornerstones of alternative dispute resolution processes. We are confident the positive responses to this new option will continue.

While we believe that the immediate advocacy process represents a significant step forward in ensuring the timely, appropriate, and cost-efficient resolution of Medicare beneficiaries' concerns, we recognize that additional changes are needed to improve the QIOs' review process in general. Therefore, we are proposing regulations governing written beneficiary complaint reviews as well as general quality of care reviews. We are proposing to add a new § 476.120 that would govern a Medicare beneficiary's submission of a written complaint, and are proposing under proposed § 476.120(a), language limiting the time period for submitting a written complaint to 3 years from the date on which the care giving rise to the complaint occurred. We believe this is necessary because the ability of a QIO to thoroughly review a complaint becomes more problematic the longer the period of time is between the circumstances giving rise to a complaint and the actual filing of the complaint. An individual's memory can fade, and we are aware of some instances where Medicare beneficiaries have submitted complaints about issues that have occurred decades ago. In these situations, the QIOs' ability to obtain the necessary information, let alone render a valid decision, has been severely compromised. As such, we believe that a 3-year look back period should be sufficient to ensure that a QIO can effectively complete its review.

We are specifying in proposed § 476.120(a)(1) that a complaint submitted electronically to the QIO meets the requirement for the submission of a written complaint. We are specifying in proposed § 476.120(a)(2) that if a beneficiary contacts a QIO about a potential complaint, but decides not to submit it in writing (and the QIO did not offer immediate advocacy), the QIO may use its authority under section 1154(a)(1)(B) of the Act to complete a general quality of care review in accordance with new proposed procedures at proposed § 476.160. We note that, in these situations, the beneficiary would not receive any results of the QIO's review. We also are proposing to limit the QIO's authority to conduct a general quality of care review in response to an oral complaint to those situations where the QIO makes a preliminary determination that the complaint contains a potential gross and flagrant, substantial, or significant quality of care concern.

In proposed § 476.120(b), we are proposing instructions for QIOs when a beneficiary submits additional concerns after the initial submission of a written complaint. We believe that the focus on an episode of care, which we are proposing in § 476.130(a)(1), gives the QIO adequate flexibility to consider all related concerns surrounding a complaint, but for those rare instances where a beneficiary does convey a new concern, the QIO would now have specific instructions regarding the right to consider the additional concerns either during the same complaint review or as a separate complaint.

In proposed § 476.130(a), we are proposing to convey the QIO's obligation to consider any information submitted by the beneficiary or his/her representative and by the provider and/or practitioner, along with the QIO's obligation to maintain the information received as confidential information, if that information falls within the definition of ''confidential information'' under existing § 480.101. Moreover, proposed § 476.130(a)(1) also would convey that the focus of the QIO's review will be on the episode of care from which the complaint arose and that in completing its review, the QIO will respond to the specific concerns raised by the beneficiary along with any additional concerns the QIO identifies while processing the complaint. We believe that the focus on the episode of care will significantly reduce the burden on providers and practitioners and reduce timeframes for completing reviews. Historically, QIOs would closely track the complaint as originally conveyed by a Medicare beneficiary. Often, however, Medicare beneficiaries would become dissatisfied with the focus and/or results of the QIO's review, and the QIO would be forced to reexamine the complaint in light of these new issues. On occasion, this could even require the submission of an entirely new complaint for issues that were related to, but not reviewed in, the original complaint. These situations also added to the burden on providers and practitioners because they would be required to participate in the review of the additional concerns and even provide additional medical documentation that may not have originally been requested.

In addition, proposed § 476.130(a)(1) would specify the details of the QIO's authority to separate a beneficiary's concerns into separate complaints if the QIO determines that the concerns relate to different episodes of care. We believe that focusing on the episode of care will put QIOs in a better position to identify all potential concerns at the onset and help alleviate any potential back and forth based on the specter of new or different concerns arising after the review has begun.

Proposed § 476.130(a)(2) would set forth the QIO's use of evidence-based standards of care to the maximum extent practicable, and specify the method that the QIO must use to establish standards if no standard exists. Moreover, this paragraph (a)(2) also conveys the finality of a QIO's determination regarding the standard to be used for a particular concern, in that the QIO's determination regarding the standard used is not subject to appeal. We believe that the focus on evidence-based standards of care is vital to the improvement of health care nationally.

In proposed § 476.130(b), we are proposing to specify the timeframes that practitioners and providers must follow when a QIO requests medical information in response to a written beneficiary complaint. We are proposing a 10 calendar day timeframe for responding to these requests. While this timeframe is significantly shorter than the 21 and 30 calendar day timeframes specified in existing § 476.78, we believe that it is warranted in light of the need to give Medicare beneficiaries a more timely resolution to their complaints. We believe providers and practitioners would also benefit from the faster resolution of complaints and would shift the focus from being available during the lengthy review process to moving forward with improvements to the health care given to Medicare beneficiaries. In addition, where, for other review activities, a QIO may be requesting multiple medical records, most often a single medical record will be requested in response to a written beneficiary complaint. Thus, the ability to respond within the shorter 10 calendar day timeframe should be much easier and less burdensome. Moreover, we also considered that an increasing number of providers and practitioners are using vendors to respond to requests for medical information, and this timeframe is comparable to models typically used by these vendors in responding to requests. In fact, even shorter timeframes can exist for larger providers and/or

practitioner groups. In addition, QIOs have historically employed a different, shorter timeframe for reviews where a Medicare beneficiary is still receiving care (concurrent review), compared to those situations where a Medicare beneficiary has already been discharged (retrospective review). For concurrent reviews, QIOs request that medical information be received within 1 calendar day, and typically this timeframe has been adhered to by providers and practitioners. Although we are not proposing the continued use of the concurrent and retrospective review framework for responding to written complaints, we recognize that there could be circumstances in which an even shorter timeframe for receiving medical information is warranted, and we are proposing to include language detailing a QIO's right to earlier receipt of medical information. We are proposing that this right to earlier receipt of medical information be related to potential gross and flagrant or substantial quality of care concerns. However, we are requesting public comments on whether there are other circumstances, involving less serious kinds of concerns, for which this authority to employ a shorter timeframe should be used. In addition, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we included proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which currently refer only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. We also proposed changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these proposed changes in the FY 2013 IPPS/LTCH PPS proposed rule have not been finalized, in this proposed rule, we are requesting public comment on whether changes similar to those we are proposing for beneficiary complaints, including shortening of the 30-day and 21-day timeframes, should be incorporated into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. We are proposing to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to quality reviews in just one instance: Where secure transmissions of electronic versions of medical information are available. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

In proposed § 476.130(c), we are proposing to include a requirement for beneficiary complaints that the QIO issue its interim initial determination within 7 calendar days after receiving all medical information. We believe that this timeframe is sufficient to evaluate a complaint and identify the key aspects of the care provided. Proposed § 476.130(c)(1) would specify the provider's and/or practitioner's right to discuss the QIO's determination before it is finalized, and would specify that the QIO's initial notification will be made by telephone. We are proposing a 7-calendar day timeframe for completion of the discussion. In addition, we are proposing that the QIO's interim initial determination would become the QIO's final determination if the discussion is not completed timely because the provider and/or practitioner has failed to respond (proposed § 476.130(c)(2)). Again, our focus is on obtaining resolutions to complaints within reasonable timeframes, and the completion of the discussion is an area where improved instructions may benefit the timeliness of complaint processing because we have experienced significant delays in completing this particular step. The term ''final initial determination'' should not be confused with the term used in 42 CFR Part 405, because Part 405 relates to whether a beneficiary is entitled to services or the amount of those services, while this regulation covers only the quality of services as specified in the QIO statute. At the same time, we are proposing under proposed § 476.130(c)(3) the provider's or practitioner's right to submit a written statement in lieu of a discussion, with the requirement that the written statement be received within the same 7-calendar day timeframe from the date of the initial offer. We believe that allowing the submission of a written statement would benefit practitioners or providers that may have trouble being available at a specific time within the 7-calendar day timeframe. Moreover, in proposed § 476.130(c)(4), we have included the QIO's right to extend the timeframe for holding the discussion or submission of a written statement in lieu of a discussion in those rare instances where a practitioner or provider is unavailable, whether because of military tours of duty, travel or other unforeseen circumstances.

In addition, we are considering restricting a provider's or practitioner's right to submit new or additional medical evidence in the form of test results, x-rays, and other evidence, as part of this discussion. We believe that doing so would emphasize the need for providers and practitioners to supply all relevant evidence when first requested by the QIO and also would maintain the focus on the discussion a physician or provider is due in accordance with section 1154(a)(14) of the Act. Allowing the submission of additional or new evidence could also substantially raise the possibility that the discussion will become, in effect, an entirely new review by the QIO. Moreover, providers and practitioners will still be able to submit information as part of a request for a reconsideration review. We are requesting public comments on whether providers and/or practitioners should be prohibited from submitting new or additional medical evidence in response to the offer of a discussion.

In proposed § 476.130(d), we are specifying the QIO's obligation to issue a written final initial determination, regardless of whether care did or did not meet standards for all concerns, and that this determination must be issued within 72 hours after completion of the QIO's review or, in cases where the standard was not met, the QIO's discussion or receipt of the provider's and/or practitioner's written statement. In addition, proposed § 476.130(d)(1) would specify that the notice of the final initial determination will be forwarded to all parties, and paragraph (d)(2) lists the actual content of the notice. We are specifying that the QIO would not forward the notice if either party requests a reconsideration of the final initial determination.

These proposed changes represent significant departures from the process QIOs have historically used when resolving beneficiary complaints and are necessary to improve the fairness of the review process and increase the transparency of the QIO review process. When the process was originally established, CMS determined that physicians, providers, or Medicare beneficiaries would not be afforded the right to request a reconsideration of these determinations under section 1155 of the Act. However, providers and practitioners were afforded an administratively created option, referred to as a ''re-review,'' if the provider or practitioner disagreed with the QIO's initial decision. Medicare beneficiaries were not provided this re-review opportunity and, in fact, were not given any response until after completion of the re-review. Moreover, the actual information a beneficiary received in response to the submission of a complaint was further limited by certain other provisions in the existing regulations. Section 480.132 covers the

general requirements that a QIO must meet in disclosing information to a beneficiary when that beneficiary has requested information about him or herself. Section 480.132(a)(1)(iii) states that this information cannot include any practitioner-specific information. We have read this provision in conjunction with § 480.133(a)(2)(iii), which authorizes a QIO to disclose practitioner-specific information when the practitioner has consented to the disclosure. In the past, we have interpreted these provisions as applying in the context of beneficiary complaints. This limitation greatly reduced a beneficiary's access to information related to the QIO's specific findings. In fact, § 480.132 also gave attending practitioners the authority to direct that a QIO not provide results directly to a Medicare beneficiary should that practitioner determine that the released information could ''harm the patient.'' This same provision gave QIOs a full 30 calendar days before they had to respond to a beneficiary's request for information, which would apply even in the context of a complaint. Thus, the QIO was required to obtain a practitioner's consent to disclose information within this 30-calendar day timeframe before the QIO could disclose the specific results of its complaint review to the beneficiary.

As a result of the current provisions in the regulation, the QIO was often delayed in its ability to respond to the beneficiary, and was sometimes forced to identify a representative and then give the results to the representative even if the Medicare beneficiary believed he or she was able to represent himself or herself and legally had not been deemed otherwise. Clearly, this scenario has frustrated Medicare beneficiaries over time and placed QIOs in difficult situations. Furthermore, if a practitioner did not consent to any disclosures or to limited disclosures of information that would identify the practitioner, a QIO's decision typically contained a conclusory statement about the results of the QIO's review but no information about the standards of care the QIO used, the evidence the QIO considered, or the rationale for how the QIO arrived at its conclusion. The limitations on what information Medicare beneficiaries received and broad authority given to attending practitioners have been particularly troubling in those instances in which the beneficiary's complaint relates to care that an attending physician provided. In fact, the lack of information given to Medicare beneficiaries in response to a complaint was the precise issue addressed in the Public Citizen decision.

We believe that the proposed changes to § 476.130(d), including paragraphs (d)(1) and (d)(2), are necessary to ensure beneficiaries are given the same information and rights as practitioners and providers. The proposed changes make clear that the timeframe given to QIOs for issuing the final initial determination in response to a complaint is separate and distinct from the timeframe given to QIOs when responding to a beneficiary's request for information. Any requests for information, including requests for information pertaining to beneficiary complaint reviews that are unrelated to a QIO's issuance of its final initial determination, would continue to be governed by § 480.132. Moreover, while the proposed 72-hour timeframe in § 476.130 appears short in comparison to the 30-calendar day timeframe in § 480.132 that has historically been used, we believe that the 72-hour timeframe represents a more appropriate and reasonable period of time in which to issue these decisions. In most cases, the QIO's final initial determination may not change significantly from the interim initial determination. Thus, QIOs would be able to rely heavily upon the interim initial determination in most instances, with only minor adjustments being made in light of information received in response to the opportunity for discussion. In addition, paragraph (d)(2) proposes the content of the written decision to be given to the beneficiary, provider, and/or practitioner. We are proposing that the content include a statement for each concern that the care did or did not meet the standard of care, the standard identified by the QIO for each of the concerns, and a summary of the specific facts that the QIO determines are pertinent to its findings. This list makes clear that § 480.132 will no longer govern what information a QIO may provide to a beneficiary in resolving a complaint. We believe this approach more fully supports the Court's decision in the Public Citizen case.

In addition, we believe that the language under section 1155 of the Act supports the decision to give all parties the right to request that the QIO reconsider its initial decision, and we are proposing to offer providers, practitioners, and beneficiaries the right to request a reconsideration in proposed § 476.140(a) for complaints filed after July 31, 2014. This includes proposed specific requirements regarding the manner in which these requests are to be submitted and the obligations of beneficiaries, providers, and practitioners to participate in the reconsideration process in proposed § 476.140(a)(1) through (a)(3). We are delaying implementation of this new proposed right to ensure all processing requirements are fully developed for QIOs to follow in reviewing these reconsideration requests.

In addition to proposing the specific content of the notice at proposed § 476.130(d)(2) when a final initial determination is issued and under proposed § 476.140(b) when a reconsideration final decision is issued, we are proposing to make corresponding changes to existing §§ 480.132(a) and (b) and 480.133(a) (proposed new paragraph (a)(2)(iv)). In order to make clear that § 480.132 relates solely to a beneficiary's request for information, but not to a beneficiary's receipt of information from a QIO in resolution of a complaint review, we are proposing the inclusion of a cross-reference to §§ 476.130(d) and 476.140(b) in paragraph (a). Similarly, we are proposing to include language in § 480.132 (a)(1)(iii) to denote that the removal of all other patient and practitioner identifiers does not apply to disclosures described in § 480.132 (b). We also are proposing clarifications to § 480.132(b) to improve the link between paragraph (b) and the provisions of § 478.24, which are cross-referenced in paragraph (b). We note that § 478.24 does not require seeking the advice or consent of the practitioner that treated the patient, nor does it prohibit the QIO from disclosing practitioner identifiers. We have made this clear by proposing the deletion of paragraph (b)(1)(i) and added language to the end of current paragraph (b)(1)(ii) to indicate that the information provided under § 478.24 includes relevant practitioner identifiers. With the deletion of paragraph (b)(1)(i), there is no longer a need for multiple paragraphs in (b)(1). Therefore, we are proposing to eliminate the current designation for paragraph (b)(1)(ii), with the provision being included as part of paragraph (b)(1). We also are proposing a corresponding change to § 480.133(a)(2)(iv) that makes clear a practitioner's or provider's consent is not required prior to releasing information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the results of the QIO's findings related to a beneficiary complaint review as described in §§ 476.130(d) and 476.140(b).

We also are proposing to remove from existing § 480.132(a)(2) and (c)(1) the right of an attending practitioner to direct a QIO to withhold information

based on a ''harm'' determination. This includes the proposed removal of the requirement from existing § 480.132(c)(2) that a QIO release results to a beneficiary's representative if a ''harm'' determination has been made by the attending practitioner. This also includes our proposed decrease in the timeframe that QIOs must follow in responding to a beneficiary's request for information (in any situation, as well as in the context of a beneficiary complaint) in § 480.132(a)(2) from 30 calendar days to 14 calendar days. This timeframe is strictly related to those situations where a beneficiary is making a request for information and will no longer be associated with obtaining responses to beneficiary complaints, which are detailed in proposed §§ 476.130(d) and 476.140(b). We believe the decrease from 30 calendar days to 14 calendar days is warranted in light of the improved ability to maintain data, including in electronic formats, so that less time is needed when responding to requests. The proposed changes would ensure that Medicare beneficiaries have more control over the designation of their representatives and also give a QIO more appropriate steps to follow in identifying a representative when one is actually needed. As an example, the existing regulations at § 480.132(c)(3) direct a QIO to ''first'' look to the medical record to identify a representative but then direct the QIO to ''rely on the attending practitioner'' if no information is contained in the medical record. The changes we are proposing to § 480.132(c) place more emphasis on the obligation of the QIO to follow the requirements under State law regarding the designation of health care representatives or agents, rather than focusing on ''where'' the information might be contained.

Lastly, at proposed § 476.140(b), we are specifying that the QIO must notify the beneficiary and the practitioner and/or provider of its final, reconsidered, decision within 72 hours after receipt of the request for a reconsideration or, if later, 72 hours after receipt of any medical or other records needed for such a reconsideration. The QIO may do so orally, by telephone, in order to meet this timeframe. Proposed § 476.140(b)(1) also would specify that a written notice must be mailed by noon of the next calendar day and specifies the content of the notice. In addition, proposed § 476.140(b)(2) describes the QIO's authority to provide information in its final decision to beneficiaries, providers and/or practitioners regarding improvement opportunities. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or the provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or the providers. Some QIOs have, in fact, been providing this information to beneficiaries since it can offer the beneficiaries assurance that their complaints and any underlying problems are being addressed.

We are proposing to include under proposed new § 476.150 specific requirements for QIOs to follow in response to abandoned complaints. We believe that these instructions are necessary in light of a QIO's experience when handling complaints where a Medicare beneficiary initially submits a complaint but then all attempts by the QIO to contact the beneficiary are unsuccessful. Historically, QIOs have been responsible for continual follow-up with beneficiaries, even if months later the beneficiary still had not responded. We believe that giving QIOs the discretion to close these cases will eliminate this unnecessary follow-up and reduce costs. Moreover, it will alleviate provider's and/or practitioner's concern in those situations where the QIO may have already reached out to them about a potential complaint. We also are proposing to add under proposed § 476.150(b) instructions for QIOs to follow in those situations, which we believe will be rare, where a QIO must reopen a beneficiary complaint review. We would have QIOs apply the same procedures that appear in the already existing regulations at § 476.96 for the reopening of cases involving initial denial determinations and changes as a result of DRG validation, simply using those same procedures for a different purpose. We are proposing to do this by placing a reference in § 476.150(b) to the procedures in § 476.96.

2. Completion of General Quality of Care Reviews

Although the QIO's responsibility for completing quality of care reviews is already set forth in the QIO program regulations at existing § 476.71(a)(2), the procedures that QIOs use in completing these reviews are not. Again, the precise steps that QIOs use in completing these reviews were established through manual instructions. However, we believe that the proposed changes discussed below are necessary to the processing of these reviews in light of the knowledge we have gained since the program began. We believe that these proposed changes can bring about necessary improvements as quickly as possible and also support our efforts to thoroughly evaluate how the program should be structured moving forward.

First, in proposed new § 476.160(a)(1), we are proposing to specify those circumstances in which a QIO may conduct a general quality of care review. These circumstances would include those situations where a potential quality of care issue is referred to the QIO by another source, such as by another CMS contractor, an individual submitting a request anonymously, or another Federal or State entity. In addition, we recognize that more frequently the QIOs are working to use the substantial data available to them to identify potential areas where improvements in the quality of health care could be attained, and we believe these instances should be accounted for as we move forward. We also are aware that QIOs frequently identify potential quality of care issues when conducting other case review activities, including medical necessity reviews, expedited discharge appeals, among others; therefore, we have included this as an instance where a general quality of care review can be initiated.

In proposed new § 476.160(a)(2), we are specifying that the QIO's review will focus on all concerns raised by the source of a referral or report and/or identified by the QIO. While the episode of care should still be considered, it may be less significant for these reviews than those in response to a complaint submitted by a beneficiary, because the main goal of complaint reviews is to address a beneficiary's particular experiences with receiving certain services at a particular time. However, we again are proposing under proposed § 476.160(a)(3) that the QIO will use evidence-based standards of care to the maximum extent practicable in completing these reviews, and that the QIO's determination regarding the standard used in completing the review is not subject to appeal.

In proposed new § 476.160(b), we are proposing to specify the responsibility of providers and practitioners to supply requested medical information. This language is identical to the language in proposed new § 476.130(b) applicable to written beneficiary complaints, including the same 10-calendar day timeframe for practitioners and providers to respond to requests for medical information and the QIO's right to request even earlier receipt when the QIO preliminarily determines that a concern may be serious enough to qualify as a gross and flagrant or substantial quality of care concern. Although the decreased timeframe is not related to the goal of providing

beneficiaries with more timely resolution of their complaints (because beneficiaries will not be getting results of these reviews), we still believe there is ample justification to warrant the reduced timeframe. Providers and practitioners will benefit from the faster resolution of these reviews and the increased focus on identifying and resolving impediments to improved health care (particularly in cases involving potential serious concerns). These improvements will ultimately benefit patients. Additionally, as with written beneficiary complaints, the timeframes are comparable to models typically used by vendors. We also considered that, as with written beneficiary complaints, the QIOs currently use shorter timeframes where the beneficiaries impacted by the general quality of care review are still receiving care (concurrent review), compared to those situations where a beneficiary has already been discharged (retrospective review). Again, while we are not proposing the continued use of the concurrent and retrospective designations, we recognize that there are circumstances, even with general quality of care reviews, where decreased timeframes are necessary, including the 10-calendar day, or even shorter, timeframe.

As mentioned previously, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we included proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which currently refer only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. We also proposed changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these proposed changes in the FY 2013 IPPS/LTCH PPS proposed rule have not been finalized, we are proposing here to modify the current general 30-day and 21-day timeframes in § 476.78(b) to reflect the new timeframes in §§ 476.130(b) and 476.160(b), which apply only to records submitted for purposes of beneficiary complaint and general quality reviews. We also are requesting public comment on whether changes similar to those we are proposing for beneficiary complaints and general quality of care reviews, including shortening of the 30-day and 21-day timeframes, should be incorporated more broadly into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. We are proposing to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to beneficiary complaints or general quality reviews in just one instance: Where secure transmissions of electronic versions of medical information are available. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

We also are proposing new § 476.160(c), which would specify that the QIO peer reviewer will render the initial determination within 7 calendar days of the receipt of all medical information; this paragraph is substantially different from the proposed beneficiary complaint review procedures in proposed new § 476.130 in two areas. First, beneficiaries would not be provided any information regarding these reviews. Although we recognize that, at times, potential quality concerns a QIO identifies could impact a specific beneficiary, we believe that this type of review does not warrant any communication directly to the beneficiary. In fact, we believe that giving feedback of potentially poor care to an unknowing beneficiary could cause more anxiety than is warranted by the circumstances, and that is not our goal. We also recognize that, in many situations, the reviews could relate to or involve numerous beneficiaries. However, those beneficiaries may only be a sample of the beneficiaries potentially impacted. This is particularly true in those circumstances where the QIO is reviewing system-related aspects of care, and it will be incumbent upon the QIO to determine what medical information—and by extension the sample of beneficiaries receiving care—to be analyzed in completing these reviews.

Second, we are proposing that practitioners and providers not be given an opportunity to discuss the QIO's initial determination before it becomes final. The QIO's obligation to provide an opportunity for discussion is specific to the QIO's responsibility to review beneficiary complaints under section 1154(a)(14) of the Act. This same obligation is not dictated by section 1154(a)(1)(B) of the Act on which the QIO's authority to conduct general quality of care reviews is based. We believe that giving such an opportunity is not necessary, particularly because these discussions frequently become, in effect, an entirely new review by the QIO and not merely a discussion, and because we are already proposing at proposed new § 476.170(a) that the practitioner and/or provider be given the right to request a reconsideration of the QIO's initial determination. As with beneficiary complaint reviews, we are proposing that this right not be available until after July 31, 2014, to give us time to fully establish the process requirements and ensure that this right is meaningful for providers and practitioners.

In addition, under proposed new § 476.170(a)(1) through (a)(3), we are proposing requirements similar to those in § 476.140 regarding the timeframe for submitting a request for a reconsideration, the obligation of a practitioner and/or provider to be available to answer questions or supply information, as well as the QIO's obligation to offer the provider the opportunity to provide information as part of the reconsideration request. We also proposed provisions under proposed new § 476.170(b) concerning the QIO's issuance of its final decision. This includes the requirement that the QIO's decision be issued within 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical information or other records needed for such a reconsideration, the specific content of the final decision, and the right of the QIO to provide information to the provider or practitioner regarding opportunities for improving care given to beneficiaries based on the specific findings of its review. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or providers.

C. Use of Confidential Information That Explicitly or Implicitly Identifies Patients

The QIO regulations at § 480.101(b) define any information that explicitly or implicitly identifies an individual patient as confidential information. Although provisions are included in 42 CFR Part 480 governing a practitioner's and/or provider's right to allow a QIO to use or disclose confidential information about the named practitioner or provider (§§ 480.105(b), 480.133(a)(2)(iii), and 480.140(d)), a similar right is not conveyed for beneficiaries. Thus, QIOs are prohibited from obtaining a beneficiary's authorization to use or disclose the beneficiary's confidential information, even in situations where a use or disclosure could be helpful to the beneficiary and his or her health care or even where the beneficiary specifically

asks the QIO to disclose the information.

One of the key challenges for the QIOs is identifying improvements in health care delivery systems. In fact, the ''patient-centeredness'' aim of the QIO's current scope of work requires more patient involvement, and the goal of many patient and family engagement efforts is to incorporate ''real-world person's'' experiences to demonstrate the compelling and urgent need for healthcare delivery reform. Additionally, beneficiaries have asked to participate in the QIO's work in a meaningful way. Unfortunately, we are often unable to accommodate these requests in light of the current regulatory restriction. We believe that this restriction, which was developed many years ago, is outdated, and that beneficiaries should be given the right to make choices regarding the use and disclosure of their confidential information.

As such, we are proposing new § 480.145 that will govern a beneficiary's right to authorize a QIO's use or disclosure of the beneficiary's confidential information. Under proposed § 480.145(a), we are proposing that a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary and that the QIO's use or disclosure must be consistent with the authorization. In proposed § 480.145(b)(1) through (b)(6), we have listed those aspects of an authorization necessary to make the authorization valid. This includes the requirements that a specific and meaningful description of the confidential information be included, the name(s) of the QIO and QIO point of contact making the request to use or disclose the information, the name or other specific identification of the person, or class of persons to whom the QIO may make the requested use or disclosure, a description of the purpose(s) of the use or disclosure, the date or event upon which the authorization will expire, and the signature and date of the beneficiary authorizing the use and/or disclosure of the information. We also are proposing in § 480.145(c)(1) and (c)(2) that the authorization must contain a statement that the beneficiary maintains the right to revoke his or her authorization in writing and that the QIO must specify any exceptions to the right to revoke, as well as the process a beneficiary must use to revoke the authorization. In addition, at § 480.145(c)(3), we are proposing the requirement that the QIO convey to the beneficiary its inability to condition the review or other activities it is responsible for (such as beneficiary complaint reviews, medical necessity of a beneficiary's services, or discharge appeals) on the beneficiary's authorization. We also are proposing under § 480.145(c)(4) to make clear the consequences of authorizing the use or disclosure of information, and the fact that the QIO may be unable to protect the information from redisclosure. In § 480.145(d), we are proposing that an authorization must be written in plain language, and in § 480.145(e) that a QIO must provide the beneficiary with a copy of the signed authorization. Lastly, although we make reference to a beneficiary's right to revoke authorization in proposed § 480.145(c)(1), in paragraph (f) we are proposing a specific provision that will make clear that a beneficiary may revoke, in writing, an authorization at any time, except when the QIO has taken action in reliance upon the authorization.

We believe that these proposed changes appropriately relax some of the historical restraints on the QIO's use of a beneficiary's confidential information, enable QIOs to better meet the needs of Medicare beneficiaries, and give beneficiaries the opportunity to participate in efforts to improve the quality of their health care.

D. Secure Transmissions of Electronic Versions of Medical Information

When the QIO program regulations were first written in 1985, computers, along with digitally or electronically stored information, were still in their infancy. Thus, the QIO program regulations were written based on the perspective that most information sharing would be through the exchange of paper copies of medical records and other information. Since that time, we have seen great advances in the ability to electronically share data, whether through the use of mass storage devices (flash drives), the sending and receipt of electronic facsimiles, and even the use of email. At the same time, several laws, including HIPAA and the Federal Information Security and Management Act (FISMA), have been established to protect sensitive information. However, because the QIO program regulations have not undergone significant modification since they were originally adopted, the regulations do not account for electronic sharing of information and the QIOs' work is carried out within the context of exchanging paper copies of documents and information. At times, this creates additional work and costs because those providers and practitioners who have the ability to securely share electronic versions of medical records must actually print out the records and pay to have the paper copies mailed to the QIOs. To address these issues, we are proposing to revise existing § 476.78(b)(2) to add a new paragraph (iii) to make clear the QIOs' right to exchange secure transmissions of electronic versions of medical information, subject to a QIO's ability to support the exchange of the electronic version. We believe that this proposal would enable QIOs to receive and send medical information in a variety of formats, including through secure electronic faxes, and would reduce costs for providers and practitioners because they would no longer have to print and mail paper copies. In addition, to fully take advantage of the ability to receive and send electronic versions of medical information, we believe that a reduced timeframe is warranted for those instances where electronic versions are to be forwarded in response to requests from a QIO. Therefore, we are proposing under proposed § 476.78(b)(2)(iii) to require providers and practitioners to deliver electronic versions of medical information within 10 calendar days of the request from the QIO. As we noted previously, changes to existing § 476.78(b) have already been proposed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119). As discussed earlier in this preamble, we are now proposing in this CY 2013 OPPS/ASC proposed rule additional changes to § 476.78 to take into account the different, more expedited timeframes we are proposing for medical records related to beneficiary complaint and general quality of care reviews. We also are requesting public comments in this proposed rule on whether additional changes should be made to § 476.78(b) to expand the different timeframes to cover medical records for all kinds of reviews. We also are requesting public comments on whether any modifications should be made to the reimbursement methodologies for paper copies described in § 476.78(c). We note that we are carrying forth in this proposed rule the proposed change to the section heading for § 476.78 that was included in the FY 2013 IPPS/LTCH PPS proposed rule, that is, the proposed change from ''Responsibilities of health care facilities'' to ''Responsibilities of providers and practitioners''.

E. Active Staff Privileges

In our efforts to ensure the QIO program is able to meet the needs of Medicare beneficiaries and improve the quality of health care moving forward, we have identified an aspect of the QIO program regulations that has become increasingly problematic for the QIOs.

Under existing § 476.98(a)(1), QIOs are required to use an individual with ''active staff privileges in one or more hospitals'' in making initial denial determinations. However, there is an accelerating trend toward generalist (family physicians/internists) physicians who provide care solely in the inpatient or outpatient care settings and a corresponding decline in the number of family practice physicians who provide any care in hospitals. In fact, many of these individuals do not provide any inpatient care and either have no hospital privileges or only ''courtesy'' privileges, which do not meet the definition in existing § 476.1 of ''active staff privileges.'' While we believe that the continued use of peer reviewers is necessary and vital to the success of the QIO program, the need to use physicians with ''active staff privileges'' is not. We believe that proposing to remove this requirement would increase the number of peer reviewers available for use by the QIOs, which, at times, has become particularly problematic for the QIOs. Therefore, in this proposed rule, we are proposing to remove the definition of ''active staff privileges'' under § 476.1 and to remove the phrase referring to using individuals ''with active staff privileges in one or more hospitals in the QIO area'' in making initial denial determinations under § 476.98(a)(1).

F. Proposed Technical Corrections

In addition to the proposed changes discussed above, we are proposing to make the following technical corrections to the QIO regulations:

• In 1989, several sections in 42 CFR Part 405 were redesignated to 42 CFR part 411 (54 FR 41746), but the cross-references to these sections in the QIO regulations was never made. Therefore, we are proposing to make the following reference changes:

+- Changing the reference ''§ 405.330(b)'' in existing § 476.71(b) to ''§ 411.400(b)'';

+- Changing the reference ''§ 405.332'' in § 476.74 to ''§ 411.402'';

+ Changing the references ''§ 405.310(g) or § 405.310(k)'' in § 476.86 to ''§ 411.15(g) or § 411.15(k)''.

• In 1999, 42 CFR parts 466, 473, and 476 were redesignated as 42 CFR parts 476, 478, and 480, respectively (64 FR 66236). Therefore, we are proposing to make changes to correct several cross-references to sections in these Parts:

+ Changing the reference ''§ 466.73(b)(3)'' in § 476.73 to ''§ 476.78(b)(3)''.

+ Changing the reference ''part 473'' in § 476.78(f) to ''part 478''.

+ Changing the reference ''part 473'' in § 476.94(c)(3) to ''part 478''.

+ Changing the reference ''§ 473.24'' in §§ 480.132 and 480.133 to ''§ 478.24''.

+ Changing the reference ''§ 466.98'' in § 478.28 to ''§ 476.98''.

+ Changing the reference to ''Part 478'' in §§ 478.15, 478.16, 478.20, 478.38, 478.42, and 478.48 to ''Part 473''.

+ Changing the reference ''§ 473.24'' in § 480.132 to ''§ 478.24''.

+ Changing the references ''Part 466'' and ''§ 473.24'' in § 480.133(b) to ''Part 476'' and ''§ 478.24'', respectively.

• We are proposing the deletion of several provisions in Part 476 regarding risk-basis contracts because risk-basis contracts previously under section 1876 of the Act no longer exist. As such, these provisions are obsolete and no longer used under the QIO program. Specifically, we are deleting the following sentence from § 476.70(a): ''Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.'' We are proposing to delete the following sentence from § 476.70(b): ''Section 466.72 of this part also applies, for purposes of quality of care review under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.'' We are proposing to delete § 476.72—Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans, in its entirety for the same reason.

• In § 476.70(a), we are proposing to change the word ''basis'' to ''bases'' to match the title of this section and to correctly denote that there is more than one statutory basis described in paragraph (a).

• We are proposing technical corrections to sections in Part 476 and 480 to accurately reflect the transition to Medicare administrative contractors (MACs) to process Medicare claims and conduct other actions. This transition is ongoing, and fiscal intermediaries and carriers still exist. However, we believe that the presence of MACs should be accounted for to accurately reflect current contractual relationships. As such, we are proposing to incorporate references to ''Medicare administrator contractors'' in the following sections, where appropriate:

+ § 476.1, in the definition of ''Preadmission Certification'';

+ § 476.71(c)(1);

+ § 476.73(a);

+ § 476.74(b) and (c)(1);

+ § 476.80 section heading, and §§ 476.80(a), (a)(1), (a)(2), (b)(1), (c), (c)(3)(ii), (d)(1), (d)(2), (e) paragraph heading, (e)(1), and (e)(2);

+ § 476.86(a)(2), (c) introductory text, (c)(1), and (d);

+ § 476.94(a)(1)(iv) and (d);

+ § 476.104(a); and

+ § 480.105(a).

• We are proposing a technical correction to § 480.139 by adding a paragraph ''(a)'' in front of ''(1)'' to the beginning of the text of the section to correct an inadvertent coding error.

• We are proposing to correct the statutory citation in § 480.132(b) by changing ''section 1154(a)(3)'' to ''section 1154(a)(2)''.

XIX. Files Available to the Public via the Internet

The Addenda of the proposed rules and the final rules with comment period will be published and available only via the Internet on the CMS Web site. To view the Addenda of this proposed rule pertaining to the proposed CY 2013 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html* and select ''1589–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''2013 OPPS 1589–P Addenda'' at the bottom of the page.

To view the Addenda of this proposed rule pertaining to the proposed CY 2013 payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html* and select ''1589–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''Addenda AA, BB, DD1 and DD2'', and ''Addendum EE'' at the bottom of the page.

XX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Proposed Requirements in Regulation Text

1. Proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs (§ 495.8)

Under 42 CFR 495.6(f)(9), we require eligible hospitals and CAHs participating in the Medicare EHR Incentive Program (which would include those participating in the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report hospital clinical quality measures (CQMs) to CMS in the manner specified by CMS. As discussed in section XV.K. of this proposed rule, although we are proposing that eligible hospitals and CAHs may continue to attest CQMs in 2013, they may also choose to participate in the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs. We are proposing that eligible hospitals and CAHs participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Program) to CMS, via a secure transmission based on data obtained from the eligible hospital or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 meaningful use. The reporting of clinical quality measures is part of the core set. We estimate that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information via the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot. Therefore, the estimated total burden for all 4,922 Medicare eligible hospitals and CAHs participating in the reporting Pilot (3,620 acute care hospitals and 1,302 CAHs) is 2,461 hours.

We believe that an eligible hospital or CAH might assign a computer and information systems manager to submit the CQM information on its behalf. We estimate the cost burden for an eligible hospital or CAH to submit to the CQMs and hospital quality requirements is $30.21 (0.5 hour × $60.41 mean hourly rate for a computer and information systems manager based on the 2011 Bureau of Labor Statistics) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $148,694 ($30.21 × 4,922 hospitals and CAHs). We are soliciting public comments on the estimated numbers of eligible hospitals and CAHs that may register for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in FY 2013. We also are inviting comments on the type of personnel or staff that would most likely submit on behalf of eligible hospitals and CAHs.

C. Proposed Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that are not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As previously 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. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110 and 72111 through 72114) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014, and CY 2015 Payment Determinations

a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we retained the 7 chart-abstracted measures we used in CY 2009 and adopted 4 new claims-based imaging measures for the CY 2010 payment determination, bringing the total number of quality measures for which hospitals had to submit data to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we required hospitals to continue to submit data on the same 11 measures for the CY 2011 payment determination. The burden associated with the aforementioned data submission requirements is currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), we adopted measures for the CY 2012, CY 2013, and CY 2014 payment determinations.

For the CY 2012 payment determination, we retained the 7 chart-abstracted measures and the 4 claims-based imaging measures we used for the CY 2011 payment determination. We also adopted 1 structural HIT measure that tracks HOPDs' ability to receive laboratory results electronically, and 3 claims-based imaging efficiency measures. These actions bring the total number of measures for the CY 2012 payment determination for which hospitals must submit data to 15 measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

For the CY 2013 payment determination, we required that hospitals continue to submit data for all of the quality measures that we adopted for the CY 2012 payment determination. We also adopted 1 structural HIT measure assessing the ability to track clinical results between visits, 6 new chart-abstracted measures on the topics of HOPD care transitions and ED efficiency, as well as 1 chart-abstracted ED–AMI measure that we proposed for the CY 2012 payment determination but which we decided to finalize for the CY 2013 payment determination. These actions bring the total number of quality measures for the CY 2013 payment determination for which hospitals must submit data to 23 measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), for the CY 2014 payment determination, we retained the CY 2013 payment determination measures, but did not adopt any additional measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with

these information collection requirements.

b. Hospital OQR Program Measures for the CY 2014 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we did not adopt any new measures for the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period, we added, for the CY 2014 payment determination, 1 chart-abstracted measure and 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures). However, as discussed at 76 FR 74456, we did not implement public reporting of the claims-based OP: 15 Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache. Because this is a claims-based measure, hospitals continue to submit relevant claims to be paid, but these administrative data and any measure calculations from them are not being made publicly available as specified for required hospital outpatient hospital quality of care measure data under section 1833(t)(17)(E) of the Act. In addition, in section XV.C. of this proposed rule, we are confirming that, using a subregulatory process, we have suspended indefinitely data collection for one measure, OP–19: Transition Record with Specified Elements Received by Discharged Patients, and we are proposing to defer data collection for another, OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. Thus, if this proposal is finalized, for the CY 2014 and subsequent years payment determinations, there would be a total of 26 measures, with hospitals reporting data on only 23 of them. The complete measure set for the CY 2014 and subsequent years payment determinations would include the measures shown below; all measures were previously adopted.

MEASURES REQUIRED FOR HOSPITAL OQR PROGRAM CY 2014 AND SUBSEQUENT YEARS PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis
OP–2: Fibrinolytic Therapy Received Within 30 Minutes
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP–4: Aspirin at Arrival
OP–5: Median Time to ECG
OP–6: Timing of Antibiotic Prophylaxis
OP–7: Prophylactic Antibiotic Selection for Surgical Patients
OP–8: MRI Lumbar Spine for Low Back Pain
OP–9: Mammography Follow-up Rates
OP–10: Abdomen CT—Use of Contrast Material
OP–11: Thorax CT—Use of Contrast Material
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache *
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival
OP–17: Tracking Clinical Results between Visits
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP–19: Transition Record with Specified Elements Received by discharged ED Patients **
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP–21: ED—Median Time to Pain Management for Long Bone Fracture
OP–22: ED—Patient Left Without Being Seen
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
OP–24: Cardiac Rehabilitation Patient Referral from an Outpatient Setting ***
OP–25: Safety Surgery Checklist
OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

Procedure category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

* Information for OP–15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.
** Data collection for OP–19 was suspended effective with January 1, 2012 encounters until further notice.
*** Data collection for OP–24 would be deferred from January 1, 2013 to January 1, 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

We will calculate the seven claims-based measures using Medicare FFS claims data and do not require additional hospital data submissions. With the exception of OP–22, we are using the same data submission requirements related to the chart-abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the four structural measures, including the collection of data for all-patient volume for selected outpatient procedures, hospitals will enter data into a Web-based collection

tool during a specified collection period once annually. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they have not already done so or have withdrawn from participation. By submitting this document, hospitals agree that they will allow CMS to publicly report the measures for which they have submitted data under the Hospital OQR Program.

For the CY 2014 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, and collecting and submitting the data on the 23 measures. For the 12 chart-abstracted measures (including those measures for which data are submitted directly to CMS, as well as the OP–22 measure for which data will be submitted via a Web-based tool rather than via an electronic file), we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimate there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

For the chart-abstracted OP–22 measure plus the structural measures, excluding the all-patient volume for selected surgical procedures measure, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 1,603 hours (3,200 hospitals × 0.167 hours per measure × 3 measures per hospital).

For the collection of all-patient volume for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes, we believe the only additional burden associated with this requirement is the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 53 hours (3,200 hospitals × 0.167 hours per measure × 1 all-patient volume measure per hospital).

c. Hospital OQR Program Measures for CY 2015

In the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination, we retained the requirement that hospitals must complete and submit a notice of participation form in order to participate in the Hospital OQR Program. For the CY 2015 payment determination, we also retained the measures used for CY 2014 payment determination (including the measures adopted in the CY 2012 final rule with comment period) and did not add any additional measures.

For the CY 2015 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the measures, and collecting and submitting all-patient volume data for selected outpatient surgical procedures. For the chart-abstracted measures, we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures where data is submitted directly to CMS, we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimate there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the aforementioned submission requirements for the chart-abstracted data is 949,590 hours (1,628,800 cases per year × 0.583 hours per case). For the structural measures, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 1,603 hours (3,200 hospitals × 0.167 hours per hospital × 3 structural measures per hospital).

For the collection of all-patient volume data for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR purposes, we believe the only additional burden associated with this requirement will be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 53 hours (3,200 hospitals × 0.167 hours per hospital).

We invite public comment on the burden associated with the information collection requirements.

3. Proposed Hospital OQR Program Validation Requirements for CY 2014

In this proposed rule, we are proposing to retain the requirements related to data validation for CY 2014 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (76 FR 74486) for CY 2013, and that we revised in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74553). While these requirements are subject to the PRA, they are currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

Similar to our approach for the CY 2013 Hospital OQR Program payment determination (76 FR 74484 through 74485), we are proposing to continue to validate data from randomly selected hospitals for the CY 2014 payment determination, selecting 450 hospitals. We note that, because hospitals would be selected randomly, every hospital participating in the Hospital OQR Program would be eligible each year for validation selection.

In the CY 2011 OPPS/ASC proposed rule and final rule with comment period (75 FR 46381 and 75 FR 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 and 76 FR 74553), we finalized a policy under which we will select for validation up to 50 additional hospitals based upon targeting criteria.

For each selected hospital (random or targeted), generally we will randomly select up to 48 patient encounters per year (12 per quarter) for validation purposes from the total number of cases that the hospital successfully submitted to the OPPS Clinical Warehouse during the applicable time period. However, if a selected hospital submitted less than 12 cases in one or more quarters, only those cases available would be validated.

The burden associated with the CY 2014 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it would take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimate each hospital must submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would

result in a total of up to 24,000 charts being submitted by the sampled hospitals. The estimated annual burden associated with the data validation process for CY 2014 is approximately 6,000 hours.

We are proposing to maintain the deadline of 45 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process.

We invite public comment on the burden associated with these information collection requirements.

4. Proposed Hospital OQR Program Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modifications. We eliminated the requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74487 and 74488 and 76 FR 74553 and 74554), we specified that we were continuing this process for the CY 2013 and subsequent years' payment determinations. In this CY 2013 OPPS/ASC proposed rule, we are proposing to make one change to this process—to add a requirement that the CEO or designated personnel must sign the reconsideration request. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

5. ASCQR Program Requirements

a. Claims-Based Outcome Measures for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74504), we adopted five claims-based measures (four outcome and one process) to be used for the CY 2014 payment determination. We will collect quality measure data for the five claims-based measures by using QDCs placed on submitted claims beginning with services furnished from October 1, 2012 through December 31, 2012. The five outcome measures are:

- Patient Burns (NQF #0263)
- Patient Falls (NQF #0266)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
- Hospital Transfer/Admission (NQF #0265)
- Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

The first four measures listed above are outcome measures and the fifth measure is a process measure.

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four claims-based measures listed above. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgery Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T)). Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (less than 1 case per month per ASC, or about 11.8 events per year).

For the remaining claims-based measure, Prophylactic IV Antibiotic Timing, we estimate the burden associated with submitting QDCs to be nominal, as few procedures performed by ASCs will require prophylactic antibiotic administration.

b. Claims-Based Process, Structural, and Volume Measures for the CY 2015 and CY 2016 Payment Determinations

For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2015 payment determination, we are proposing that the data collection period for claims-based measures would be for services furnished from January 1, 2013, through December 31, 2013, that are paid by the administrative contractor by April 30, 2014.

For the CY 2016 payment determination, we finalized the retention of the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509). For the CY 2016 payment determination, we are proposing that the data collection period for claims-based measures would be for services furnished from January 1, 2014, through December 31, 2014, that are paid by the administrative contractor by April 30, 2015.

Based on our data for CY 2014 payment determinations above, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CYs 2015 and CY 2016 payment determinations. We estimate the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, for the structural measures, ASCs will enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 864 hours (5,175 ASCs $\times$ 1 measure $\times$ 0.167 hours per ASC).

For the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure, 864 hours (5,175 ASCs $\times$ 1 measure $\times$ 0.167 hours per ASC).

6. IRF QRP

In the FY 2012 IRF PPS final rule (76 FR 47873 through 47883), we finalized the initial reporting requirements of the IRF QRP, including two quality measures for CY 2012 reporting. These two quality measures are: (1) Percent of Residents with Pressure Ulcers that are New or Worsened (NQF # 0678); and (2) Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients (NQF#0138).

We also established reporting mechanisms for these two measures in the FY 2012 IRF PPS final rule. IRFs were instructed to use the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) (approved under OCN: 0938–0842) to collect pressure ulcer measure data on Medicare Part A, Part B, and Medicare Advantage beneficiaries, and they were to collect CAUTI measure data on all

patients and report that data to CDC's National Healthcare Safety Network (NHSN). The burden associated with this collection of information for IRFs was included in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885).

Section XVII. of this proposed rule includes three proposals for the IRF QRP, which are: (1) A proposal to implement updates made by the NQF to the CAUTI measure which will affect the annual payment update in FY 2014; (2) a proposal that any measure selected for use in the IRF QRP would remain in effect until actively removed, suspended, or replaced; and (3) a proposal to implement policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

The first proposal, if finalized, would allow us to incorporate recent updates that were made to the CAUTI measure (NQF#0138) by the NQF. However, these changes will not affect the type or amount of data that IRFs will be required to collect and submit.

The second proposal involves the implementation of a policy that IRF quality measures will remain in effect until a measure is actively removed, suspended, or replaced. This policy, if implemented, would not add any additional information collection requirements for CY 2013 and beyond as discussed below.

The third proposal involves implementing a policy regarding when notice-and-comment rulemaking would be used to update existing IRF QRP measures that have been updated by the NQF. This proposal would likewise not cause any increased information collection requirements to IRFs.

a. Pressure Ulcer Measure

In this proposed rule, we are not proposing to make any changes in the way the pressure ulcer data are to be collected and submitted to CMS using the current version of the IRF–PAI. Therefore, the information collection burden that IRFs will incur for the reporting of pressure ulcer data will not differ from that which was stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885). Likewise, the information collection burden will not differ from the burden estimate that is currently approved for the IRF–PAI under OCN: 0938–0842. It is important to note that, while the FY 2012 IRF PPS final rule mainly discusses the reporting requirement that will be incurred by IRFs for the FY 2014 payment determination, we do not anticipate that our proposals will cause an increase in the information collection requirements for subsequent fiscal years.

b. CAUTI Measure

As discussed above, the FY 2012 IRF PPS final rule adopted the ''Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients'' (NQF #0138) measure for the IRF QRP. However, subsequent to the publication of the FY 2012 IRF PPS final rule, this measure was expanded to several non-ICU settings, including IRFs. The CDC also changed the way the CAUTI measure is calculated from an infection rate per 1,000 days to a standardized infection ratio (''SIR''). The SIR calculation is comprised of the actual rate of infection over the expected rate of infection.

These changes will not impact the type or amount of data that IRFs will be required to collect and submit. Therefore, the information collection estimates that are stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885) for reporting CAUTI data remain unchanged for the FY 2014 payment determination as well as for subsequent years payment determinations.

XXI. 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.

XXII. 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)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated 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, the 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. In this proposed rule, we are soliciting public comments on the regulatory impact analysis provided.

2. Statement of Need

This proposed rule is necessary to update the Medicare hospital outpatient prospective payment rates and the ASC payment rates for CY 2013. The proposed rule is necessary to propose changes to payment policies and rates for outpatient services furnished by hospitals and CMHCs for CY 2013. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the APC payment rates. 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 relative APC payment weights using claims data for services furnished on and after January 1, 2011, through and including December 31, 2011, and updated cost report information.

We are proposing to continue the current payment adjustment for rural SCHs, including EACHs. In addition, section 10324 of the Affordable Care Act, as amended by HCERA, authorizes a wage index of 1.00 for certain frontier States. Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In this proposed rule, we are implementing these payment provisions. Also, we list the 23 drugs and biologicals in Table 22 of this proposed rule that we are

proposing to remove from pass-through payment status for CY 2013.

This proposed rule is also necessary to update the ASC payment rates for CY 2013, enabling CMS to propose changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC for CY 2013. Because the 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, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. 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. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved for ASCs that fail to meet the quality reporting requirements. For CY 2013, there are no impacts associated with this payment reduction because it will not be applied until CY 2014.

3. Overall Impacts for OPPS and ASC Provisions

We estimate that the effects of the proposed OPPS payment provisions will result in expenditures exceeding $100 million in any 1 year. We estimate that the total increase from the proposed changes in this proposed rule in expenditures under the OPPS for CY 2013 compared to CY 2012 would be approximately $700 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2013 would be approximately $4.571 billion relative to CY 2012. Because this proposed rule for the OPPS is ''economically significant'' as measured by the $100 million threshold, we have prepared this regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rulemaking. Table 45 of this proposed rule displays the redistributional impact of the proposed CY 2013 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update change to the conversion factor and other proposed adjustments (but not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2013) would increase total OPPS payments by 2.1 percent in CY 2013. The proposed changes to the APC weights, the proposed changes to the wage indices, 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 changes to the OPPS would be budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the total proposed change in payments between CY 2012 and CY 2013, considering all payments, including 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 increase total estimated OPPS payments by 2.1 percent.

We estimate that the effects of the proposed ASC provisions in this proposed rule for the ASC payment system would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from proposed changes in this proposed rule as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2013 compared to CY 2012 to be approximately $211 million. Because this proposed rule for the ASC payment system 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 proposed rulemaking. Tables 46 and Table 47 of this proposed rule display the redistributional impact of the proposed CY 2013 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

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2013 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2013 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–1589–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 45 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 individual proposed policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In this proposed rule, as we have done in previous proposed rules, 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 45 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 because we include CMHCs in our weight scalar estimate. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 45 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 2012, we are paying CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). For CY 2013, we are proposing to continue this APC payment structure and are basing payment fully on the geometric mean costs calculated using data for the type of provider for which rates are being set, that is, hospital or CMHC. We display separately the impact of this proposed policy on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

The estimated increase in the proposed total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. 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 estimated IPPS market basket increase for FY 2013 is 3.0 percent (77 FR 27870). Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.8 percentage points (which is also the proposed MFP adjustment for FY 2013 in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27870); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 2.1 percent, which we are using in the calculation of the proposed CY 2013 OPPS conversion factor. 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 of 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the proposed CY 2013 estimates in Table 45.

To illustrate the impact of the proposed CY 2013 changes, our analysis begins with a baseline simulation model that uses the CY 2012 relative payment weights, the FY 2012 final IPPS wage indices that include reclassifications, and the final CY 2012 conversion factor. Table 45 shows the estimated redistribution of the increase in payments for CY 2013 over CY 2012 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration based on our historical methodology using median costs (Column 2); the marginal impact of basing the APC relative payment weights on geometric mean costs over basing them on median costs (Column 3); APC recalibration based on geometric mean costs (Column 4, the combined effect of Columns 2 and 3); the wage indices and the rural adjustment (Column 5); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, and the OPD fee schedule increase factor update to the conversion factor (Column 6); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, the conversion factor update, and the frontier State wage index adjustment (Column 7); and the estimated redistribution taking into account all payments for CY 2013 relative to all payments for CY 2012 (Column 8), including the impact of proposed changes in estimated outlier payments and proposed changes to the pass-through payment estimate.

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2013. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2012 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 would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also would depend on changes in volume, practice patterns, and the mix of services billed between CY 2012 and CY 2013 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2013 would have a positive effect for providers paid under the OPPS, resulting in a 2.1 percent estimated increase in Medicare payments. 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 suggest that these proposed changes would still result in a 2.1 percent estimated increase in Medicare payments to all other hospitals. Those estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 45 shows the total number of facilities (4,070), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2011 hospital outpatient and CMHC claims data to model CY 2012 and proposed CY 2013 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not accurately estimate CY 2012 or proposed CY 2013 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 (DSH) variable for hospitals not participating in 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 (3,853) of OPPS hospitals, 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 154 CMHCs at the bottom of the impact table and discuss that impact separately below.

Columns 2, 3, and 4: APC Recalibration

These columns show the combined effects of the proposed reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+6 under our CY 2013 proposal to apply the statutory default). Column 2 shows the reclassification effects if we were to base the relative payment weights on the median costs of services. Column 3 shows the marginal effects of using the geometric mean costs compared to the effects if we were to base the relative payment weights on the median costs of services, in other words the effects of our proposed policy change from medians to geometric means. Column 4 shows the combined effect of Columns 2 and 3, in other words the effect of our proposal to base the relative payment weights on geometric mean costs. It reflects the impacts of the proposed reclassification of services among APC groups and the proposed recalibration of APC relative payment weights, based on 12 months of CY 2011 OPPS hospital claims data and the most recent cost report data, and determining relative payment weights using the geometric mean costs of services. We modeled the effect of the proposed APC recalibration changes by varying only the relative payment weights (the final CY 2012 relative weights versus the proposed CY 2013 relative weights calculated using the service-mix and volume in the CY 2011 claims used for this proposed rule) and calculating the percent difference in the relative weight. Column 4 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights.

Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS would slightly decrease payments to urban hospitals by 0.1 percent. However, the smallest urban hospitals would receive slight payment increases of 0.6 percent (hospitals with 0–99 beds), attributable to increased payments for partial hospitalization, group psychotherapy and cardiac rehabilitation monitoring services furnished in the hospital. Due to recalibration, we estimate that low volume urban hospitals billing fewer than 21,000 lines for OPPS services would experience increases ranging from 0.8 percent to 4.0 percent. The increase of 4.0 percent for urban hospitals billing fewer than 5,000 lines per year is similarly attributable to an increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital.

Overall, we estimate that rural hospitals would experience a small increase of 0.3 percent as a result of proposed changes to the APC structure, with the largest increases going to the smallest hospitals both by number of beds (0.9 percent to those with less than 50 beds) and volume (2.5 percent to those with fewer than 5,000 lines). As a result of the recalibration, we estimate that rural hospitals that report 5,000 or more lines for OPPS services would experience payment increases ranging from 0.2 percent to 1.0 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration would lead to small payment decreases of 0.1 to 0.2 percent for major and minor teaching hospitals, respectively. We estimate that nonteaching hospitals would experience an increase of 0.1 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience changes ranging from a decrease of 0.1 percent to an increase of 0.2 percent as a result of the proposed APC recalibration.

For most hospitals, we estimate insignificant impacts of our proposal to use geometric mean-based relative payment weights. Most providers would receive small increases in payments of up to 2.5 percent. We estimate that hospitals for which DSH payments are not available (mostly urban hospitals) would experience an increase of 6.1 percent. Hospitals for which DSH data are not available (non-IPPS hospitals) furnish a large number of psychiatric services and we believe that the estimated increase in payment is due to increased payment for partial hospitalization and group psychotherapy services, as well as for hemodialysis services furnished in the hospital.

Column 5: Proposed New Wage Indices and the Effect of the Proposed Rural and Cancer Hospital Adjustments

Column 5 demonstrates the combined budget neutral impact of APC recalibration using geometric means; the wage index update; the rural adjustment; and the cancer hospital adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indices for each year, and using a CY 2012 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 5 reflects the independent effects of the updated wage indices, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 7. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2013. Similarly, the differential impact between the CY 2012 cancer hospital payment adjustment and the proposed CY 2013 cancer hospital payment adjustment had no effect on the budget neutral adjustment to the conversion factor. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2013 scaled weights and a CY 2012 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2012 and CY 2013. This column estimates the impact of applying the proposed FY 2013 IPPS wage indices for the CY 2013 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The frontier State wage index adjustment is reflected in the combined impact shown in Column 7. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2013, as described in section II.E.2. of this proposed rule. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality would redistribute payment among regions. We also updated the list of counties qualifying for the section 505 out-migration adjustments.

Overall, we estimate that as a result of the proposed updated wage indices and the rural adjustment, urban hospitals would experience no change from CY 2012 to CY 2013, although urban hospitals would experience small changes ranging from increases of 0.2 percent (for large urban hospitals) to decreases of 0.2 percent (for other urban hospitals). Sole community hospitals would not be affected, but other rural hospitals would experience decreases of 0.3 percent. Urban hospitals in the New England and Pacific regions would experience the most significant payment

changes with a decrease of 1.2 percent in New England and an increase of 1.6 percent in the Pacific region. Overall, we estimate that rural hospitals would experience a decrease of 0.2 percent as a result of changes to the proposed wage index for CY 2013. Regionally, the changes would range from a decrease of 0.9 in rural Pacific States to an increase of 0.4 in rural New England States.

Column 6: All Proposed Budget Neutrality Changes Combined With the Proposed OPD Fee Schedule Increase

Column 6 demonstrates the cumulative impact of the budget neutral adjustments from Column 5 and the proposed OPD fee schedule increase factor of 2.1 percent. We estimate that for most hospitals, the addition of the proposed OPD fee schedule increase factor of 2.1 percent would mitigate the negative impacts created by the budget neutrality adjustments made in Column 5.

While most classes of hospitals would receive an increase that is more in line with the 2.1 percent overall increase after the proposed update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 11,000 lines, rural hospitals that bill fewer than 5,000 lines, and hospitals for which DSH information is not available would experience larger increases ranging from 4.1 percent to 8.3 percent. In particular, urban hospitals that report fewer than 5,000 lines would experience a cumulative increase, after application of the proposed OPD fee schedule increase factor and the budget neutrality adjustments, of 6.4 percent, largely as a result of proposed increases in payments to partial hospitalization and group psychotherapy services furnished in the hospital. Similarly, urban hospitals for which DSH data are not available would experience an increase of 8.1 percent, also largely as a result of proposed increases in payment for partial hospitalization, group psychotherapy and hemodialysis services furnished in hospitals.

Overall, we estimate that these proposed changes would increase payments to urban hospitals by 2.1 percent. We estimate that large urban hospitals and ''other'' urban hospitals would also experience increases of 2.3 and 1.9 percent, respectively. Urban hospitals in the Pacific region would experience an increase of 3.6 percent, largely as a result of the proposed change in wage index shown under column 3 and discussed above. We estimate that rural hospitals would experience a 2.3 percent increase as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments.

Classifying hospitals by teaching status suggests that the proposed OPD fee schedule increase factor and the proposed budget neutrality adjustments would result in an increase of 2.1 percent for major teaching hospitals, 1.9 percent for minor teaching hospitals and 2.3 percent for nonteaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals would experience an estimated increase of 2.3 percent, while voluntary hospitals would experience an estimated increase of 2.1 percent and government hospitals would experience an estimated increase of 2.1 percent.

Column 7: All Proposed Adjustments With the Proposed Frontier State Wage Index Adjustment

This column shows the impact of all proposed budget neutrality adjustments, application of the proposed 2.1 percent OPD fee schedule increase factor, and the non-budget neutral impact of applying the proposed frontier State wage adjustment (that is, the proposed frontier State wage index change in addition to all proposed changes reflected in Column 6). This column differs from Column 6 solely based on application of the non-budget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals would experience a combined increase of 0.1 percent due to the frontier wage index. The index would only affect hospitals in the West North Central and Mountain regions. Urban hospitals in those regions would experience increases of 0.9 percent (West North Central) and 0.4 percent (Mountain) that are attributable to the frontier wage index, and rural hospitals would experience increases of 1.1 percent (West North Central) and 2.2 percent (Mountain) that are attributable to the frontier State wage index.

Column 8: All Proposed Changes for CY 2013

Column 8 depicts the full impact of the proposed CY 2013 policies on each hospital group by including the effect of all the proposed changes for CY 2013 and comparing them to all estimated payments in CY 2012. Column 8 shows the combined budget neutral effects of Columns 2 through 5; the proposed OPD fee schedule increase; the impact of the frontier State wage index adjustment; the proposed change in the fixed-dollar outlier threshold from $2,025 to $2,400 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 XV. of this proposed rule); and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of the 101 hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2012 update (and assumed, for modeling purposes, to be the same number for CY 2013), we included 9 hospitals in our model because they had both CY 2011 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2013 would increase payments to all providers by 2.1 percent for CY 2013. We modeled the independent effect of all proposed changes in Column 8 using the final relative payment weights for CY 2012 and the proposed relative payment weights for CY 2013. We used the final conversion factor for CY 2012 of $70.016 and the proposed CY 2013 conversion factor of $71.537 discussed in section II.B. of this proposed rule in this model.

Column 8 contains simulated outlier payments for each year. We used the one year charge inflation factor used in the FY 2013 IPPS/LTCH PPS proposed rule of 6.80 percent (1.0680) to increase individual costs on the CY 2011 claims, and we used the most recent overall CCR in the April 2012 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2012. Using the CY 2011 claims and a 6.80 percent charge inflation factor, we currently estimate that outlier payments for CY 2012, using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,025 should be approximately 1.03 percent of total payments. The estimated current outlier payments of 1.03 percent are incorporated in the CY 2013 comparison in Column 8. We used the same set of claims and a charge inflation factor of 14.06 percent (1.1406) and the CCRs in the April 2012 OPSF, with an adjustment of 0.9790, to reflect relative changes in cost and charge inflation between CY 2011 and CY 2013, to model the proposed CY 2013 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,400.

We estimate that the anticipated change in payment between CY 2012 and CY 2013 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience an increase of 2.1 percent under this proposed rule in CY

2013 relative to total spending in CY 2012. This projected increase (shown in Column 8) of Table 45 reflects the proposed 2.1 percent OPD fee schedule increase factor, with proposed 0.04 percent for the change in the pass-through estimate between CY 2012 and CY 2013, less 0.03 percent for the difference in estimated outlier payments between CY 2012 (1.03 percent) and CY 2013 (1.0 percent), less 0.04 percent due to the section 508 wage adjustment, less 0.1 percent due to the frontier adjustment in CY 2012, plus 0.1 percent due to the proposed frontier State wage index adjustment. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase continues to be 2.1 percent after rounding. We estimate that the combined effect of all proposed changes for CY 2013 would increase payments to urban hospitals by 2.1 percent, with large urban hospitals experiencing an estimated 2.2 percent increase and ''other'' urban hospitals experiencing an estimated 1.9 percent increase. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 6.0 percent, largely attributable to the proposed increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital. We estimate that urban hospitals that bill 11,000 or more lines of OPPS services would experience increases between 1.9 percent and 3.0 percent, while urban hospitals that report between 5,000 and 10,999 lines would experience an increase of 4.2 percent.

Overall, we estimate that rural hospitals would experience a 2.2 percent increase as a result of the combined effects of all proposed changes for CY 2013. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 4.2 percent and that rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 2.2 to 2.8 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 2.0 percent for major teaching hospitals and 2.3 percent for nonteaching hospitals. Minor teaching hospitals would experience an increase of 1.9 percent.

In our analysis, we also have stratified hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.0 percent, proprietary hospitals would experience an increase of 2.3 percent, and governmental hospitals would experience an increase of 2.1 percent.

TABLE 45—ESTIMATED IMPACT OF THE PROPOSED CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	Number of hospitals	APC recalibration (median)	Impact of basing weights using geometric mean	APC recalibration (Geo mean)	New wage index and provider adjustments	Combine (cols 4, 5) with market basket update	Column 6 with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL FACILITIES*	4,070	0.0	0.0	0.0	0.0	2.1	2.2	2.1
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,853	0.0	0.0	0.0	0.0	2.1	2.2	2.1
URBAN HOSPITALS	2,907	−0.1	0.0	−0.1	0.0	2.1	2.2	2.1
LARGE URBAN (GT 1 MILL.)	1,592	0.0	0.0	0.0	0.2	2.3	2.3	2.2
OTHER URBAN (LE 1 MILL.)	1,315	−0.1	0.0	−0.1	−0.2	1.9	2.1	1.9
RURAL HOSPITALS	946	0.2	0.1	0.3	−0.2	2.3	2.5	2.2
SOLE COMMUNITY	384	0.3	0.1	0.4	0.0	2.5	3.0	2.5
OTHER RURAL	562	0.1	0.2	0.3	−0.3	2.1	2.1	2.0
BEDS (URBAN)								
0–99 BEDS	1,000	0.4	0.2	0.6	0.0	2.7	2.8	2.8
100–199 BEDS	831	0.1	0.1	0.2	0.1	2.3	2.4	2.3
200–299 BEDS	457	−0.1	0.0	−0.1	0.1	2.0	2.2	2.0
300–499 BEDS	415	−0.2	0.0	−0.2	0.1	2.0	2.1	2.0
500 + BEDS	204	−0.1	−0.1	−0.2	−0.1	1.8	1.8	1.8
BEDS (RURAL)								
0–49 BEDS	353	0.5	0.4	0.9	−0.2	2.8	3.1	2.8
50–100 BEDS	352	0.4	0.1	0.5	−0.1	2.5	2.7	2.4
101–149 BEDS	138	0.0	0.1	0.1	−0.5	1.7	1.9	1.8
150–199 BEDS	55	0.1	0.1	0.2	−0.3	2.1	2.7	2.2
200 + BEDS	48	−0.2	0.0	−0.1	0.3	2.2	2.2	2.1
VOLUME (URBAN)								
LT 5,000 Lines	573	1.9	2.1	4.0	0.2	6.4	6.5	6.0
5,000–10,999 Lines	135	1.2	1.1	2.4	−0.3	4.1	4.5	4.2
11,000–20,999 Lines	213	0.5	0.3	0.8	0.1	3.0	3.0	3.0
21,000–42,999 Lines	474	0.2	0.1	0.3	0.2	2.6	2.7	2.6
42,999–89,999 Lines	698	−0.1	0.0	0.0	0.1	2.2	2.2	2.1
GT 89,999 Lines	814	−0.1	0.0	−0.2	0.0	2.0	2.1	1.9
VOLUME (RURAL)								
LT 5,000 Lines	63	1.4	1.1	2.5	−0.3	4.3	7.2	4.2
5,000–10,999 Lines	69	0.2	0.7	1.0	−0.9	2.2	2.4	2.2
11,000–20,999 Lines	157	0.3	0.6	0.9	−0.2	2.8	3.1	2.8
21,000–42,999 Lines	292	0.4	0.2	0.6	−0.3	2.4	2.7	2.4
GT 42,999 Lines	365	0.1	0.1	0.2	−0.1	2.2	2.4	2.2
REGION (URBAN)								
NEW ENGLAND	148	0.2	0.0	0.2	−1.2	1.1	1.1	1.1
MIDDLE ATLANTIC	345	−0.1	−0.1	−0.2	−0.2	1.8	1.8	1.6
SOUTH ATLANTIC	450	−0.1	−0.1	−0.1	−0.4	1.5	1.5	1.6
EAST NORTH CENT	469	−0.1	0.0	−0.1	0.3	2.3	2.3	2.2
EAST SOUTH CENT	173	−0.2	−0.1	−0.3	−0.7	1.1	1.1	1.1
WEST NORTH CENT	185	0.0	0.0	0.1	0.5	2.7	3.6	2.8
WEST SOUTH CENT	494	−0.1	0.1	0.0	−0.2	1.9	1.9	2.0

TABLE 45—ESTIMATED IMPACT OF THE PROPOSED CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM—Continued

	Number of hospitals	APC recalibration (median)	Impact of basing weights using geometric mean	APC recalibration (Geo mean)	New wage index and provider adjustments	Combine (cols 4, 5) with market basket update	Column 6 with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
MOUNTAIN	203	0.1	0.0	0.1	−0.1	2.1	2.5	2.1
PACIFIC	393	−0.2	0.1	0.0	1.6	3.6	3.6	3.5
PUERTO RICO	47	0.3	0.1	0.3	0.3	2.7	2.7	2.8
REGION (RURAL)								
NEW ENGLAND	25	0.4	0.0	0.4	0.4	2.9	2.9	2.8
MIDDLE ATLANTIC	67	0.3	0.0	0.3	0.2	2.6	2.6	2.4
SOUTH ATLANTIC	161	0.0	0.1	0.2	−0.4	1.9	1.9	1.9
EAST NORTH CENT	126	0.2	0.1	0.3	0.3	2.7	2.7	2.5
EAST SOUTH CENT	174	−0.1	0.1	0.0	−0.3	1.7	1.7	1.8
WEST NORTH CENT	99	0.4	0.1	0.5	−0.3	2.3	3.4	2.3
WEST SOUTH CENT	200	0.3	0.4	0.8	−0.3	2.6	2.6	2.6
MOUNTAIN	65	0.4	0.0	0.4	0.1	2.6	4.8	2.9
PACIFIC	29	0.4	0.1	0.5	−0.9	1.7	1.7	1.6
TEACHING STATUS								
NON-TEACHING	2,878	0.0	0.1	0.1	0.0	2.3	2.4	2.3
MINOR	687	−0.1	0.0	−0.2	−0.1	1.9	2.1	1.9
MAJOR	288	0.0	−0.1	−0.1	0.1	2.1	2.1	2.0
DSH PATIENT PERCENT								
0	17	0.9	−0.1	0.8	−0.1	2.8	2.8	2.9
GT 0–0.10	365	0.1	−0.1	0.0	0.0	2.1	2.2	2.1
0.10–0.16	375	0.1	0.0	0.0	−0.1	2.0	2.1	1.9
0.16–0.23	742	0.0	0.0	0.0	0.0	2.1	2.3	2.0
0.23–0.35	1,018	−0.1	0.0	−0.1	0.0	2.0	2.1	2.0
GE 0.35	748	−0.1	0.1	0.0	0.1	2.2	2.2	2.1
DSH NOT AVAILABLE **	588	2.1	4.0	6.1	0.0	8.3	8.3	8.2
URBAN TEACHING/DSH								
TEACHING & DSH	886	−0.1	−0.1	−0.1	0.0	1.9	2.0	1.9
NO TEACHING/DSH	1,453	0.0	0.0	0.0	0.1	2.2	2.3	2.2
NO TEACHING/NO DSH	17	0.9	−0.1	0.8	−0.1	2.8	2.8	2.9
DSH NOT AVAILABLE **	551	2.1	3.7	5.9	0.1	8.1	8.1	8.0
TYPE OF OWNERSHIP								
VOLUNTARY	2,042	0.0	0.0	−0.1	0.0	2.1	2.2	2.0
PROPRIETARY	1,254	0.0	0.2	0.2	0.0	2.3	2.4	2.3
GOVERNMENT	557	0.0	0.0	0.1	−0.1	2.1	2.1	2.1
CMHCs	154	0.8	−6.9	−6.2	−0.4	−4.4	−4.4	−4.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of median costs in developing relative payment weights, and the proposed recalibration of APC weights based on CY 2011 hospital claims data.

Column (3) shows the estimated impact of basing the CY 2013 OPPS proposed payments on geometric mean costs, by comparing estimated CY 2013 payments under the proposal for a geometric mean cost based system to those under a median based OPPS.

Column (4) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of geometric mean costs in developing the CY 2013 proposed OPPS relative payment weights, and the proposed recalibration of APC weights based on CY 2011 hospital claims data.

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2013 hospital inpatient wage index. The rural adjustment is 7.1 percent in both years so its budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the proposed adjustment is minimal and thus results in a budget neutrality factor of 1.

Column (6) shows the impact of all budget neutrality adjustments and the proposed addition of the 2.1 percent OPD fee schedule increase factor (3.0 percent reduced by 0.8 percentage points for the proposed productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2013, after application of the CY 2013 proposed OPD fee schedule increase factor.

Column (8) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds estimated outlier payments. This column also shows the expiration of section 508 wages on March 30, 2012, and the application of the frontier State wage adjustment for CY 2012 and 2013.

* These 4,070 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 45 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2012, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). In contrast, hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We first implemented these four APCs for CY 2011. We adopted payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific and provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2013, we are proposing to continue the provider-specific APC structure that we adopted for CY 2011 and to base payment fully on the data for the type of provider furnishing the service. We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2011 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. Because the relative payment weights for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2013 using geometric mean-based relative payment weights as opposed to median-based relative payment weights, we estimate that there would be a 4.4 percent decrease in payments to CMHCs (shown in Columns 3 and 4).

Column 5 shows that the estimated impact of adopting the proposed CY 2013 wage index values would result in a small decrease of 0.4 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, would receive a proposed 2.1 percent OPD fee schedule increase factor. Column 6 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2013 and the proposed CY 2013 wage index updates, results in an estimated decrease of 4.4 percent. Column 7 shows that adding the proposed frontier State wage adjustment would result in no change to the cumulative 4.4 percent decrease. Column 8 shows that adding the proposed changes in outlier and pass-through payments would result in no change to the 4.4 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2013.

(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 example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2012 OPPS, the national unadjusted copayment is $227.35, and the minimum unadjusted copayment is $215.00, 20 percent of the national unadjusted payment rate of $1,074.99. For CY 2013, the proposed national unadjusted copayment for APC 0037 is $227.35, the same amount as the national unadjusted copayment in effect for CY 2012. The proposed minimum unadjusted copayment for APC 0037 is $224.34 or 20 percent of the proposed CY 2013 national unadjusted payment rate for APC 0037 of $1,121.70. The minimum unadjusted copayment would increase for CY 2013 compared to CY 2012 because the payment rate for APC 0037 would increase for CY 2013. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. of this proposed rule. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2012 hospital inpatient deductible is $1,156. The amount of the CY 2013 hospital inpatient deductible is not available at the time of publication of this proposed rule.

In order to better understand the impact of proposed changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2011 claims. We estimate, using the claims of the 4,070 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would decrease as an overall percentage of total payments, from 22.1 percent in CY 2012 to 21.6 percent in CY 2013 due largely to changes in service-mix.

(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 XIV. 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 $700 million in additional program payments for OPPS services furnished in CY 2013. The effect on the Medicaid program is expected to be limited to increased 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 XXII.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule. In this section, we discuss some of the major issues and the alternatives considered.

• Alternatives Considered for Our Proposal To Base the APC Relative Payment Weights on Geometric Mean Costs Rather Than Median Costs

As described in section II.A.2.f. of this proposed rule, we are proposing to base the CY 2013 relative payment weights on which OPPS payments are calculated using geometric mean costs rather than median costs. We are proposing to establish this policy based on public stakeholder comments, the improvements we have made to the data process to obtain more data and additional accuracy in estimating cost, and the other reasons described in the geometric mean based relative payment weights section.

In developing this proposal, we considered another alternative, which was to continue basing the relative payment weights based on median costs. As discussed in the geometric mean based weights section, medians have historically served as a good measure of central tendency and continue to do so. In the initial establishment of the OPPS, we selected medians as the measure of central tendency on which to base the weights for a number of reasons. Those included statistical bases such as medians' resistance to outlier observations and their impact as well as reasons surrounding the practical implementation of the OPPS as a new payment system. While some of those reasons for selecting medians continue to apply, others are now less relevant because of changes we have made in our data process, or no longer apply because of factors such as actual development of a working payment system. We have made a number of changes to the OPPS to address some of the challenges in arriving at better estimates of service cost, including trims, more specific application of cost to charge ratios in estimating cost, modeling changes to better simulate payment mechanisms, and methods of obtaining additional claims data through what is already available such as the bypass list.

We believe that those changes have helped to improve the relative costs on which the payment system is based. We also believe that geometric mean costs would better incorporate the range of costs associated with providing a service, and thus would represent one such additional improvement. Therefore, in order to improve the accuracy at which we arrive at service costs used to set relative payment weights, to be responsive to stakeholder concerns regarding the degree to which OPPS payment appropriately reflects service cost, and the other reasons described in section II.A.2.f of this proposed rule, we are proposing to establish the CY 2013 OPPS relative payment weights based on geometric means rather than continuing our historical practice of modeling costs using median costs.

• Alternatives Considered for Payment of Drugs and Biologicals That Do Not Have Pass-Through Status

We are proposing to pay for separately payable drugs and biologicals at ASP+6 percent, based on section 1833(t)(14)(A)(iii)(II) of the Act, also referred to as the statutory default. As detailed in greater depth in section V.B.3 of this proposed rule, this payment will represent the combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals.

We considered three alternatives for payment for drugs and biologicals that do not have pass-through status for CY 2013 (separately payable drugs and biologicals). The first alternative we considered was to use the standard methodology, as described in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68642). We compared 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, to calculate the estimated percent of ASP that would serve as the best proxy for the combined acquisition and pharmacy overhead costs of separately payable drugs and biologicals, but without redistribution of estimated pharmacy overhead costs. Under this methodology, without a redistribution of overhead costs from packaged drugs to separately payable drugs, using April 2012 ASP information and costs derived from CY 2011 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP+0 percent. As discussed in section V.B.3. of this proposed rule, we also determined that the combined acquisition and overhead costs of packaged drugs are 311 percent of ASP.

We did not choose this alternative because we believe that this analysis indicates that hospital charging practices reflected in our standard drug payment methodology have the potential to ''compress'' the calculated costs of separately payable drugs and biologicals to some degree when there is no redistribution of estimated pharmacy overhead costs. Further, we recognize that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products.

The second alternative we considered was to propose to continue our overhead adjustment methodology for CY 2013 and redistribute $270 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. Using this approach, we adjusted the CY 2011 pharmacy overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use, resulting in a redistribution amount of $270 million and a payment rate for separately payable drugs of ASP+6 percent. We did not choose this alternative because of the reasons discussed below and in further detail in section V.B.3 of this proposed rule.

The third option that we considered, and the one that we are proposing for CY 2013, is to pay for separately payable drugs and biologicals administered in the hospital outpatient department, at ASP+6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act, which 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), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. We are proposing that this ASP+6 percent payment amount for separately payable drugs and biologicals represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013.

As described in further detail in section V.B.3 of this proposed rule, we chose this alternative because we are uncertain about the full cost of pharmacy overhead and acquisition cost, due to the limitations of the submitted hospital charge and claims data for drugs. We believe that the continued use of our current drug payment methodologies may not appropriately account for average acquisition and pharmacy overhead cost and therefore could result in future payment rates that are not appropriate.

Therefore, we are proposing to pay for separately payable drugs and biologicals based on the statutory default at the physician's office Part B payment rates, as established in 1842(o) and 1847A of the Act, at ASP+6 percent. We believe that paying for separately payable drugs and biologicals at ASP+6 percent based on the statutory default is appropriate at this time as it yields increased predictability in payment for drugs and biologicals under the OPPS while appropriately paying for drugs at a level consistent with payment amounts yielded by our methodology of the past 7 years.

b. Estimated Effects of ASC Payment System Proposals

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Public Law 108–173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased in over 4 years.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIV. of this proposed rule, we set the proposed CY 2013 ASC relative payment weights by scaling the proposed CY 2013 OPPS relative payment weights by the proposed ASC scaler of 0.9331. 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 46 and 47 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). Because the ASCQR Program would not affect payment rates until CY 2014, there would be no reduction to the CPI–U for failure to meet the requirements of the ASCQR Program for CY 2013. We calculated the proposed CY 2013 ASC conversion factor by adjusting the CY 2012 ASC conversion

factor by 1.0002 to account for changes in the proposed pre-floor and pre-reclassified hospital wage indices between CY 2012 and CY 2013 and by applying the proposed CY 2013 MFP-adjusted CPI–U update factor of 1.3 percent (projected CPI–U update of 2.2 percent minus a projected productivity adjustment of 0.9 percent). The proposed CY 2013 ASC conversion factor is $43.190.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2013 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2011 and CY 2013 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2013 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 ASC Payment System Proposals 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 2013 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 2013 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2011 claims data. Table 46 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2012 payments to estimated CY 2013 payments, and Table 47 shows a comparison of estimated CY 2012 payments to estimated CY 2013 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 46 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 46.

- 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 2012 ASC Payments* were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and CY 2012 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2012 ASC payments.
- Column 3—*Estimated CY 2013 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 would be attributable to proposed updates to ASC payment rates for CY 2013 compared to CY 2012.

As seen in Table 46, we estimate that the proposed update to ASC rates for CY 2013 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, and a 5 percent increase in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the proposed CY 2013 update are variable. For instance, we estimate that, in the aggregate, payment for integumentary system procedures, respiratory system procedures, and cardiovascular systems procedures would decrease by 2 percent, whereas auditory system procedures would increase by 1 percent under the proposed CY 2013 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the proposed estimated increase for CY 2013 for nervous system procedures is likely due to an increase in the proposed ASC payment weight for some of the high volume procedures, such as CPT code 63685 (Insrt/redo spine n generator) where estimated payment would increase by 10 percent for CY 2013.

Also displayed in Table 46 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 unchanged for CY 2013.

TABLE 46—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)
Total	$3,430	1
Eye and ocular adnexa	1,448	1

TABLE 46—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP—Continued

Surgical specialty group	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)
Digestive system	715	3
Nervous system	436	5
Musculoskeletal system	430	−1
Genitourinary system	159	0
Integumentary system	129	−2
Respiratory system	45	−2
Cardiovascular system	31	−2
Ancillary items and services	21	0
Auditory system	11	1
Hematologic & lymphatic systems	5	0

Table 47 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 2013. The table displays 30 of the procedures receiving the greatest estimated CY 2012 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2012 program payment.

- Column 1—CPT/*HCPCS code*.
- Column 2—*Short Descriptor* of the HCPCS code.
- Column 3—*Estimated CY 2012 ASC Payments* were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and the CY 2012 ASC payment rates. The estimated CY 2012 payments are expressed in millions of dollars.
- Column 4—*Estimated CY 2013 Percent Change* reflects the percent differences between the estimated ASC payment for CY 2012 and the estimated payment for CY 2013 based on the proposed update.

TABLE 47—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code *	Short descriptor	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol, 1 stage	$1,076	1
43239	Upper GI endoscopy, biopsy	156	3
45380	Colonoscopy and biopsy	144	3
45385	Lesion removal colonoscopy	92	3
45378	Diagnostic colonoscopy	89	3
66982	Cataract surgery, complex	83	1
64483	Inj foramen epidural l/s	72	6
62311	Inject spine l/s (cd)	68	6
66821	After cataract laser surgery	55	6
63650	Implant neuroelectrodes	39	−1
15823	Revision of upper eyelid	39	−1
G0105	Colorectal scrn; hi risk ind	38	3
64493	Inj paravert f jnt l/s 1 lev	35	6
29827	Arthroscop rotator cuff repr	32	−6
64721	Carpal tunnel surgery	31	0
G0121	Colon ca scrn not hi rsk ind	30	3
29881	Knee arthroscopy/surgery	30	0
63685	Insrt/redo spine n generator	28	10
64590	Insrt/redo pn/gastr stimul	25	10
29880	Knee arthroscopy/surgery	24	0
45384	Lesion remove colonoscopy	23	3
43235	Uppr gi endoscopy diagnosis	23	3
52000	Cystoscopy	19	6
28285	Repair of hammertoe	19	0
62310	Inject spine c/t	18	6
26055	Incise finger tendon sheath	17	−4
29826	Shoulder arthroscopy/surgery	17	0
67042	Vit for macular hole	17	−1
67904	Repair eyelid defect	17	−3
50590	Fragmenting of kidney stone	17	−4

* Note that HCPCS codes we are proposing to delete for CY 2013 are not displayed in this table.

(3) Estimated Effects of ASC Payment System Proposals on Beneficiaries

We estimate that the proposed CY 2013 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 2013. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 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, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. 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.) Furthermore, the additions to the ASC list of covered surgical procedures will provide beneficiaries access to more surgical procedures in ASCs. 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 for that service in the physician's office compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2013, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office because the coinsurance in both settings is 20 percent (except for certain preventive services where the coinsurance is waived in both settings).

(4) Alternative ASC Payment Policies Considered

Alternatives to the changes we are proposing to make to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this proposed rule. Some of the major ASC issues discussed in this proposed rule and the options considered are discussed below.

• Alternatives Considered for the Annual Update to ASC Payments for Inflation

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.'' The statute, therefore, 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 under the revised payment system, we are not compelled to increase the ASC payment amounts by the CPI–U. Nonetheless, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. While we believe the CPI–U is appropriate to apply to update the ASC payment system, the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. Therefore, as alternatives to using the CPI–U to update ASC payment rates for inflation, in developing this proposed rule, we considered using: (1) The hospital market basket, which is used to update OPPS rates for inflation; (2) the PE component of the MEI update, which is used to update the MPFS payment rates for inflation; or (3) the average of the hospital market basket update and the PE component of the MEI update.

We did not select the use of any of the above alternatives to using the CPI–U to update ASC payments for inflation because, until we have more information regarding the cost inputs of ASCs, we are not confident that any of the alternatives are a better proxy for ASC cost inputs than the CPI–U.

• Alternatives Considered for Office-Based Procedures

According to our existing policy for the ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years and that we determine are predominantly performed in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure HCPCS code and/or, if appropriate, the clinical characteristics, utilization, and volume of related HCPCS codes. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility practice expense payment amount or the ASC rate developed according to the standard methodology of the ASC payment system.

In developing this proposed rule, we reviewed CY 2011 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 or later years and for those procedures for which the office-based designation is temporary in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74406 through 74408). Based on that review and as discussed in section XIV.C.1.b. of this proposed rule, we are proposing to newly designate 6 surgical procedures as permanently office-based, to make temporary office-based designations for 6 procedures in CY 2013 that were designated as temporarily office-based for CY 2012, and to make temporary office-based designations for 2 procedures that are proposed as new ASC covered surgical procedures for CY 2013. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would pay for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 6 procedures we proposed to designate as permanently office-based, as well as the 8 procedures that we proposed to designate temporarily as office-based, are considered to be predominantly performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 final rule (72 FR 42509 through 42513), we were concerned that making payments at the standard ASC payment rate for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical decisions regarding the most appropriate setting for surgical care. Further, consistent with our policy, we believe that when adequate data become available to make permanent determinations about procedures with

temporary office-based designations, maintaining the temporary designation is no longer appropriate.

The second alternative we considered and the one we are proposing for CY 2013 is to designate 6 additional procedures as permanently office-based for CY 2013 and to designate 8 procedures as temporarily office-based in CY 2013. We chose this alternative because our claims data and clinical review indicate that these procedures would be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2013 ASC payment rate for these procedures potentially being capped at the CY 2013 physicians' office rate (that is, the MPFS nonfacility practice expense payment amount), if applicable, is an appropriate step to ensure that Medicare payment policy does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 final rule.

c. Effects of the Proposed Revisions to the QIO Regulations

In section XVIII. of this proposed rule, we discuss our proposed changes to the QIO program regulations, including: Adding provisions for processing beneficiary complaints that will give beneficiaries more information about the QIO's review process, which includes a new alternative dispute resolution option (immediate advocacy); giving QIOs the authority to send and receive secure transmissions of electronic versions of health information; conveying beneficiaries the right to authorize the QIOs' use and disclosure of confidential information; and removing outdated regulatory provisions that will enable QIOs to give more information regarding the results of reviews. We believe the proposed changes will improve the QIO program, give beneficiaries better information regarding review activities and reduce burden for both providers and practitioners.

The QIO program requests approximately 62,400 medical records each year for the Hospital IQR and Hospital OQR Programs combined (38,400 for inpatient and 24,000 for outpatient). For the Hospital IQR Program, the average number of pages per medical record is 289 pages, and for the Hospital OQR Program, the average number of pages is 74. Reimbursement is made at a rate of $0.12 per page for PPS hospitals, which includes the costs of toner, paper, and labor associated with the copying of paper medical records. We also note that the labor associated with copying the medical records can be considerable. In fact, many providers and practitioners store health information electronically, and these same providers and practitioners are forced to print hard copies of the information for shipment to the QIOs. Sometimes this may entail using the ''print screen'' function to create the record to be shipped. On average, the cost of shipping the records is approximately $32.35 per shipment, with approximately 5,200 shipments being made. The shipping amount takes into consideration that, for some QIO review activities, multiple records are shipped at one time, which can involve the use of several boxes.

Under our proposal, by example, assuming all hospitals operate under a PPS, should all hospitals transfer health information on a digital versatile device (DVD), the costs associated with the toner and paper would be replaced by the costs of a DVD. In fact, numerous medical records could be copied to a single DVD. Moreover, the labor in copying the records would be substantially reduced because, for example, rather than copying the average 289 pages related to a Hospital IQR Program review, the file could be electronically transferred to a DVD for shipping. We estimate that the $0.12 per page rate could be reduced by as much as $0.07 per page. Based on the overall average number of pages for the Hospital IQR Program and Hospital OQR Program, respectively, reducing the per page rate to $0.05 per page would save $901,152 ((11,097,600 pages × $0.12 = $1,331,712) + (1,776,000 pages × $0.12 = $213,120) − (11,097,600 pages × $0.05 = $554,880) − (1,776,000 pages × $0.05 = $88,800)).

The proposed changes also would reduce the costs associated with mailing the records. For the Hospital IQR Program, hospitals sometimes need to ship as many as four or five large boxes of medical records. By comparison, a single DVD can house multiple medical records and even if multiple DVDs were required, all the DVDs could be mailed in a single envelope at a significantly lower costs. Potentially, the per envelope mailing cost could be as low as $5 compared to the per shipment average cost of $32.35. Thus, if all records were shipped on DVDs, the program would save $142,220 ($168,220 − $26,000).

The proposed changes allowing the sending and receiving of electronic versions of health information also would reduce costs for other QIO review activities. QIOs request approximately 100,000 medical records in completing other review activities, including but not limited to requests related to the processing of general quality of care reviews, written beneficiary complaint reviews, medical necessity reviews, and expedited discharge appeal reviews. The average number of pages associated with each of these reviews varies greatly, and we have estimated an overall average of approximately 175 pages per request. The reimbursement rate for requests associated with these activities is $0.12 per page for PPS providers and $0.15 per page for practitioners and non-PPS providers. Assuming an overall average number of 175 pages for each record, we estimate that the total number of pages requested is approximately 17,500,000. Assuming that approximately 75 percent (13,125,000) of the pages are from practitioners and non-PPS providers, with the remaining 25 percent (4,375,000) from PPS providers, based on the $0.12 or $0.15 per page reimbursement rate, we estimate that the total costs would be approximately $1,968,750 and $525,000, respectively. If all these requests were fulfilled using a DVD or other electronic means, we estimate that the cost per page could be reduced to approximately $0.05 per page for PPS providers and $0.06 per page for practitioners and non-PPS providers. Thus, the estimated savings related to PPS providers would be approximately $306,250 ($525,000 − $218,750) and the estimated savings related to practitioners and non-PPS providers would be approximately $1,181,250 ($1,968,750 − $787,500).

With regard to mailing, we also believe the proposed changes would significantly reduce the costs for other QIO review activities. Moreover, unlike the Hospital IQR and Hospital OQR Programs, the number of medical records requested for these other QIO review activities more closely mirrors the actual number of shipments made. For example, on average, the QIOs request 100,000 medical records related to these other activities, and we estimate that this equates to approximately 82,000 shipments. We estimate that there is a corresponding decrease in the cost per shipment ($7 per shipment compared to $32.35 per shipment for the Hospital IQR and OQR Programs). If DVDs were used instead of paper copies of the medical records, we estimate saving of $164,000 (82,000 × $7 − 82,000 × $5).

Beginning with the QIOs' most recent scope of work, which began August 1, 2011, QIOs began offering immediate advocacy to Medicare beneficiaries for the resolution of certain types of oral complaints. We believe that cost savings

will be realized as a result. In developing this new proposed process, we had several goals. One of these goals was to create a way for Medicare beneficiaries to obtain resolutions of complaints much faster than the traditional peer review process, which usually take over 158 days to complete because, inevitably, various timeframes throughout the review process are not met (for example, providers and practitioners sometimes take more time that allowed to respond to medical record requests or the opportunity for discussion). By comparison, we believe that immediate advocacy normally can be completed within 2 calendar days. However, this proposed process could result in reductions of more than merely a reduction in days. Because immediate advocacy is completed without reviewing a beneficiary's medical record, QIOs would save the costs associated with requesting the records, which includes the labor, supplies (toner and paper), and mailing of the records. Moreover, although there may be some variation among QIOs, immediate advocacy would typically be carried out by a nurse or social worker, and, thus, the QIO can avoid the more expensive costs associated with the use of a physician reviewer.

In addition, for a traditional complaint review, the QIO's peer reviewer completes three separate and distinct reviews (the interim initial determination, the final initial determination, and the reconsideration determination), each time reviewing the medical information and providing his/her conclusion about the quality of care provided. Moreover, the provider and/or practitioner who is the subject of the complaint will be brought into the complaint process each time to respond to the conclusions. With immediate advocacy, the nurse or social work would be involved once, early in the process, with the primary role being to listen to the beneficiary's concerns and then coordinate a resolution with the provider or practitioner, instead of merely reviewing information contained in the beneficiary's medical information. Not only would this process enable beneficiaries to obtain resolution of complaints quicker, but it would decrease the amount of time and energy practitioners and providers would devote to responding to the complaints. This is especially true for certain types of complaints where the issues involved are not even documented in the medical information the physician reviewers would review in the traditional complaint process. Typically, we have estimated a total cost per case of $960 for each case processed using the traditional peer review process. We estimate that, for those instances where immediate advocacy is used, the average cost per case would be approximately $87. On average, QIOs complete approximately 3,500 complaint reviews each year, and we estimate that approximately 10 percent of these reviews (350) would be resolved using immediate advocacy instead of the traditional peer review process. This would result in savings of $305,550 each year (($960 × 350 = $336,000) − ($87 × 350 = $30,450)).

The technical changes to the QIO regulations under section XVIII.F. of this proposed rule that we are proposing to improve the regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

Below is a table summarizing the savings associated with both of these provisions.

Provision	Savings per year
Authority to transmit information electronically	$2,388,622 total per year.
Quality Reporting Information (Copying)	901,152.
Quality Reporting Information (Mailing)	142,220.
Other QIO Activities (Copying)	1,181,250.
Other QIO Activities (Mailing)	164,000.
Immediate Advocacy	305,550 total per year.
Total Savings	2,694,172 per year.

d. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web Site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*, we have prepared three accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 48 below, illustrates the classification of expenditures for the CY 2013 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2013 OPD fee schedule increase, based on the FY 2013 President's Budget. The second accounting statement, Table 49 below, illustrates the classification of expenditures associated with the proposed 1.3 percent CY 2013 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the FY 2013 President's Budget. The third accounting statement, Table 50 below, illustrates the estimated impact based on the proposed provisions allowing QIOs to securely send and receive electronic versions of health information as well as the use of alternative dispute resolution process called immediate advocacy. Lastly, the three tables classify all estimated impacts as transfers.

TABLE 48—ACCOUNTING STATEMENT: CY 2013 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2012 TO CY 2013 ASSOCIATED WITH THE PROPOSED CY 2013 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$700 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS.
Total	$700 million.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2012 TO CY 2013 AS A RESULT OF THE PROPOSED CY 2013 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$40 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$40 million.

TABLE 50—ACCOUNTING STATEMENT: CY 2013 ESTIMATED SAVINGS TO MEDICARE FROM THE PROPOSED REVISIONS OF THE QIO REGULATIONS

Category	Transfers
Annualized Monetized Transfers	−$2.7 million.
From whom to Whom	Federal Government to Medicare Providers.
Total	−$2.7 million.

e. Effects of Proposed Requirements for the Hospital OQR Program

In section XVI. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68781), section XVI. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60629 through 60655), section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110), and section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74492), we discussed the requirements for subsection (d) hospitals to report quality data under the Hospital OQR Program in order to receive the full OPD fee schedule increase factor for CY 2010, CY 2011, and CYs 2012 through 2014, respectively. In section XV. of this proposed rule, we are proposing to adopt additional policies affecting the Hospital OQR Program.

We determined that 114 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2012. Most of these hospitals (106 of the 114) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2015.

In section XVI.E.3.a. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2.0 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that this approach was suitable for the CY 2012 Hospital OQR Program because it would: Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we adopted in the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program)) (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for CY 2011, CY 2012, and CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

In this proposed rule, for CY 2014 and subsequent years payment determinations, we are proposing some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we are not proposing any modifications to our validation requirements. We expect these proposals to have minimal impact on the program.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2015. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the proposed CY 2015 payment update.

The validation requirements for CY 2014 would result in medical record documentation for approximately 6,000 cases per quarter for CY 2014, being submitted to a designated CMS contractor. We will pay for the cost of sending this medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for CY 2014, we estimate that we will have expenditures of approximately $13,200 per quarter for CY 2014. Because we will pay for the

data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

We are proposing to maintain a 45-day timeframe for hospitals to submit requested medical record documentation to meet our validation requirement. The total burden would be a maximum of 12 charts for each of the four quarters that must be copied and mailed within a 45-day period after the end of each quarter.

f. Effects of the Proposed EHR Electronic Reporting Pilot

Under section XV.K. of this proposed rule, we are proposing to allow eligible hospitals and CAHs that are participating in the EHR Incentive Program to meet the CQM reporting requirement of the program for payment year 2013 by participating in the Medicare EHR Incentive Program Electronic Reporting Pilot. This proposal would facilitate the use of an electronic infrastructure that supports the use of EHRs by hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we have encouraged hospitals and CAHs to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from EHRs to a CMS data repository. We expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Hospitals that choose to participate in the EHR Incentive Program by means of this pilot for the purpose of meeting the CQM reporting requirement of Meaningful Use will be taking those first steps toward reporting clinical quality data in such a way.

There are no changes to the costs or impact in the 2012 OPPS/ASC final rule for the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs.

g. Effects of Proposals for the ASCQR Program

In section XVI. of this proposed rule, for the ASCQR Program, we are seeking public comment on our approach for future measures selection and development as well as proposing certain measures for future inclusion in the ASCQR Program measure set. For the CY 2015 payment determination and subsequent year payment determinations, we are proposing requirements regarding the dates for submission, payment, and completeness for claims-based measures. We also are proposing how the payment rates would be reduced for ASCs that fail to meet program requirements beginning in CY 2014 and are clarifying our policy on updating measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do not expect our proposals to significantly affect the number of facilities that do not receive a full annual payment update.

h. Effects of Proposed Updates to the IRF QRP

In section XVII. of this proposed rule, we discuss our proposals to retain the measures that were finalized for the IRF QRP for the previous annual payment determination year, for all subsequent annual payment determination years, unless we propose otherwise. Specifically, we are proposing to apply this policy to the two quality measures that were previously finalized in the FY 2012 IRF PPS final rule. We are proposing to use the CAUTI measure that was previously finalized in the FY 2012 IRF PPS final rule with revisions which were made by the NQF after publication of the FY 2012 IRF PPS final rule. We are proposing to apply the revised CAUTI measure to the 2012 reporting period and each subsequent reporting period thereafter.

These proposed changes would not impose any additional burden on IRFs, nor would they result in any increase in costs.

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 $34.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 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 705 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 $139 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

D. Conclusion

The changes we are proposing will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2013. Table 45 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.1 percent increase in payments for all services paid under the OPPS in CY 2013, after considering all proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, 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 and others would experience modest losses in OPPS payments in CY 2013. We estimate that hospitals for whom DSH data are not available (non-IPPS, largely urban hospitals) would experience an increase of 8.2 percent due to increased payments for partial hospitalization, group psychotherapy and hemodialysis

services. CMHCs would see an overall decrease in payment of 4.4 percent as a result of a decrease in their estimated costs.

The proposed updates to the ASC payment system for CY 2013 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would 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 46 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 1.3 percent for CY 2013.

XXIII. 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 45 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.1 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 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Privacy, Reporting and recordkeeping requirements.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

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 416—AMBULATORY SURGICAL SERVICES

1. 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 and1395hh).

2. Section 416.160 is amended by revising paragraph (a)(1) to read as follows:

§ 416.160 Basis and scope.

(a) * * *

(1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

* * * * *

3. Section 416.171 is amended by—

a. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(iv) and revising the redesignated paragraph (a)(2)(iv).

b. Adding paragraph (a)(2)(iii).

The revision and addition read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2014 and subsequent calendar years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(iv) *Productivity adjustment.* (A) For calendar year 2011 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) The application of the provisions of paragraph (a)(2)(iv)(A) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

* * * * *

4. Section 416.195 is amended by revising paragraphs (a)(2) and (a)(4) introductory text, to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The FDA-approved labeling shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

* * * * *

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

5. 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, 1395(t), and 1395hh).

6. Section 419.2 is amended by revising paragraph (b) heading and introductory text to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs include, but are not limited to, the following items and services, the payments for which are packaged into the payments for the related procedures or services.

* * * * *

7. Section 419.31 is amended by revising paragraphs (a)(1), (b), and (c)(2) to read as follows:

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) * * *

(1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the lowest geometric mean cost for an item or service within the group.

* * * * *

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the geometric mean costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative geometric mean costs for the services within the APC group compared to the geometric mean costs for the services in all APC groups.

(c) * * *

(2) CMS standardizes the geometric mean costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

8. Section 419.32 is amended by:

a. Revising paragraph (b)(1)(iv)(A).

b. Removing ''and'' from the end of paragraph (b)(1)(iv)(B)(*2*).

c. Removing the period from the end of paragraph (b)(1)(iv)(B)(*3*) and adding ''; and'' in its place.

d. Adding paragraph (b)(1)(iv)(B)(*4*).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the OPD fee schedule increase factor, which, subject to the adjustments specified in paragraph (b)(1)(iv)(B) of this section and §§ 419.43(h)(1) and (h)(2), if applicable, is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) * * *

(*4*) For calendar year 2013, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

9. Section 419.70 is amended by—

a. Revising paragraph (d)(2) introductory text.

b. Adding paragraph (d)(7).

The revision and addition read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, 2011, and 2012 if the hospital—

* * * * *

(7) *Temporary treatment of sole community hospitals on or after January 1, 2012 through December 31, 2012.* (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(A) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

* * * * *

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

10. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

11. Section 476.1 is amended by—

a. Removing the definition of ''Active staff privileges''.

b. Adding definitions of ''Appointed representative'', ''Authorized representative'', ''Beneficiary complaint'', ''Beneficiary complaint review'', ''Beneficiary representative'', ''General quality of care review'', ''Gross and flagrant violation'', ''Immediate advocacy'', ''Quality improvement initiative'', ''Quality of care concern'', ''Quality of care review'', ''Significant quality of care concern'', and ''Substantial violation in a substantial number of cases''.

c. Revising the definition of ''Preadmission certification''.

The additions and revisions read as follows:

§ 476.1 Definitions.

* * * * *

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

* * * * *

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

* * * * *

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

* * * * *

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary or the Medicare administrative contractor, approving the patient's admission for payment purposes.

* * * * *

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

* * * * *

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

* * * * *

12. Section 476.70 is revised to read as follows:

§ 476.70 Statutory bases and applicability.

(a) *Statutory bases.* Sections 1154, 1866(a)(1)(F), and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

13. Section 476.71 is amended by—

a. Revising paragraph (a)(2).

b. In paragraph (b), removing the reference ''§ 405.330(b)'' and adding in its place the reference ''§ 411.400(b) of this chapter''.

c. Revising paragraph (c)(1).

The revisions read as follows:

§ 476.71 QIO review requirements.

(a) * * *

(2) Whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints as specified in § 476.110, written beneficiary complaints as specified in § 476.120, or the completion of general quality of care reviews as specified in § 476.160.

* * * * *

(c) * * *

(1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare administrative contractor, fiscal intermediary, or carrier if it determines that the information submitted by the hospital was incorrect.

* * * * *

§ 476.72 [Removed]

14. Section 476.72 is removed.

§ 476.73 [Amended]

15. In § 476.73—

a. In paragraph (a), the phrase ''and Medicare fiscal intermediaries and carriers.'' is removed and the phrase '', Medicare administrative contractors, fiscal intermediaries, and carriers.'' is added in its place.

b. In paragraph (b)(1), the reference ''§ 466.78(b)(3) of this part'' is removed and the reference ''§ 476.78(b)(3)'' is added in its place.

§ 476.74 [Amended]

16. In § 476.74—

a. In paragraph (b), the phrase ''appropriate Medicare fiscal intermediary or carrier'' is removed and the phrase ''appropriate Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

b. In paragraph (c)(1), the phrase ''Medicare fiscal intermediaries and

carriers'' is removed, and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

c. In paragraph (e), the reference ''§ 405.332'' is removed and the reference ''§ 411.402'' is added in its place.

17. Section 476.78 is amended by—

a. Revising the section heading.

b. Revising paragraphs (b)(2)(i) and (b)(2)(ii).

c. Adding paragraph (b)(2)(iii).

The revisions and addition read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, photocopy and deliver to the QIO all required information within 30 calendar days of a request.

(ii) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, deliver all required medical information to the QIO within 21 calendar days from the date of the request in those situations where a potential ''serious reportable event'' has been identified or where other circumstances as deemed by the QIO warrant earlier receipt of all required medical information. For purposes of this paragraph (b)(2)(iii), a ''serious reportable event'' is defined as a preventable, serious and unambiguous adverse event that should never occur.

(iii) Secure transmission of an electronic version of medical information, subject to the QIO's ability to support receipt and transmission of the electronic version. Providers and practitioners must deliver electronic versions of medical information within 10 calendar days of the request.

* * * * *

18. In § 476.80—

a. The section heading is revised to read as set forth below.

b. In paragraphs (b)(1) introductory text and (c)(1) (two places), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

c. In paragraph (a) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

d. In paragraphs (a)(1), (a)(2) introductory text (two places), (c)(3)(ii), (d)(1), and (d)(2), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

e. In paragraph (e), in the paragraph heading and in paragraphs (e)(1) and (e)(2), the phrase ''fiscal intermediary'' is removed and the phrase ''Medicare administrative contractor or fiscal intermediary'' is added in its place.

The revision reads as follows:

§ 476.80 Coordination with Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

§ 476.86 [Amended]

19. In § 476.86—

a. In paragraph (a)(1)(iii), the reference ''§ 405.310(g) or § 405.310(k)'' is removed and the reference ''§ 411.15(g) or § 411.15(k)'' is added in its place.

b. In paragraph (a)(2), the phrase ''Medicare fiscal intermediaries or carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, or carriers'' is added in its place.

c. In paragraph (c) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

d. In paragraph (c)(1), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

e. In paragraph (d), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

f. In paragraph (e), the phrase ''intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

g. In paragraph (f), the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.94 [Amended]

20. In § 476.94—

a. In paragraph (a)(1)(iv), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

b. In paragraph (d), the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

c. In paragraph (c)(3) introductory text, the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.98 [Amended]

21. In § 476.98, in paragraph (a)(1), the phrase ''with active staff privileges in one or more hospitals in the QIO area'' is removed.

22. Section 476.104 is amended by revising paragraph (a) to read as follows:

§ 476.104 Coordination of activities.

* * * * *

(a) Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

23. New §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, 476.170 are added to subpart C to read as follows:

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

Sec.

* * * * *

476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

476.120 Submission of written beneficiary complaints.

476.130 Beneficiary complaint review procedures.

476.140 Beneficiary complaint reconsideration procedures.

476.150 Abandoned complaints and reopening rights.

476.160 General quality of care review procedures.

476.170 General quality of care reconsideration procedures.

* * * * *

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) *Immediate advocacy.* A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that—

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) *Discontinuation of immediate advocacy.* The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) *Confidentiality requirements.* All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) *Abandoned complaints.* If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

§ 476.120 Submission of written beneficiary complaints.

(a) *Timeframe for submission of written complaints.* A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) *New concerns raised by a Medicare beneficiary.* If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

§ 476.130 Beneficiary complaint review procedures.

(a) *Scope of the QIO review.* In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider and/or practitioner. All information obtained by the QIO that fits within the definition of ''confidential information'' under § 480.101 of this chapter, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 10 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in 42 CFR Part 1004 and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) *Interim initial determination.* The QIO peer reviewer will complete the review and notify the practitioner and/or provider of its interim initial determination within 7 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) *Final initial determination.* The QIO must issue notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed. No later than 72 hours after completion of its review, or for cases in which the standard was not met, no later than 72 hours after the discussion or receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(1) Written notice of the QIO's final initial determination will be forwarded to all parties, unless either party requests a reconsideration of the final initial determination. If a reconsideration request is submitted, the QIO will notify the parties that a written decision will be issued once the reconsideration review is completed in accordance with § 476.140(b).

(2) If a reconsideration request is not received, the written decision will be issued within 72 hours after the QIO has contacted the parties, as described in

paragraph (d) of this section, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

§ 476.140 Beneficiary complaint reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than noon of the calendar day following initial notification (whether by telephone or in writing) of the QIO's determination. In rare circumstances, the QIO may grant an additional calendar day. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes—

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

§ 476.150 Abandoned complaints and reopening rights.

(a) *Abandoned complaints.* If a Medicare beneficiary fails to participate or otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) *Reopening complaint reviews.* A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

§ 476.160 General quality of care review procedures.

(a) *Scope of the QIO review.* A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on—

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 10 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established time frame may result in the QIO taking action pursuant to § 476.90.

(c) *Initial determination.* The QIO peer reviewer will complete the review and notify the practitioner and/or provider within 7 calendar days of the receipt of all medical information.

§ 476.170 General quality of care reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) of the QIO's determination. In rare circumstances, the QIO may grant an additional calendar day. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the

mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

PART 478—RECONSIDERATIONS AND APPEALS

24. The authority citation for Part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 478.15 [Amended]

25. In § 478.15(b), the reference ''§§ 473.18 through 473.36, and 473.48(a) and (c)'' is removed and the reference ''§§ 478.18 through 478.36 and § 478.48(a) and (c)'' is added in its place.

§ 478.16 [Amended]

26. In § 478.16, the reference ''§ 473.14(a)'' is removed and the reference ''§ 478.14'' is added in its place.

§ 478.20 [Amended]

27. In § 478.20—

a. In paragraph (a)(1), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

c. In paragraph (c), the reference ''§ 473.18(c)'' is removed and the reference ''§ 478.18(c)'' is added in its place.

§ 478.28 [Amended]

28. In § 478.28 (a), the reference ''§ 466.98'' is removed and the reference ''§ 476.98'' is added in its place.

§ 478.38 [Amended]

29. In § 478.38—

a. In paragraph (a), the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

b. In paragraph (b), the reference ''§ 473.48'' is removed and the reference ''§ 478.48'' is added in its place.

§ 478.42 [Amended]

30. In § 478.42—

a. In paragraph (a) introductory text, the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

§ 478.48 [Amended]

31. In § 478.48—

a. In paragraph (a)(1), the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

b. In paragraph (a)(2) introductory text, the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

32. The authority citation for Part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 480.105 [Amended]

33. In § 480.105(a), the phrase ''Medicare fiscal intermediaries'' is removed and the phrase ''Medicare administrative contractors or fiscal intermediaries'' is added in its place.

34. Section 480.107 is amended by adding a new paragraph (l) to read as follows:

§ 480.107 Limitations on redisclosure.

* * * * *

(l) Redisclosures of information that is confidential because it identifies the parties involved in immediate advocacy may occur if all parties have consented to the redisclosure, as provided for under § 476.110(c) of this chapter.

35. Section 480.132 is amended by—

a. Revising paragraph (a) introductory text, paragraph (a)(1)(iii), and paragraph (a)(2).

b. Revising paragraph (b)(1).

c. Revising paragraph (c).

d. Removing the undesignated text following paragraph (c)(3).

The revisions read as follows.

§ 480.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in §§ 476.130(d) and 476.140(b) of this chapter and paragraph (b) of this section, a QIO must—

(1) * * *

(iii) Except as provided under paragraph (b) of this section, all other patient and practitioner identifiers have been removed.

(2) Make disclosure to the patient or the patient's representative within 14 calendar days of receipt of the request.

(b) * * *

(1) If a request for information is in connection with an initial denial determination under section 1154(a)(2) of the Act, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information related to determinations under § 478.24, including relevant practitioner identifiers.

* * * * *

(c) Manner of disclosure. (1) The QIO must disclose the patient information directly to the patient or the patient's representative when the representative has been authorized or appointed to receive that information.

(2) In identifying a representative, the QIO must follow pertinent State law requirements regarding the designation of health care representatives and agents. If the patient is unable to designate a representative and the identity of the representative is not already dictated by State law, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

36. Section 480.133 is amended by—

a. Adding a new paragraph (a)(2)(iv).

b. In paragraph (b)(1), removing the reference to ''Part 466'' and adding the reference ''Part 476'' in its place; and removing the reference ''§ 473.24'' and adding the reference ''§ 478.24 of this subchapter'' is its place.

The addition reads as follows:

§ 480.133 Disclosure of information about practitioners, reviewers, and institutions.

(a) * * *

(2) * * *

(iv) A QIO is not required to obtain the consent of a practitioner or provider prior to the release of information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the QIO's findings in response to a beneficiary complaint. Information that must be specified in a QIO's final decision in a complaint review is specified in §§ 476.130(d) and 476.140(b) of this subchapter.

* * * * *

§ 480.139 [Amended]

37. Section 480.139 is amended by redesignating the existing paragraph (1) as paragraph (a)(1).

38. A new § 480.145 is added to read as follows:

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this part, a QIO may not use or

disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of persons, to whom the QIO(s) may disclose the information or allow the requested use.

(4) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.

(5) An expiration date or an expiration event that relates to the beneficiary or the purpose of the use or disclosure. The statement ''end of the QIO research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of confidential information for QIO research, including for the creation and maintenance of a research database or research repository.

(6) Signature of the individual and date. If the authorization is signed by a beneficiary's representative, a description of such representative's authority to act for the beneficiary must also be provided.

(c) In addition to those items contained in paragraph (b) of this section, the authorization must contain statements adequate to place the individual on notice of all of the following:

(1) The individual's right to revoke the authorization in writing; and

(2) Any exceptions to the right to revoke and a description of how the individual may revoke the authorization;

(3) The ability or inability of the QIO to condition its review activities on the authorization, by stating either:

(i) That the QIO may not condition the review of complaints, appeals, or payment determinations, or any other QIO reviews or other tasks within the QIO's responsibility on whether the individual signs the authorization;

(ii) The consequences to the individual of a refusal to sign the authorization when the refusal will render the QIO unable to carry out an activity.

(4) The potential for information disclosed pursuant to the authorization to be subject to either appropriate or inappropriate redisclosure by a recipient, after which the information would no longer be protected by this subpart.

(d) The authorization must be written in plain language.

(e) If a QIO seeks an authorization from a beneficiary for a use or disclosure of confidential information, the QIO must provide the beneficiary with a copy of the signed authorization.

(f) A beneficiary may revoke an authorization provided under this section at any time, provided the revocation is in writing, except to the extent that the QIO has taken action in reliance upon the authorization.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

39. The authority citation for Part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

40. Section 495.8 is amended by revising paragraph (b)(2)(vi) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vi) Exception for Medicare eligible hospitals and CAHs for FY 2012 and 2013—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot. In order to satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance)

Dated: June 28, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 29, 2012.

Kathleen Sebelius,

Secretary.

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