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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1468

[Docket No. NRCS–2014–0011]

RIN 0578–AA61

Agricultural Conservation Easement Program

AGENCY: The Natural Resources Conservation Service (NRCS) and the Commodity Credit Corporation (CCC), United States Department of Agriculture (USDA).

ACTION: Interim rule; reopening of comment period.

SUMMARY: NRCS and CCC published an interim rule for the Agricultural Conservation Easement Program (ACEP) with a request for comments, and a comment period ending April 28, 2015. This document reopens the comment period.

DATES: The comment period for the interim rule for ACEP (80 FR 11032, Feb. 27, 2015) is hereby reopened and will end Thursday, May 28, 2015.

ADDRESSES: Comments may be submitted by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments for Docket No. NRCS–2014–0011.
- *Mail or hand delivery:* Public Comments Processing, Attention: Docket No. NRCS–2014–0011, Regulatory and Agency Policy Team, Strategic Planning and Accountability, U.S. Department of Agriculture, Natural Resources Conservation Service, 5601 Sunnyside Avenue, Building 1–1112D, Beltsville, Maryland 20705.

NRCS will post all comments on *http://www.regulations.gov*. Personal information provided with comments will be posted. If your comment includes your address, phone number, email address, or other personal identifying information, please be aware that your entire comment, including your personal information, will be made publicly available. Do not include personal information with your comment submission if you do not wish for it to be made public. This interim rule may be accessed via Internet. Users can access the NRCS homepage at: *http://www.nrcs.usda.gov/;* select the Farm Bill link from the menu; select the Interim final link from beneath the Final and Interim rules Index title under the heading ''2014 NRCS Farm Bill Conservation Program Rules.'' Select Agricultural Conservation Easement Program.

FOR FURTHER INFORMATION CONTACT: Kim Berns, Acting Deputy Chief for Programs, at 202–720–1882.

Persons with disabilities who require alternative means for communication (*e.g.,* Braille, large print, audio tape, etc.) should contact the USDA Technology and Accessible Resources Give Employment Today Center at 202–720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION: In response to requests from the public, the comment period for this rule is being reopened to provide the public additional time to submit comments.

Signed this 24th day of April, 2015, in Washington, DC.

Leonard Jordon,

Acting Chief, Natural Resources Conservation Service, Acting Vice President, Commodity Credit Corporation.

[FR Doc. 2015–10055 Filed 4–29–15; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–0757; Special Conditions No. 25–581–SC]

Special Conditions: Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 Airplanes; Design Roll-Maneuver Condition

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes will have a novel or unusual design feature associated with an electronic flight-control system that provides roll control of the airplanes through pilot inputs to the flight computers. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Bombardier Inc. on April 30, 2015. We must receive your comments by June 15, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–0757 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at

http://www.regulations.gov/ at any time. Follow the online instructions for accessing the docket, or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 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: Mark Freisthler, FAA, Airframe and Cabin Safety Branch, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1119; facsimile 425–227–1232.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplane(s).

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On June 13, 2012, Bombardier Inc. applied for an amended type certificate for their new Model BD–700–2A12 and BD–700–2A13 airplanes. The BD–700–2A12 and BD–700–2A13 augment the existing BD–700 family of airplanes, and are marketed as the Bombardier Global 7000 and Global 8000, respectively. These are ultra-long-range, executive-interior business jets equipped with Rockwell Collins ProLine Fusion Integrated Avionics System. These airplanes have a maximum certified passenger capacity of 19.

The design of the Model BD–700–2A12 and BD–700–2A13 airplanes includes new high-speed transonic wings with improved aerodynamic efficiency, a pressurized cabin for luxury interiors, and they share an identical supplier base and significant common design elements. The current design roll-maneuver requirement in Title 14, Code of Federal Regulations (14 CFR) part 25 is inadequate for addressing an airplane with electronic flight controls that affect maneuvering. These special conditions adjust the current roll-maneuver requirement, § 25.349, to take into account the effects of an electronic flight-control system.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Bombardier Inc. must show that the Model BD–700–2A12 and BD–700–2A13 airplanes meet the applicable provisions of part 25 as amended by Amendments 25–1 through 25–136.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model BD–700–2A12 and BD–700–2A13 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the Model BD–700–2A12 and BD–700–2A13 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Model BD–700–2A12 and BD–700–2A13 airplanes will incorporate the following novel or unusual design features:

The airplanes are equipped with an electronic flight-control system that provides control through pilot inputs to the flight computer. Current part 25 airworthiness regulations account for control laws for which aileron deflection is proportional to control-stick deflection. They do not address nonlinearities or other effects on aileron actuation that electronic flight controls may cause. Because this type of system may affect flight loads, and therefore the structural capability of the airplanes, special conditions are needed to address these effects.

Discussion

These special conditions differ from current requirements in that they require that the roll maneuver is based on defined actuation of the cockpit roll control as opposed to defined deflections of the aileron itself. Also, the special conditions require an additional load condition at V_A, in which the cockpit roll control is returned to neutral following the initial roll input.

These special conditions differ from similar special conditions applied on previous programs. These special conditions are limited to the roll axis only, whereas previous special conditions also included the pitch and yaw axes. Special conditions are no longer needed for the pitch or yaw axes, because Amendment 25–91 takes into account the effects of an electronic flight-control system in those axes (§ 25.331 for pitch and § 25.351 for yaw).

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Model BD–700–2A12 and BD–700–2A13 airplanes. Should Bombardier Inc. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and

impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for the Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 airplanes.

Design Roll Maneuver Condition

In lieu of compliance to § 25.349(a):

The following conditions, speeds, and cockpit roll-control motions (except as the motions may be limited by pilot effort) must be considered in combination with an airplane load factor of zero and of two-thirds of the positive maneuvering factor used in design. In determining the resulting control-surface deflections, the torsional flexibility of the wing must be considered in accordance with § 25.301(b):

1. Bombardier Inc. must investigate conditions corresponding to steady rolling velocities. In addition, conditions corresponding to maximum angular acceleration must be investigated for airplanes with engines or other weight concentrations outboard of the fuselage. For the angular acceleration conditions, zero rolling velocity may be assumed in the absence of a rational time-history investigation of the maneuver.

2. At V_A, sudden movement of the cockpit roll control up to the limit is assumed. The position of the cockpit roll control must be maintained until a steady roll rate is achieved and then must be returned suddenly to the neutral position.

3. At V_C, the cockpit roll control must be moved suddenly and maintained so as to achieve a roll rate not less than that obtained in Special Condition 2, above.

4. At V_D, the cockpit roll control must be moved suddenly and maintained so as to achieve a roll rate not less than one third of that obtained in Special Condition 2, above.

Issued in Renton, Washington, on April 17, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–10102 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2014–1080; Special Conditions No. 25–582–SC]

Special Conditions: Airbus Model A319–151n/171n, A320–251n/271n, and A321–251n/271n (SAneo) Series Airplanes; Transient Engine-Failure Loads

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Airbus Model A319–151n/171n, A320–251n/271n, and A321–251n/271n (collectively known as Single Aisle new engine option (SA neo)) series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is a new generation of high-bypass engines, and the potential loads resulting from extreme engine-failure conditions.

The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Airbus on April 30, 2015. We must receive your comments by June 15, 2015.

ADDRESSES: Send comments identified by docket number FAA–2014–1080 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 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: Todd Martin, FAA, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1178; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is unnecessary.

The substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for

comments. We may change these special conditions based on the comments we receive.

Background

On February 29, 2012, Airbus applied for amended type certificate no. A28NM for their new Model SAneo series airplanes. Later, Airbus requested, and the FAA approved, an extension to the application date for FAA type certification to June 30, 2012.

The Airbus Model SAneo series airplanes are derivatives of the A319–100, A320–200, and A321–200 series airplanes equipped with Sharklets™ (large winglets). The changes include installation of new CFM™ LEAP™ A engines on the A319–151n, A320–251n, and A321–251n series airplanes, and installation of new Pratt & Whitney PW–1100G engines on the A319–171n, A320–271n, and A321–271n series airplanes with larger fan diameters and reduced fuel consumption as compared to the current engines. The changes also include new nacelles, new pylons, new engine mounts, new bleed-air systems, structural reinforcements, software changes for the bleed-air system, an auto-flight system, an indicating and recording system, flight-warning and flight-control computers, and small changes to certified weights.

The existing regulations are inadequate because the new high-bypass fan engines of the Airbus Model SAneo series airplanes can cause more damage in a failure event than could the previous engines.

Type Certification Basis

The certification basis for the SAneo series airplanes is the certification basis for the A319–100, A320–200 and A321–200 series airplanes with Sharklets, as defined in type-certificate data sheet A28NM for components or areas not affected by the SAneo change; and sections of 14 CFR part 25 as amended by Amendments 25–1 through 25–136 (*i.e.,* the amendment in effect on the date of the new reference date of application, June 30, 2012) applied to the components and areas affected by the SAneo change. Under the provisions of § 21.101, these regulations will be incorporated into type certificate no. A28NM after type certification approval of the Airbus Model SAneo series airplanes.

In addition, the certification basis includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Airbus Model SAneo series airplane because of a novel or unusual design feature, special conditions are prescribed under § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the Airbus Model SAneo series airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

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

Novel or Unusual Design Features

The Airbus Model SAneo series airplanes will incorporate the following novel or unusual design feature:

Engines with large, high-bypass fans capable of producing much higher failure loads than previous engine designs.

The Airbus Model SAneo series airplanes therefore require additional dynamic-load analyses to assess the most severe engine-failure events. The loads resulting from these conditions would be considered as ultimate loads, with an additional safety factor applied to the airframe-supporting structure.

Discussion

The size, configuration, and failure modes of jet engines has changed considerably from those envisioned in § 25.361(b), when the engine-seizure requirement was first adopted. Engines have become larger and are now designed with large, high-bypass fans capable of producing much higher failure loads. Relative to the engine configurations that existed when the rule was developed in 1957, the present generation of engines are sufficiently different and novel to justify special conditions for Model SAneo series airplanes and related future airplane models. Service history has shown that the engine-failure events that tend to cause the most severe loads are fan-blade failures, and these events occur much less frequently than the typical ''limit'' load condition.

To maintain the level of safety envisioned by § 25.361(b), more comprehensive criteria are required for the new generation of high-bypass engines. These special conditions would distinguish between the more-common engine-failure event and those rare events resulting from structural failures. The more-common events would continue to be treated as static torque limit-load conditions. The more-severe events resulting from extreme engine-failure conditions (such as loss of a full fan blade at redline speed) would be treated as full dynamic-load conditions. These would be considered ultimate loads and include all transient loads associated with the event. An additional safety factor would be applied to the more-critical airframe supporting structure.

The regulatory authorities and industry developed a standardized requirement in the Aviation Rulemaking Advisory Committee (ARAC) forum. The technical aspects of this requirement have been agreed upon, and have been accepted by, the ARAC Loads and Dynamics Harmonization Working Group. These special conditions reflect the ARAC recommendation and are essentially harmonized with the corresponding EASA Certification Specifications (CS) 25. In addition, the ARAC recommendation includes corresponding advisory material that is incorporated into CS–25. This advisory material is considered an acceptable means of compliance to the special conditions.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions apply to the Airbus Model SAneo series airplanes. Should Airbus apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Airbus Model SAneo series airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Airbus Model SAneo series airplanes.

In lieu of § 25.361(b), the following special conditions apply:

1. For turbine engine installations, the engine mounts, pylons, and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum torque limit loads imposed by each of the following:

a. Sudden engine deceleration due to a malfunction that could result in a temporary loss of power or thrust; and

b. the maximum acceleration of the engine.

2. For auxiliary power-unit installations, the power-unit mounts and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum torque limit loads imposed by each of the following:

a. Sudden auxiliary power-unit deceleration due to malfunction or structural failure; and

b. the maximum acceleration of the power unit.

3. For engine supporting structure, an ultimate loading condition must be considered that combines 1g flight loads with the transient dynamic loads resulting from:

a. The loss of any fan, compressor, or turbine blade; and separately,

b. where applicable to a specific engine design, any other engine structural failure that results in higher loads.

4. The ultimate loads developed from the conditions specified in Special Conditions 3.a. and 3.b., above, are to be multiplied by a factor of 1.0 when applied to engine mounts and pylons; and multiplied by a factor of 1.25 when applied to adjacent supporting airframe structure.

5. The airplane must be capable of continued safe flight considering the aerodynamic effects on controllability due to any permanent deformation that results from the conditions specified in Special Condition 3, above.

Issued in Renton, Washington, on April 19, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–10098 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0286; Directorate Identifier 2014–NM–004–AD; Amendment 39–18145; AD 2015–08–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–600 and –700 series airplanes. This AD was prompted by reports of cracking in the body station (STA) 727 bulkhead lower frame. This AD requires a detailed and open hole high frequency eddy current (HFEC) inspection of the left- and right-side lower frame webs and inner chords for cracking, and corrective actions and preventative modifications if necessary. This AD also provides for optional terminating action of the repetitive inspections, under certain conditions. We are issuing this AD to detect and correct cracking in a bulkhead lower frame web and inner chord, which could result in a severed frame and induced skin cracks, and could lead to rapid decompression of the fuselage.

DATES: This AD is effective June 4, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 4, 2015.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0286.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0286; 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 address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6450; fax: 425–917–6590; email: *alan.pohl@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–600 and –700 series airplanes. The NPRM published in the **Federal Register** on May 28, 2014 (79 FR 30490). The NPRM was prompted by reports of cracking in the body STA 727 bulkhead lower frame. The NPRM proposed to require a detailed and open hole high frequency eddy current (HFEC) inspection of the left- and right-side lower frame webs and inner chords for cracking, as applicable, and corrective actions and preventative modifications if necessary. The NPRM also proposed to provide for an optional terminating action for the repetitive inspections under certain conditions. We are issuing this AD to detect and correct cracking in a bulkhead lower frame web and inner chord, which could result in a severed frame and induced skin cracks, and could lead to rapid decompression of the fuselage.

Comments

We gave the public the opportunity to participate in developing this AD. Boeing and United Airlines stated that they support the NPRM (79 FR 30490, May 28, 2014). The following presents the comments received on the NPRM, and the FAA's response to each comment.

Request To Clarify Modification and Repair Requirements

Southwest Airlines (SWA) requested that we clarify whether the preventative modifications and repairs of the lower frame webs and inner chords (if

accomplished) must be done on both the left and right sides at the same time.

SWA stated that paragraph (h) of the NPRM (79 FR 30490, May 28, 2014) reads, ''Accomplishment of a modification or a repair, in accordance with Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, terminates the repetitive inspections in this AD for the repaired or modified side only.''

SWA stated that Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, provides that for each airplane group, if a repair is installed on one side, a preventative modification must be installed on the opposing side. SWA also stated that, for airplanes with no cracks, a preventative modification is optional, but that the service information specifies that in this situation, both sides must be modified.

We agree that clarification is necessary. Groups 2 and 3 airplanes are comprised of four airplanes on which a repair to the left side was installed prior to the issuance of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013. Therefore, SWA's comments are primarily for Group 1 airplanes.

As specified in Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, if a crack is found on one side, then that side must be repaired and the preventative modification concurrently installed on the other side, even if that other side is not cracked. We also agree that if no cracking is found on either side and the operator chooses to install the preventative modification, then both sides must be modified, as specified in paragraph 3.B., Part 2, Step 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013. Installing the preventative modification terminates the repetitive inspections. We have removed the wording ''for the repaired or modified side only'' from paragraph (h) of this AD.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST00830SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/932b6080caa1856e86257d6c005c5a37/$FILE/ST00830SE.pdf*) does not affect the actions specified in the NPRM (79 FR 30490, May 28, 2014).

We concur with the commenter. We have redesignated paragraph (c) of the NPRM (79 FR 30490, May 28, 2014) as paragraph (c)(1) and added new paragraph (c)(2) to this AD to state that installation of STC ST00830SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/932b6080caa1856e86257d6c005c5a37/$FILE/ST00830SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 30490, May 28, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 30490, May 28, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013. The service information describes procedures for a detailed and open hole HFEC inspection of the left- and right-side lower frame webs and inner chords for cracking, and corrective actions and preventative modifications if necessary. The service information also provides for an optional terminating action of the repetitive inspections, under certain conditions. This service information is reasonably available at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0286. Or see **ADDRESSES** for other ways to access this service information.

Costs of Compliance

We estimate that this AD affects 489 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per roduct	Cost on U.S. operators
Inspections	37 work-hours × $85 per hour = $3,145	$0	$3,145	$1,537,905

We estimate the following costs to do any necessary repairs that would be required based on the results of the inspections. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair (per side)	11 work-hours × $85 per hour = $935	$2,820	$3,755
Modification	17 work-hours × $85 per hour = $1,445	1,132	2,577

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, 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 airworthiness directive (AD):

2015–08–09 The Boeing Company: Amendment 39–18145; Docket No. FAA–2014–0286; Directorate Identifier 2014–NM–004–AD.

(a) Effective Date

This AD is effective June 4, 2015.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–600 and -700 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/932b6080caa1856e86257d6c005c5a37/$FILE/ST00830SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the body station 727 bulkhead lower frame. We are issuing this AD to detect and correct cracking in a bulkhead lower frame web and inner chord, which could result in a severed framed and induced skin cracks, and could lead to rapid decompression of the fuselage.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections

At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, except as provided by paragraph (i)(1) of this AD: Do a detailed and open hole high frequency eddy current (HFEC) inspection of the left- and right-side lower frame webs and inner chords for cracking, as applicable, and do all applicable corrective actions and preventative modifications, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, except as required by paragraph (i)(2) of this AD. Repeat the applicable inspections required by this paragraph thereafter at the applicable intervals specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013. Do all applicable corrective actions and preventative modifications before further flight.

(h) Terminating Action

Accomplishment of a modification or a repair, in accordance with Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, terminates the repetitive inspections required by this AD.

(i) Exceptions to Service Information Specifications

(1) Where Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, specifies to contact Boeing for appropriate action: Before further flight, accomplish the corresponding action using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(j) Post-Repair Inspections

The post-repair inspections specified in tables 4, 5, and 6 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, are not required by this AD.

Note 1 to paragraph (j) of this AD: The damage tolerance inspections specified in tables 4, 5, and 6 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, may be used in support of compliance with Section 121.1109(c)(2) or 129.109(b)(2) of the Federal Aviation Regulations (14 CFR 121.1109(c)(2) or 14 CFR 129.109(b)(2)). The corresponding actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013, are not required by this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), 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 manager of the ACO, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) 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.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Related Information

For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6450; fax: 425–917–6590; email: *alan.pohl@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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) Boeing Alert Service Bulletin 737–53A1325, dated December 3, 2013.

(ii) Reserved.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

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

(5) You may view this 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/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 13, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–09805 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0074; Directorate Identifier 2014–NM–138–AD; Amendment 39–18147; AD 2015–09–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by a determination that without an effective maintenance task to maintain the airplane's inherent level of safety, there is a potential that a dormant failure of the alternate release system of the landing gear could occur. This AD requires revising the maintenance or inspection program, as applicable, to incorporate a maintenance task for an operational check of the electro-mechanical actuator and release mechanism of the alternate extension system for the nose landing gear and main landing gear. We are issuing this AD to prevent failure of the alternate release system of the landing gear, which could prevent the landing gear from extending during a failure of the normal landing gear extension system.

DATES: This AD becomes effective June 4, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 4, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0074* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0074.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7318; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM published in the **Federal Register** on January 23, 2015 (80 FR 3498).

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2014–16, dated June 11, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The MCAI states:

> During a design review, an error was identified which led to the development of a new certification maintenance requirement (CMR) task. Without an effective maintenance task to maintain the aeroplane's inherent level of safety, there is a potential that a dormant failure of the alternate release system of the landing gear could occur. Failure of the landing gear alternate release system could prevent the landing gear from extending in the case of a failure of the normal landing gear extension system.
>
> This [Canadian] AD mandates the incorporation of a new maintenance task to ensure operation of the landing gear alternate extension system.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0074-0003.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 3498, January 23, 2015) or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this 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 (80 FR 3498, January 23, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 3498, January 23, 2015).

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Temporary Revision (TR) ALI–0472, dated February 27, 2014, to Section 1–32 of Part 2, Bombardier Airworthiness Limitations, of the CRJ Series Regional Jet Maintenance Requirements Manual, CSP B–053. This service information describes a maintenance task for an operational check of the electro-mechanical actuator and release mechanism of the alternate extension system for the nose landing gear and main landing gear. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI. This service information is reasonably available at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–

0074. Or see **ADDRESSES** for other ways to access this service information.

Costs of Compliance

We estimate that this AD affects 35 airplanes 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 on U.S. operators to be $2,975, or $85 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.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0074;* 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 Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

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):

2015–09–02 Bombardier, Inc.: Amendment 39–18147. Docket No. FAA–2015–0074; Directorate Identifier 2014–NM–138–AD.

(a) Effective Date

This AD becomes effective June 4, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2E25 (Regional Jet Series 1000) airplanes, certificated in any category, serial numbers 19002 and subsequent.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that without an effective maintenance task to maintain the airplane's inherent level of safety, there is a potential that a dormant failure of the alternate release system of the landing gear can occur. We are issuing this AD to prevent failure of the alternate release system of the landing gear, which could prevent the landing gear from extending during a failure of the normal landing gear extension system.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance or Inspection Program Revision

Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate Task 32–01–00–101, ''Operational Check of the MLG [Main Landing Gear] and NLG [Nose Landing Gear] AES [Alternate Extension System] EMA [Electro-mechanical Actuator] and Release Mechanism (CRJ1000),'' for the operational check of the MLG and NLG AES EMA and release mechanism, as specified in Bombardier Temporary Revision (TR) ALI–0472, dated February 27, 2014, to Section 1–32 of Part 2, Airworthiness Limitations, of the Bombardier CRJ Series Regional Jet, Maintenance Requirements Manual, CSP B–053. The initial compliance time for the operational check is at the applicable time specified in paragraphs (g)(1) and (g)(2) of this AD.

(1) For airplanes that have accumulated 540 total flight hours or more as of the effective date of this AD: Within 660 flight hours after the effective date of this AD.

(2) For airplanes that have accumulated less than 540 total flight hours as of the effective date of this AD: Before the accumulation of 1,200 total flight hours.

(h) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Organization Approval (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2014–16, dated June 11, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0074-0003.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 this AD specifies otherwise.

(i) Bombardier Temporary Revision ALI–0472, dated February 27, 2014, to Section 1–32 of Part 2, Airworthiness Limitations, of the Bombardier CRJ Series Regional Jet Maintenance Requirements Manual, CSP B–053.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

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

(5) You may view this 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/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 14, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–09813 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0491; Directorate Identifier 2014–NM–023–AD; Amendment 39–18130; AD 2015–07–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–1A11 (CL–600), CL–600–2A12 (CL–601), and CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. This AD was prompted by a determination that the forward lugs of the flap hinge box might not conform to engineering drawings, which could result in premature fatigue cracking. This AD requires revising the maintenance or inspection program to include new airworthiness limitations tasks; and measuring the forward lug edge distance of each flap hinge box, inspecting for cracking and damage (*i.e.,* deformation or bearing failure) of the forward lug edge of each flap hinge box, and repairing any cracking or damage if necessary. We are issuing this AD to detect and correct non-conforming flap hinge box forward lugs, which could result in failure of the lugs and detachment of the flap hinge box and consequent detachment of the flap surface.

DATES: This AD becomes effective June 4, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 4, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0491* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com*; Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0491.

FOR FURTHER INFORMATION CONTACT: Ricardo Garcia, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7331; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model CL–600–1A11 (CL–600), CL–600–2A12 (CL–601), and CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. The NPRM published in the **Federal Register** on August 4, 2014 (79 FR 45140). The NPRM was prompted by a determination that the forward lugs of the flap hinge box might not conform to engineering drawings, which could result in premature fatigue cracking. The NPRM proposed to require revising the maintenance or inspection program to include new airworthiness limitations tasks; and measuring the forward lug edge distance of each flap hinge box, inspecting for cracking and damage (*i.e.,* deformation or bearing failure) of the forward lug edge of each flap hinge box, and repairing any cracking or damage if necessary. We are issuing this AD to detect and correct non-conforming flap hinge box forward lugs, which could result in failure of the lugs and detachment of the flap hinge box and consequent detachment of the flap surface.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2014–01, dated January 3, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–1A11 (CL–600), CL–600–2A12 (CL–601), and CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. The MCAI states:

> The aeroplane manufacturer has determined that the flap hinge box forward lugs edge distance may not conform to the engineering drawings. Non-conforming flap hinge box forward lugs may result in premature fatigue cracking.
>
> Failure of the lugs could lead to the detachment of the flap hinge box and consequently the detachment of the flap surface. The loss of a flap surface could adversely affect the continued safe operation of the aeroplane.
>
> This [Canadian] AD mandates the incorporation of new Time Limits/Maintenance Checks (TLMC) Airworthiness Limitations (AWL) tasks, and the measurement [and inspection for cracking and damage] of the forward lug edge distance of each flap hinge-box and rectification as required.

Corrective actions include repairing damage and cracking. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/*

#!documentDetail;D=FAA-2014-0491-0002.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 45140, August 4, 2014) and the FAA's response to each comment.

Request To Include Latest Revision of Service Information

Bombardier, Inc. requested that we revise the NPRM (79 FR 45140, August 4, 2014) to reflect the latest revisions of certain service information.

We agree to include the latest revisions of certain service information. Bombardier has issued Service Bulletin 604–57–007, Revision 01, dated November 12, 2014 (for Model CL–600–2B16 airplanes); and Service Bulletin 605–57–005, Revision 01, dated November 12, 2014 (for Model CL–600–2B16 airplanes). This new service information does not add new work for the affected airplanes and was revised to update labor hours needed to perform the work and clarify work instructions. We have changed this AD to reference Bombardier Service Bulletin 604–57–007, Revision 01, dated November 12, 2014; and Bombardier Service Bulletin 605–57–005, Revision 01, dated November 12, 2014, throughout. We have also added a new paragraph (k) to this AD to give credit for actions performed before the effective date of this AD using Bombardier Service Bulletin 604–57–007, dated September 26, 2013; and Bombardier Service Bulletin 605–57–005, dated September 26, 2013. We redesignated subsequent paragraphs accordingly.

Request To Correct Typographical Errors

Bombardier, Inc., and an FAA airframe and powerplant mechanic noted typographical errors in Table 1 of the NPRM (79 FR 45140, August 4, 2014) and requested they be corrected.

We agree that there are typographical errors. We have revised table 1 to paragraph (g) of this AD. The temporary revision (TR) number has been corrected to read ''5–275,'' in certain rows of table 1 to paragraph (g) of this AD, where in the NPRM (79 FR 45140, August 4, 2014) the previous TR number read ''5–276.'' The revision of Bombardier CL–604 Time Limits/Maintenance Checks Manual, dated July 8, 2013, was corrected from revision ''8'' to revision ''20.''

Explanation of Additional Change Made to This Final Rule

We have removed Note 1 to paragraph (g) from this final rule. Instead, we have included that information in paragraph (g) of this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 45140, August 4, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 45140, August 4, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information.

- Bombardier Service Bulletin 600–0762, dated September 26, 2013. This service information describes procedures for measuring the edge-to-edge distance of the forward lugs for the flap hinge boxes and contacting the manufacturer for corrective actions for Bombardier, Inc. Model CL–600–1A11 (CL–600) airplanes.

Bombardier Service Bulletin 601–0631, dated September 26, 2013. This service information describes procedures for measuring the edge-to-edge distance of the forward lugs for the flap hinge boxes and contacting the manufacturer for corrective actions for Bombardier, Inc. Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes.

- Bombardier Service Bulletin 604–57–007, Revision 01, dated November 12, 2014. This service information describes procedures for measuring the edge-to-edge distance of the forward lugs for the flap hinge boxes and contacting the manufacturer for corrective actions for Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes having serial numbers (S/Ns) 5301 through 5665 inclusive.
- Bombardier Service Bulletin 605–57–005, Revision 01, dated November 12, 2014. This service information describes procedures for measuring the edge-to-edge distance of the forward lugs for the flap hinge boxes and contacting the manufacturer for corrective actions for Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes having S/Ns 5701 through 5953 inclusive.
- Canadair Challenger Temporary Revision 5–157, dated July 8, 2013, to Outboard Flap—Hinge Box Forward Lugs, to Canadair Challenger Time Limits/Maintenance Checks Manual, PSP 605. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the outboard flap hinge box for Bombardier, Inc. Model CL–600–1A11 (CL–600) airplanes.

Canadair Challenger Temporary Revision 5–158, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadair Challenger Time Limits/Maintenance Checks Manual, PSP 605. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the inboard flap hinge box for Bombardier, Inc. Model CL–600–1A11 (CL–600) airplanes.

- Canadair Challenger Temporary Revision 5–262, Outboard and Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601. This service information describes airworthiness limitations tasks and compliance times for inspecting the forward lugs of the outboard and inboard flap hinge boxes for Bombardier, Inc. Model CL–600–2A12 (CL–601) airplanes.
- Canadair Challenger Temporary Revision 5–275, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601A–5. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the outboard flap hinge box for Bombardier, Inc. Model CL–600–2B16 (CL–601–3A Variants) airplanes.
- Canadair Challenger Temporary Revision 5–276, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601A–5. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the inboard flap hinge box for Bombardier, Inc. Model CL–600–2B16 (CL–601–3A and CL–601–3R Variant) airplanes.
- Task 57–50–00–121, Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box, of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of

Bombardier CL–605 Time Limits/Maintenance Checks Manual, Revision 8, dated July 8, 2013. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the inboard flap hinge box for Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes, having S/Ns 5701 through 5953 inclusive.

- Task 57–50–00–121, Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box, of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–604 Time Limits/Maintenance Checks Manual, Revision 20, dated July 8, 2013. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the inboard flap hinge box of Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes, having S/Ns 5301 through 5665 inclusive.
- Task 57–52–01–102, Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap, of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–605 Time Limits/Maintenance Checks Manual, Revision 8, dated July 8, 2013. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the outboard flap hinge box of Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes, having S/Ns 5701 through 5953 inclusive.
- Task 57–52–01–102, Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap, of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–604 Time Limits/Maintenance Checks Manual, Revision 20, dated July 8, 2013. This service information describes an airworthiness limitations task and compliance times for inspecting the forward lugs of the outboard flap hinge box of Bombardier, Inc. Model CL–600–2B16 (CL–604 Variant) airplanes, having S/Ns 5301 through 5665 inclusive.

This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

Costs of Compliance

We estimate that this AD affects 105 airplanes of U.S. registry.

We also estimate that it will take about 45 work-hours 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 on U.S. operators to be $401,625, or $3,825 per product.

We have received no definitive data that would enable us to provide cost estimates for the cost of parts or on-condition actions specified in this AD.

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.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0491*; 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 Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

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):

2015–07–02 Bombardier, Inc.: Amendment 39–18130. Docket No. FAA–2014–0491; Directorate Identifier 2014–NM–023–AD.

(a) Effective Date

This AD becomes effective June 4, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category.

(1) Bombardier, Inc. Model CL–600–1A11 (CL–600) airplanes, serial numbers 1004 through 1085 inclusive.

(2) Bombardier, Inc. Model CL–600–2A12 (CL–601) airplanes, serial numbers 3001 through 3066 inclusive.

(3) Bombardier, Inc. Model CL–600–2B16 (CL–601–3A and CL–601–3R Variants) airplanes, serial numbers 5001 through 5194 inclusive.

(4) Bombardier, Inc. Model CL–600–2B16 (CL–604 Variants) airplanes, serial numbers 5301 through 5665 inclusive, and 5701 through 5953 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by a determination that the forward lugs of the flap hinge box might not conform to engineering drawings, which could result in premature fatigue cracking. We are issuing this AD to detect and correct non-conforming flap hinge box forward lugs, which could result in failure of the lugs and detachment of the flap hinge box and consequent detachment of the flap surface.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, by incorporating the applicable airworthiness limitation (AWL) tasks as specified in table 1 to this paragraph. The initial compliance time for doing the task is at the applicable times specified in table 1 to this paragraph. For the incorporation of tasks specified in the temporary revisions (TRs) specified in table 1 to this paragraph of this AD that are a part of the maintenance or inspection program revision required by this paragraph, such incorporation may be done by inserting a copy of the applicable TRs specified in table 1 to this paragraph into the applicable ''time limits/maintenance checks'' (TLMC) manuals specified in table 1 to this paragraph. When the applicable TRs specified in table 1 to this paragraph have been included in general revisions of the applicable TLMC manual specified in table 1 to this paragraph, the general revisions may be inserted in the applicable TLMC manual specified in table 1 to this paragraph.

TABLE 1 TO PARAGRAPH (g) OF THIS AD—TASKS

Affected airplanes	Task No.	Canadair service information	Initial compliance time
Model CL–600–1A11 (CL–600 Variant) airplanes with inboard flaps having greater than 7,400 total flight cycles but equal to or less than 14,850 total flight cycles as of the effective date of this AD.	57–40–00–186	Canadair Challenger TR 5–158, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Within 500 flight cycles after the effective date of this AD, but not later than 15,100 total flight cycles.
Model CL–600–1A11 (CL–600 Variant) airplanes with inboard flaps having greater than 14,850 total flight cycles as of the effective date of this AD.	57–40–00–186	Canadair Challenger TR 5–158, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Within 250 flight cycles after the effective date of this AD.
Model CL–600–1A11 (CL–600 Variant) airplanes with inboard flaps having equal to or less than 7,400 total flight cycles.	57–40–00–186	Canadair Challenger TR 5–158, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Before the accumulation of 7,900 total flight cycles.
Model CL–600–1A11 (CL–600 Variant) airplanes with outboard flaps having greater than 7,500 total flight cycles, but equal to or less than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–160	Canadair Challenger TR 5–157, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Within 500 flight cycles after the effective date of this AD, but no later than 11,600 total flight cycles.
Model CL–600–1A11 (CL–600 Variant) airplanes with outboard flaps having greater than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–160	Canadair Challenger TR 5–157, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Within 250 flight cycles after the effective date of this AD.
Model CL–600–1A11 (CL–600 Variant) airplanes with outboard flaps having equal to or less than 7,500 total flight cycles.	57–40–00–160	Canadair Challenger TR 5–157, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 605.	Before the accumulation of 8,000 total flight cycles.
Model CL–600–2A12 (CL–601 Variant) airplanes with inboard flaps having greater than 7,400 total flight cycles, but equal to or less than 14,850 total flight cycles, as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–262, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Within 500 flight cycles after the effective date of this AD, but no later than 15,100 total flight cycles.
Model CL–600–2A12 (CL–601 Variant) airplanes with inboard flaps with greater than 14,850 total flight cycles as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–262, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Within 250 flight cycles after the effective date of this AD.
Model CL–600–2A12 (CL–601 Variant) airplanes with inboard flaps with equal to or less than 7,400 total flight cycles as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–262, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Before the accumulation of 7,900 total flight cycles.
Model CL–600–2A12 (CL–601 Variant) airplanes with outboard flaps with greater than 7,500 total flight cycles but equal to or less than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–175	Canadair Challenger TR 5–262, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Within 500 flight cycles after the effective date of this AD, but not later than 11,600 total flight cycles.
Model CL–600–2A12 (CL–601 Variant) airplanes with outboard flaps having greater than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–175	Canadair Challenger TR 5–262, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Within 250 flight cycles after the effective date of this AD.

TABLE 1 TO PARAGRAPH (g) OF THIS AD—TASKS—Continued

Affected airplanes	Task No.	Canadair service information	Initial compliance time
Model CL–600–2A12 (CL–601 Variant) airplanes with outboard flaps having equal to or less than 7,500 total flight cycles as of the effective date of this AD.	57–40–00–175	Canadair Challenger TR 5–262, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601–5.	Before the accumulation of 8,000 total flight cycles.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive with inboard flaps having greater than 7,400 total flight cycles but equal to or less than 14,850 total flight cycles as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–276, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Within 500 flight cycles after the effective date of this AD, but not later than 15,100 total flight cycles.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive, with inboard flaps having greater than 14,850 total flight cycles as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–276, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Within 250 flight cycles.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive, with inboard flaps having equal to or less than 7,400 total flight cycles as of the effective date of this AD.	57–40–01–101	Canadair Challenger TR 5–276, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Before the accumulation of 7,900 total flight cycles.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive, with outboard flaps having greater than 7,500 total flight cycles but equal to or less than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–174	Canadair Challenger TR 5–275, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Within 500 flight cycles after the effective date of this AD, but no later than 11,600 total flight cycles.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive, with outboard flaps having greater than 11,350 total flight cycles as of the effective date of this AD.	57–40–00–174	Canadair Challenger TR 5–275, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Within 250 flight cycles after the effective date of this AD.
Model CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/Ns 5001 through 5194 inclusive, with outboard flaps having equal to or less than 7,500 total flight cycles as of the effective date of this AD.	57–40–00–174	Canadair Challenger TR 5–275, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, of the Canadair Challenger TLMC Manual, PSP 601A–5.	Before the accumulation of 8,000 total flight cycles.
Model CL–600–2B16 (CL–604 Variant) airplanes having S/Ns 5301 through 5665 inclusive, with inboard flaps.	57–50–00–121	Section 5–10–30, Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box, of Part 2, Airworthiness Limitations, of Bombardier CL–604 TLMC Manual, Revision 20, dated July 8, 2013.	Before the accumulation of 7,800 total flight cycles, or within 500 flight cycles after the effective date of this AD, whichever occurs later.
Model CL–600–2B16 (CL–604 Variant) airplanes, S/Ns 5301 through 5665 inclusive.	57–52–01–102	Section 5–10–30, Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap, of Part 2, Airworthiness Limitations, of Bombardier CL–604 TLMC Manual, Revision 20, dated July 8, 2013.	Before the accumulation of 7,800 total flight cycles, or within 500 flight cycles after the effective date of this AD, whichever occurs later.
Model CL–600–2B16 (CL–604 Variant) airplanes, S/Ns 5701 through 5953 inclusive.	57–50–00–121	Section 5–10–30, Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box, of Part 2, Airworthiness Limitations, of Bombardier CL–605 TLMC Manual, Revision 8, dated July 8, 2013.	Before the accumulation of 7,800 total flight cycles, or within 500 flight cycles after the effective date of this AD, whichever occurs later.
Model CL–600–2B16 (CL–604 Variant) airplanes, S/Ns 5701 through 5953 inclusive.	57–52–01–102	Section 5–10–30, Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap, of Part 2, Airworthiness Limitations, of Bombardier CL–605 TLMC Manual, Revision 8, dated July 8, 2013.	Before the accumulation of 7,800 total flight cycles, or within 500 flight cycles after the effective date of this AD, whichever occurs later.

(h) Lug Edge Measurement and Inspection

At the applicable times specified in table 2 to this paragraph and paragraph (i)(1) of this AD, measure the forward lug edge distance of all flap hinge boxes, and do a general visual inspection for cracking and damage (*i.e.,* deformation or bearing failure) of the forward lug edge of all flap hinge boxes, in accordance with the applicable service bulletin specified in table 2 to this paragraph and paragraph (i)(1) of this AD.

TABLE 2 TO PARAGRAPHS (h) AND (i)(1) OF THIS AD—COMPLIANCE TIMES FOR LUG EDGE MEASUREMENT AND INSPECTION

Airplane models	Affected flaps	Compliance time	Service information
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Inboard flaps having less than or equal to 7,400 total flight cycles as of the effective date of this AD.	Before the accumulation of 7,900 total flight cycles, or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Inboard flaps having greater than 7,400 total flight cycles, but equal to or less than 14,850 total flight cycles as of the effective date of this AD.	Before the accumulation of 15,100 total flight cycles, or within 500 flight cycles or 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Inboard flaps having greater than 14,850 total flight cycles as of the effective date of this AD.	Within 250 flight cycles or 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Outboard flaps having equal to or less than 7,500 total flight cycles as of the effective date of this AD.	Before the accumulation of 8,000 total flight cycles, or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Outboard flaps having greater than 7,500 total flight cycles but less than or equal to 11,350 total flight cycles as of the effective date of this AD.	Within 500 flight cycles or 48 months after the effective date of this AD, whichever occurs first; but not exceeding 11,600 total flight cycles.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–1A11 (CL–600) airplanes having S/N 1004 through 1085 inclusive.	Outboard flaps having greater than 11,350 total flight cycles as of the effective date of this AD.	Within 250 flight cycles or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 600–0762, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variants) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Inboard flaps having less than or equal to 7,400 total flight cycles as of the effective date of this AD.	Before the accumulation of 7,900 total flight cycles, or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Inboard flaps having greater than 7,400 total flight cycles, but equal to or less than 14,850 total flight cycles, as of the effective date of this AD.	Within 500 flight cycles or within 48 months after the effective date of this AD, whichever occurs first; but not exceeding 15,100 total flight cycles.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Inboard flaps having greater than 14,850 total flight cycles as of the effective date of this AD.	Within 250 flight cycles or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Outboard flaps having less than or equal to 7,500 total flight cycles as of the effective date of this AD.	Before the accumulation of 8,000 total flight cycles, or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Outboard flaps having greater than 7,500 total flight cycles, but equal to or less than 11,350 total flight cycles, as of the effective date of this AD.	Within 500 flight cycles or within 48 months after the effective date of this AD; but not exceeding 11,600 total flight cycles.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.
Model CL–600–2A12 (CL–601 Variant) and CL–600–2B16 (CL–601–3A and –3R Variant) airplanes having S/N 3001 through 3066 inclusive, and 5001 through 5194 inclusive.	Outboard flaps having greater than 11,350 total flight cycles as of the effective date of this AD.	Within 250 flight cycles or 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 601–0631, dated September 26, 2013.

TABLE 2 TO PARAGRAPHS (h) AND (i)(1) OF THIS AD—COMPLIANCE TIMES FOR LUG EDGE MEASUREMENT AND INSPECTION—Continued

Airplane models	Affected flaps	Compliance time	Service information
Model CL–600–2B16 (CL–604 Variant) airplanes having S/Ns 5301 through 5665 inclusive.	Outboard and inboard flaps	Before the accumulation of 7,800 total flight cycles or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 604–57–007, Revision 01, dated November 12, 2014.
Model CL–600–2B16 (CL–604 Variant) airplanes having S/Ns 5701 through 5953 inclusive.	Outboard and inboard flaps	Before the accumulation of 7,800 total flight cycles or within 48 months after the effective date of this AD, whichever occurs first.	Bombardier Service Bulletin 605–57–005, Revision 01, dated November 12, 2014.

(i) Corrective Actions

(1) If, during the measurement required by paragraph (h) of this AD, the lug edge distance is equal to or greater than the limit specified in the applicable service bulletin specified in table 2 to paragraph (h) of this AD and this paragraph, no further action is required by this paragraph.

(2) If, during the measurement required by paragraph (h) of this AD, the lug edge distance is below the limit specified in the applicable service bulletin specified in table 2 to paragraphs (h) and (i)(1) of this AD, before further flight, repair using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(3) If, during the inspection required by paragraph (h) of this AD, any cracking or damage is found, before further flight, repair using a method approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(j) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance in accordance with the procedures specified in paragraph (l) of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 604–57–007, dated September 26, 2013 (for Model CL–600–2B16 airplanes); or Bombardier Service Bulletin 605–57–005, dated September 26, 2013 (for Model CL–600–2B16 airplanes); which are not incorporated by reference in this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, Engine and Propeller Directorate, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2014–01, dated January 3, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0491-0004.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 this AD specifies otherwise.

(i) Bombardier Service Bulletin 600–0762, dated September 26, 2013.

(ii) Bombardier Service Bulletin 601–0631, dated September 26, 2013.

(iii) Bombardier Service Bulletin 604–57–007, Revision 01, dated November 12, 2014.

(iv) Bombardier Service Bulletin 605–57–005, Revision 01, dated November 12, 2014.

(v) Canadair Challenger Temporary Revision 5–157, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadair Challenger Time Limits/Maintenance Checks Manual, PSP 605.

(vi) Canadair Challenger Temporary Revision 5–158, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadair Challenger Time Limits/Maintenance Checks Manual, PSP 605.

(vii) Canadair Challenger Temporary Revision 5–262, Outboard and Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601.

(viii) Canadair Challenger Temporary Revision 5–275, Outboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601A–5.

(ix) Canadair Challenger Temporary Revision 5–276, Inboard Flap—Hinge Box Forward Lugs, dated July 8, 2013, to Canadian Challenger Time Limits/Maintenance Checks Manual PSP 601A–5.

(x) Task 57–50–00–121 Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–605 Time Limits/Maintenance Checks Manual, Revision 8, dated July 8, 2013.

(xi) Task 57–50–00–121 Special Detailed Inspection of the Forward Lugs of the Inboard Flap Hinge Box of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–604 Time Limits/Maintenance Checks Manual, Revision 20, dated July 8, 2013.

(xii) Task 57–52–01–102 Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–605 Time Limits/Maintenance Checks Manual, Revision 8, dated July 8, 2013.

(xiii) Task 57–52–01–102 Special Detailed Inspection of the Hinge—Box Forward Lugs of the Outboard Flap of Section 5–10–30 of Part 2, ''Airworthiness Limitations,'' of Bombardier CL–604 Time Limits/Maintenance Checks Manual, Revision 20, dated July 8, 2013.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

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

(5) You may view this 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/cfr/ibr-locations.html.*

Issued in Renton, Washington, on March 25, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–07802 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0589; Directorate Identifier 2014–NM–069–AD; Amendment 39–18148; AD 2015–09–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A318–111 and –112 airplanes and Model A319, A320, and A321 series airplanes. This AD was prompted by reports of cracks on the forward corner fittings of engine pylon aft secondary structures. This AD requires repetitive inspections of certain forward corner fittings of the pylon aft secondary structures, and corrective actions if necessary. This AD also provides optional terminating action for the repetitive inspections. We are issuing this AD to detect and correct detachment of the lower fairing attachment and/or loss of the aft fixed fairing with the movable fairing from the airplane in flight, which could result in damage to the airplane.

DATES: This AD becomes effective June 4, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 4, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0589* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0589.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A318–111 and –112 airplanes and Model A319, A320, and A321 series airplanes. The NPRM published in the **Federal Register** on September 3, 2014 (79 FR 52267). The NPRM was prompted by reports of cracks on the forward corner fittings of engine pylon aft secondary structures. The NPRM proposed to require repetitive inspections of certain forward corner fittings of the pylon aft secondary structures, and corrective actions if necessary. The NPRM also proposed to provide optional terminating action for the repetitive inspections. We are issuing this AD to detect and correct detachment of the lower fairing attachment and/or loss of the aft fixed fairing with the movable fairing from the airplane in flight, which could result in damage to the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0064, dated March 14, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition. The MCAI states:

> Several operators of A320 family aeroplanes have reported finding cracks on the forward corner fittings of engine pylon aft secondary structures, on the lateral face (lateral panel side). In some cases, these cracks had propagated onto the forward face (Rib 11 side). Investigation results have highlighted that these cracks are initiated by stress corrosion.
>
> This condition, if not detected and corrected, could lead to loss (*i.e.* detachment from the aeroplane) of the lower fairing attachment at Rib 10, and/or loss of the aft fixed fairing with the movable fairing, possibly resulting in * * * [damage to the airplane].
>
> For the reasons described above, this [EASA] AD requires repetitive detailed inspections (DI) of the right hand (RH) Part Number (P/N) D54530014201 and left hand (LH) P/N D54530014200 corner fittings of engine pylon aft secondary structures (pre-mod 38067 or pre-Airbus Service Bulletin (SB) A320–54–1019) to detect cracks or deformation in the splicing area with corner fitting between Ribs 11–12 and, depending on findings, replacement of the corner fittings.
>
> This [EASA] AD also recognizes that replacement of the corner fittings with improved parts (as per Airbus SB A320–54–1019) constitutes a terminating action for the repetitive DI required by this [EASA] AD.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0589-0003.*

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 52267, September 3, 2014) and the FAA's response to each comment.

Requests to Reference Revised Service Bulletins

United Airlines and US Airways requested that we revise the NPRM (79 FR 52267, September 3, 2014) to reference Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014, in lieu of Airbus Service Bulletin A320–54–1019, Revision 01, dated April 10, 2008. United Airlines also requested that we revise the NPRM to reference Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014, in lieu of Airbus Service Bulletin A320–54–1022, Revision 02, dated July 12, 2013.

We agree with the commenters' requests to reference revised service bulletins. Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014, improves the test procedures, and Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014, specifies that certain actions in the Accomplishment Instructions are

required for compliance (RC). Both service bulletins state that no additional work is required for airplanes modified by any previous issue. We have revised paragraphs (g) and (h) of this AD to reference Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014, and paragraphs (h)(2) and (i) of this AD to reference Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014, as the appropriate sources of service information for accomplishing the required actions.

We have redesignated paragraph (l) of the NPRM (79 FR 52267, September 3, 2014) as paragraph (l)(1) of this AD and revised it to give credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–54–1022, Revision 02, dated July 12, 2013. We have added new paragraph (l)(2) to this AD to give credit for actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–54–1019, Revision 01, dated April 10, 2008.

Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014, steps that are identified as RC must be done to comply with the AD. However, steps that are not identified as RC are recommended. We have added an explanation of RC steps in the preamble of this AD. We have also added new paragraph (m)(3) to this AD to specify compliance with RC steps.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 52267, September 3, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 52267, September 3, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Explanation of ''RC'' Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directives Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which procedures and tests in the service information are required for compliance with an AD. Differentiating these procedures and tests from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The procedures and tests identified as RC (required for compliance) in any service information have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

Procedures and tests that are identified as RC in any service information must be done to comply with the AD. However, procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC will require approval of an AMOC.

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014. This service information describes procedures for inspections of forward corner fittings of the engine pylon aft secondary structures, and corrective actions.

We also reviewed Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014. This service information describes procedures for replacement of the corner fittings on the engine pylons.

This service information is reasonably available at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0589. Or see **ADDRESSES** for other ways to access this service information.

Costs of Compliance

We estimate that this AD affects 851 airplanes of U.S. registry.

We also estimate that it would take about 30 work-hours 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 on U.S. operators to be $2,170,050, or $2,550 per product.

In addition, we estimate the optional terminating modification would take about 60 work-hours and require parts costing about $932 per product, for a cost of $6,032 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this 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.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0589;* 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 Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

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):

2015–09–03 Airbus: Amendment 39–18148. Docket No. FAA–2014–0589; Directorate Identifier 2014–NM–069–AD.

(a) Effective Date

This AD becomes effective June 4, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, except for airplanes on which Airbus Modification 33844 or Modification 33847, as applicable, has been embodied in production.

(1) Airbus Model A318–111 and –112 airplanes.

(2) Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(4) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 54, Nacelles/pylons.

(e) Reason

This AD was prompted by reports of cracks on the forward corner fittings of engine pylon aft secondary structures. We are issuing this AD to detect and correct detachment of the lower fairing attachment and/or loss of the aft fixed fairing with the movable fairing from the airplane in flight, which could result in damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections

At the latest of the times specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD: Do a detailed inspection for cracking of forward corner fittings having part number (P/N) D54530014201 (right-hand (RH)) and P/N D54530014200 (left-hand (LH)) of the pylon aft secondary structures, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014, except as provided by paragraph (j) of this AD. Repeat the inspection thereafter at intervals not to exceed 15,000 flight cycles or 22,500 flight hours, whichever occurs first. Accomplishment of the actions specified in paragraph (i) of this AD terminates the actions required by this paragraph.

(1) Within 15,000 flight cycles or 22,500 flight hours, whichever occurs first since first flight of the airplane.

(2) Within 5,000 flight cycles or 7,500 flight hours after the effective date of this AD, without exceeding 40,750 flight cycles or 60,750 flight hours, whichever occurs first since first flight of the airplane.

(3) Within 750 flight cycles or 750 flight hours, whichever occurs first after the effective date of this AD.

(h) Related Investigative and Corrective Actions

If any crack is found on the corner fittings of a pylon during any inspection required by paragraph (g) of this AD: Before further flight, do a detailed inspection for cracking of the lower and medium spars, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014.

(1) If any damage is found: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(2) If no damage is found: Within 5,000 flight cycles or 7,500 flight hours, whichever occurs first after the detailed inspection specified in the introductory text to paragraph (h) of this AD, modify the airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014.

(i) Optional Terminating Action

Modification of an airplane by installation of corner fittings having P/N D0041092120000 (RH) and P/N D0041092120100 (LH) on both pylons, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014, constitutes terminating action for the repetitive inspections required by paragraph (g) of this AD.

(j) Parts Installation Limitation

Airplanes on which Airbus Modification 38067 (installation of new corner fittings) has been embodied in production, and airplanes already modified in service as described in Airbus Service Bulletin A320–54–1019, are not affected by the requirements of paragraph (g) of this AD, provided that no corner fittings having P/N D54530014201 (RH) or P/N D54530014200 (LH) have been installed since first flight of the airplane, or since modification, as applicable.

(k) Parts Installation Prohibition

(1) As of the effective date of this AD, for airplanes on which Airbus Modification 38067 has been embodied in production on both pylons, and for airplanes previously modified in service as described in Airbus Service Bulletin A320–54–1019: Do not install any corner fittings having P/N D54530014201 (RH) or P/N D54530014200 (LH).

(2) After modification as required by paragraph (h) of this AD, or after optional modification as specified in paragraph (i) of this AD, as applicable: Do not install any corner fittings having P/N D54530014201 (RH) or P/N D54530014200 (LH).

(l) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using a service bulletin identified in paragraph (l)(1)(i), (l)(1)(ii), or (l)(1)(iii) of this AD; this service information is not incorporated by reference in this AD.

(i) Airbus Service Bulletin A320–54–1022, dated July 7, 2009.

(ii) Airbus Service Bulletin A320–54–1022, Revision 01, dated September 29, 2011.

(iii) Airbus Service Bulletin A320–54–1022, Revision 02, dated July 12, 2013.

(2) This paragraph provides credit for actions required by paragraphs (h)(2) and (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–54–1019, Revision 01, dated April 10, 2008, which is not incorporated by reference in this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using

any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance: Except as required by paragraph (i) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information EASA Airworthiness Directive 2014–0064, dated March 14, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0589-0003.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 this AD specifies otherwise.

(i) Airbus Service Bulletin A320–54–1019, Revision 02, dated April 15, 2014.

(ii) Airbus Service Bulletin A320–54–1022, Revision 03, dated April 15, 2014.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

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

(5) You may view this 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/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 17, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–09811 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–BRCA–17884; PA.PD191235A.00.3]

RIN 1024–AE23

Special Regulations, Areas of the National Park System, Bryce Canyon National Park, Bicycling

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: The National Park Service is planning to construct a paved, multi-use visitor path in Bryce Canyon National Park. The path will be approximately 6.2 miles long and be open to several uses, including running, walking, and bicycling. National Park Service regulations require promulgation of a special regulation to designate new routes for bicycle use off park roads and outside developed areas.

DATES: This rule is effective June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Daniel J. Cloud, Chief of Facility Management, Bryce Canyon National Park, P.O. Box 640201, Bryce Canyon, UT 84764–0201. Phone: (435) 834–4720. Email: *daniel_cloud@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

Bryce Canyon National Park (BRCA or park) is in south-central Utah. The park encompasses approximately 35,835 acres and ranges between 6,600 and 9,100 feet in elevation. BRCA was originally established as a national monument by presidential proclamation in 1923. The park was renamed Utah National Park in 1924, and the name was changed to Bryce Canyon National Park in 1928.

The park's most noted feature is the eroded landscape below the east rim of the Paunsaugunt Plateau. The erosional force of frost-wedging and the dissolving power of rainwater have worn away the colorful and weak limestone rock into bizarre shapes, including slot canyons, windows, fins, and spires called ''hoodoos.'' Because the park transcends 2,500 feet of elevation, the park exists in three distinct climatic zones characterized by spruce/fir forest, ponderosa pine forest, and pinyon pine/juniper woodlands. The diversity of forest and meadow habitats provides a high degree of plant and animal diversity. BRCA is also one of the best places to experience a truly dark night sky.

The park's purpose statement, which provides the foundation for park management, administration, and use decisions, states that ''Bryce Canyon National Park protects and conserves resources integral to a landscape of unusual scenic beauty exemplified by highly colored and fantastically eroded geological features, including rock fins and spires, for the benefit and enjoyment of the people.'' (May 2014 Foundation Document). The park's Foundation Document identifies ''increased use of alternative transportation (*e.g.,* biking, hiking) within and surrounding the park'' as an opportunity to protect clean air—one of the fundamental resources of the park. The proposal to construct a multi-use path in the park will support the park's purpose statement by providing a new opportunity for safe enjoyment and protection of the fundamental resources in the park.

Purpose of the Multi-Use Path

The primary purpose of the multi-use path is to relieve safety problems for visitors of all ages who choose to use non-motorized transportation to experience the park and adjacent United States Forest Service (USFS) areas near Bryce Canyon City. Increases in visitation of the park (30% increase between 2008 and 2012) are leading to transportation system capacity problems and traffic congestion. Cyclists and pedestrians need a way to travel to and within the park that is safer, provides a better visitor experience, and promotes non-motorized travel between nearby communities and the park as well as between key destinations in the park.

The path will enhance the park's transportation system by connecting the park's gateway communities with high visitor use areas along the canyon rim in the Bryce Amphitheater and with other key features of the park. The proposed path will also connect to the existing transportation system, including visitor shuttle buses, hiking trails and walking paths, parking lots, and roads. This will link major visitor attractions and facilities with both non-motorized and motorized transportation modes. Visitor safety will be improved

by separating motor vehicles from bicyclists, pedestrians, and other non-motorized user groups where possible.

The multi-use path will consist of two contiguous sections constructed in two phases. The first segment will be approximately 3.9 miles long. This segment will begin at the park boundary near the main park road to/from Bryce Canyon City. The path will roughly parallel the main park road and continue to the visitor center and North Campground area. The path will then run southeast toward the canyon rim, behind the General Store and Lodge area, and to the Sunset Point parking lot where it will turn back to parallel the main park road. The path will then leave the main park road and branch toward Inspiration Point parking area. The NPS intends to complete construction of the first segment by the fall 2015.

The second segment will be approximately 2.3 miles long and will mostly follow Bryce Point road to a terminus at a trailhead just below the Bryce Point parking area. The NPS will construct the second segment as resources become available.

In total, the path will be approximately 6.2 miles long within the boundary of the park. No portion of the proposed path will be constructed below the canyon rim on park lands, nor in proposed wilderness areas inside the park. For most locations, the path will consist of a 10-foot wide paved asphalt surface. The path will generally parallel the main park road to provide separation between users and vehicles to reduce the likelihood of related safety problems. Spurs from the main path alignment will be designed to provide visitor access to key viewpoints and other landscape features. The path will continue outside of the boundary of the park through Bryce Canyon City and Dixie National Forest. This will provide a safe, efficient, and family-friendly way to access these connected areas.

Environmental Assessment

In September 2014, the NPS published the Multi-use Visitor Path Environmental Assessment (EA). On December 23, 2014, the Regional Director for the Intermountain Region signed a Finding of No Significant Impact (FONSI) that identified the preferred alternative (Alternative Alignment A) in the EA as the selected action. The rule implements the selected action as described in the EA and the FONSI. The EA and the FONSI, which contain a full description of the purpose and need for taking action, scoping, the alternatives considered, maps of the proposed multi-use path, and the environmental impacts associated with the project, may be viewed on the park's planning Web site at *http://parkplanning.nps.gov/brca,* by clicking on the link entitled ''Bryce Canyon National Park Multi-Use Path'' and then clicking on the link entitled ''Document List.''

Final Rule

The rule complies with the requirement of 36 CFR 4.30, which requires a special regulation to designate new bicycle routes off park roads and outside of developed areas. The EA and FONSI address bicycle use on the multi-use path and evaluate (i) the suitability of the trail surface for bicycle use; and (ii) life cycle maintenance costs, safety considerations, methods to prevent or minimize user conflict, methods to protect natural and cultural resources and mitigate impacts, and integration with commercial services and alternative transportation systems in compliance with 36 CFR 4.30(d)(1)–(2).

The rule adds a new section 7.94 to 36 CFR part 7—Special Regulations, Areas of the National Park Service for Bryce Canyon National Park. The rule authorizes the superintendent to designate all or a portion of two segments of the proposed 6.2-mile-long multi-use path as a route for bicycle use. The Superintendent will notify the public of any such designation through one or more of the methods outlined in 36 CFR 1.7, and place the designation on maps that are available in the office of the Superintendent and other places convenient to the public.

The rule also authorizes the superintendent to establish closures or restrictions for bicycle use on designated routes after considering public health and safety, resource protection, and other management activities and objectives, provided public notice is given under 36 CFR 1.7.

Summary of Public Comments

We published the proposed rule at 79 FR 70137 (November 25, 2014). We accepted comments through the mail, hand delivery, and through the Federal eRulemaking Portal at *http://www.regulations.gov.* Comments were accepted through January 26, 2015, and we received eight timely comments. Seven comments supported the proposed rule and did not request any change. One comment opposed the proposed rule. A summary of this comment and the NPS response is provided below. After considering the public comments and after additional review, we did not make any changes in the final rule.

Comment: One comment stated that mountain biking is harmful to wildlife, people, and the environment. Specifically, this comment raised concerns that mountain biking destroys habitat, accelerates erosion, kills animals and plants, and creates conflicts with wildlife and other park visitors, including hikers and equestrians.

NPS Response: This rule allows the superintendent to authorize bicycle use on the paved, shared-use path, and not off-trail or on non-paved, soft-surface trails. The multi-use path will not be a soft surface backcountry mountain bike path, and will not go below the canyon rim on park lands, or in proposed wilderness areas inside the park. The path will use a hardened surface to accommodate a wide range of non-motorized uses in the front country only. Potential impacts to park resources, including wildlife and habitat, soils, special status species and vegetation, as well as impacts to visitor use and experience were evaluated in the EA. Adverse impacts to these resources and visitor use were determined to be minor. The FONSI documented the finding that no significant impacts will occur, and concluded that bicycle use on the proposed path does not pose any significant impact that would rise to the levels that would constitute impairment.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and

an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on information contained in the economic analyses found in the report entitled ''Cost-Benefit Analysis: Proposed Regulations to Designate New Routes for Bicycle Use in Bryce Canyon National Park'' which is available online at *http://parkplanning.nps.gov/brca* by clicking on the link entitled ''Bryce Canyon National Park Multi-Use Path'' and then clicking on the link entitled ''Document List.''

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This rule does not affect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This rule only affects use of NPS administered lands and waters. It has no outside effects on other areas. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175. During the environmental assessment process, we consulted with the 10 Native American groups associated with BRCA and determined that there are no substantial direct effects on federally recognized Indian tribes.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required because we reached the FONSI. A copy of the EA and FONSI can be found online at *http://parkplanning.nps.gov/brca* by clicking on the link entitled ''Bryce Canyon National Park Multi-Use Path'' and then clicking on the link entitled ''Document List.''

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects in not required.

Drafting Information: The primary author of this regulation is Jay P. Calhoun, Regulations Program Specialist, National Park Service.

List of Subjects in 36 CFR Part 7

National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service amends 36 CFR part 7 as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for Part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 462(k); Sec. 7.96 also issued under 36 U.S.C. 501–511, D.C. Code 10–137 (2001) and D.C. Code 50–2201.07 (2001).

■ 2. Add § 7.94 to read as follows:

§ 7.94 Bryce Canyon National Park.

(a) The Superintendent may designate for bicycle use routes or portions of routes on the following sections of the park's multi-use recreational path:

(1) A section between the park boundary near Bryce Canyon City and Inspiration Point parking area (approximately 3.9 miles);

(2) A section between the intersection of Bryce Point road and Inspiration Point road, and a trailhead near Bryce Point parking area (approximately 2.3 miles).

(b) The Superintendent will provide notice of all bicycle route designations through one or more of the methods listed in § 1.7 of this chapter, and place the designations on maps that are available in the office of the Superintendent and other places convenient to the public.

(c) The Superintendent may open or close designated bicycle routes, or portions thereof, or establish conditions or restrictions for bicycle use after considering public health and safety, natural and cultural resource protection, carrying capacity, and other management activities and objectives.

(1) The Superintendent will provide public notice of all such actions through one or more of the methods listed in § 1.7 of this chapter.

(2) Violating a closure, condition, or restriction is prohibited.

Dated: April 17, 2015.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2015–10170 Filed 4–29–15; 8:45 am]

BILLING CODE 4310–EJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52

[EPA–R06–OAR–2014–0846; FRL–9927–10–Region 6]

Approval and Promulgation of Implementation Plans; Texas; Revisions to the State Implementation Plan; Stage I Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking a direct final action to approve revisions to the Texas State Implementation Plan (SIP) related to Stage I Regulations that were submitted by the State of Texas on November 12, 2014. The EPA evaluated the SIP submittal from Texas and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under the federal CAA.

DATES: This direct final rule is effective on June 29, 2015 without further notice, unless the EPA receives relevant adverse comment by June 1, 2015. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2014–0846, by one of the following methods:

(1) *www.regulations.gov:* Follow the on-line instructions.

(2) *Email:* Ms. Tracie Donaldson at *donaldson.tracie@epa.gov*.

(3) *Mail or Delivery:* Ms. Tracie Donaldson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2014–0846. EPA's policy is that all comments received 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 information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through *http://www.regulations.gov* or email, if you believe that it is CBI or otherwise protected from disclosure. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means that 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 *http://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 along with any disk or CD–ROM submitted. 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 and any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Tracie Donaldson, (214) 665–6633, *donaldson.tracie@epa.gov*. To inspect the hard copy materials, please schedule an appointment with Ms. Donaldson or Mr. Bill Deese at (214) 665–7253.

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

Table of Contents

I. Background

A. CAA and SIPs

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets National Ambient Air Quality Standards (NAAQS). The NAAQS currently address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPA-approved SIP provisions and control strategies are federally enforceable. States revise the SIP as needed and submit revisions to the EPA for review and approval.

B. Why do we regulate VOCs?

Volatile Organic Compound is a term used to describe a class of chemicals that react in the atmosphere in the presence of sunlight to form ozone. Sources include vehicle exhaust, gasoline vapors, oil-based paints and industrial operations. A regulatory definition of Volatile Organic Compounds can be found at 40 CFR 51.100(s). The definition in Texas can be found in 30 TAC 115.10. Oxygen in the atmosphere reacts with VOCs and Oxides of Nitrogen to form ozone, a key component of urban smog. Inhaling even low levels of ozone can trigger a variety of health problems including chest pains, coughing, nausea, throat irritation, and congestion. It also can worsen bronchitis and asthma. Exposure to ozone can also reduce lung capacity in healthy adults.

C. What is Stage I Vapor Recovery?

Capturing the vapors from the gasoline station storage tanks as tank-trucks fill these tanks, and returning the vapors to the tank-truck is commonly known as Stage I vapor recovery. The tank-truck then carries the vapors back to the bulk gasoline plant or terminal. To insure the vapors are not lost in transit, the Texas rules also include requirements that the gasoline tank-trucks be tested for vapor tightness. We are approving the vapor recovery requirements and the vapor tightness requirements.

D. SIP Revision Submitted on November 12, 2014

On September 10, 2014, Texas Commission on Environmental Quality (TCEQ) adopted revisions to 30 Texas Administrative Code (TAC) Chapter 115, Control of Air Pollution from Volatile Organic Compounds,

Subchapter A. *Definitions* and Subchapter C. *Volatile Organic Compound Transfer Operations.* This review will determine if the changes to the Texas SIP are consistent with the requirements of the Clean Air Act and EPA's policy and guidance.

II. EPA's Evaluation

As detailed in the Technical Support Document (TSD) accompanying this action, the TCEQ submitted a SIP revision to the Stage I regulations found in 30 TAC 115, Subchapter A. *Definitions* and Subchapter C. *Volatile Organic Compound Transfer Operations*. The TCEQ adopted amended sections 115.10, 115.221, 115.222, 115.224–115.227 and 115.229 of 30 TAC Chapter 115, Control of Air Pollution from Volatile Organic Compounds and corresponding revisions to the state implementation plan. The revisions preserve existing Stage I testing requirements in the 1997 ozone nonattainment counties and specify Stage I testing requirements for gasoline dispensing facilities located in the 12 ozone nonattainment counties and 4 ozone maintenance counties that will be affected by the decommissioning of the Stage II vapor recovery equipment rule revision and in the 95 counties that are subject to the state Stage I rule but not Stage II requirements. The adopted revisions also establish testing requirements that are more consistent with federal Stage I testing in 40 CFR part 63, subpart CCCCCC and are more appropriate for Stage I facilities.

Previously, in separate actions, we found that Texas' Stage I regulations meet Reasonably Available Control Technology (RACT) requirements for the 1997 ozone standard in Dallas-Fort Worth area (January 14, 2009, 74 FR 1903) and for the Houston-Galveston-Brazoria area (April 2, 2013, 63 FR 19599). The current revisions update RACT where applicable for 1997 ozone nonattainment counties in Texas.

The revisions will enhance the EPA-approved SIP because they will not result in any loss in emission reductions, will become more enforceable with the test methods in place and will be more consistent with the federal Stage I testing requirements; therefore, we are approving them into the Texas SIP.

III. Final Action

For the reasons stated above and in the TSD, the EPA is taking direct final action to approve revisions to the Texas SIP pertaining to Stage I regulations at 30 TAC, Chapter 115, Subchapter A: *Definitions,* Section 115.10 and Subchapter C, Division 2: *Filling of Gasoline Storage Vessels (Stage I) for Motor Vehicle Fuel Dispensing Facilities,* Sections 115.221, 115.222, 115.224–115.227 and 115.229, adopted on September 10, 2014, and submitted as revisions to the Texas SIP on November 12, 2014.

We are approving the revisions to the Texas SIP under section 110 of the Act. We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no relevant adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on June 29, 2015 without further notice unless we receive relevant adverse comment by June 1, 2015. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Incorporation by Reference

In this direct final rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Texas Stage I requirements described in the Final Action section above. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. 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, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 29, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposed of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: April 22, 2015.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart SS—Texas

■ 2. In § 52.2270(c), the table titled ''EPA Approved Regulations in the Texas SIP'' is amended by adding, in sequential order, the entry for section 115.221; and revising the entries for sections 115.10, 115.222, 115.224 through 115.227, and 115.229 to read as follows:

§ 52.2270 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/ submittal date	EPA approval date	Explanation
*	*	*	*	*
Chapter 115 (Reg 5)—Control of Air Pollution From Volatile Organic Compounds Subchapter A—Definitions				
115.10	Definitions	9/10/2014	4/30/2015 [Insert FR citation].	
*	*	*	*	*
Subchapter C—Volatile Organic Compound Transfer Operations				
*	*	*	*	*
Division 2: Filling of Gasoline Storage Vessels (Stage I) for Motor Vehicle Fuel Dispensing Facilities				
115.221	Emission Specifications	9/10/2014	4/30/2015 [Insert FR citation].	
115.222	Control Requirements	9/10/2014	4/30/2015 [Insert FR citation].	
*	*	*	*	*
115.224	Inspection Requirements	9/10/2014	4/30/2015 [Insert FR citation].	
115.225	Testing Requirements	9/10/2014	4/30/2015 [Insert FR citation].	
115.226	Recordkeeping Requirements	9/10/2014	4/30/2015 [Insert FR citation].	
115.227	Exemptions	9/10/2014	4/30/2015 [Insert FR citation].	
115.229	Counties and Compliance Schedules.	9/10/2014	4/30/2015 [Insert FR citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2015–10122 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52

[EPA–R06–OAR–2015–0054; FRL–9926–91–Region 6]

Approval and Promulgation of Implementation Plans; State of Arkansas; Revisions to the State Implementation Plan; Fee Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking a direct final action to approve revisions to the Arkansas State Implementation Plan (SIP) related to the Fee Regulations section of the Arkansas SIP that were submitted by the State of Arkansas on November 6, 2012. The EPA has evaluated the SIP submittal from Arkansas and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under section 110 of the Act.

DATES: This direct final rule is effective on June 29, 2015 without further notice, unless the EPA receives relevant adverse comment by June 1, 2015. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2015–0054, by one of the following methods:

(1) *www.regulations.gov:* Follow the on-line instructions.

(2) *Email:* Ms. Tracie Donaldson at *donaldson.tracie@epa.gov.*

(3) *Mail or Delivery:* Ms. Tracie Donaldson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2015–0054. EPA's policy is that all comments received 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 information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through *http://www.regulations.gov* or email, if you believe that it is CBI or otherwise protected from disclosure. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means that 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 *http://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 along with any disk or CD–ROM submitted. 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 and any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm. Docket:* The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Tracie Donaldson, (214) 665–6633, *donaldson.tracie@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Donaldson or Mr. Bill Deese at (214) 665–7253.

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

Table of Contents

I. Background

A. CAA and SIPs

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets National Ambient Air Quality Standards (NAAQS). The NAAQS currently address six criteria pollutants: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPA-approved SIP provisions and control strategies are federally enforceable. States revise the SIP as needed and submit revisions to the EPA for approval.

B. SIP Revision Submitted on November 6, 2012

On June 22, 2012, the Arkansas Pollution Control and Ecology Commission (APC&EC) adopted revisions to Regulation 9—Permit Fee Regulations, Regulation 19—Regulations of the Arkansas Plan of Implementation for Air Pollution Control, and Regulation 26—Regulations of the Arkansas Operating Air Permit Program. On October 26, 2012, APC&EC adopted additional revisions to Regulation 19. Governor Beebe submitted these revised regulations as a revision to the Arkansas SIP in a letter dated November 6, 2012.

The November 6th, 2012, letter requested that the EPA repeal the current SIP-approved permit fee program provisions found in Regulation 9 and replace with the new provisions included in the submittal for Chapters 1, 2,[1] 3, 5, and 9, of Regulation 9 which relate to the State's air program. This action will repeal the current SIP-approved version of Regulation 9 and replace with the current version of Regulation 9, Chapters 1, 2,[2] 3, 5, and 9 as requested by Arkansas. This includes revisions to Regulation 9, Chapter 5 addressing fee requirements for carbon dioxide and methane. The revisions to Regulations 19 and 26 will be addressed in separate rulemaking by the EPA.

II. The EPA's Evaluation

As detailed in the Technical Support Document (TSD) accompanying this action, the ADEQ[3] submitted a SIP

[1] Only the portions of Chapter 2 that relate to the Air program are included in the Arkansas SIP. The definitions to include are specified in ADEQ letter to the EPA dated December 11, 2014, which is available in our rulemaking docket and addressed in more detail in the TSD.

[2] Ibid.

[3] The Arkansas Department of Environmental Quality (ADEQ) is the state agency that is charged with protecting, enhancing and restoring the environment for Arkansas. The Arkansas Pollution Control and Ecology Commission (APC&EC) is the environmental policy-making body for Arkansas.

revision to the fee regulations requesting a withdrawal of the current SIP-approved permit fee program and replacement with the submitted revised fee regulations containing a new fee schedule and associated provisions specific to the State's air program. The EPA has reviewed the submitted revisions and determined that the submitted revised fee program is consistent with the general requirements at CAA section 110(a)(2)(E)(i) to provide necessary assurances that the State will have adequate funding to carry out the provisions of the Arkansas SIP as it pertains to major and minor source Title I permitting and CAA section 110(a)(2)(L) that requires states to charge necessary fees for the development and implementation of major source Title I permits. The Arkansas SIP is intended to implement Title I of the CAA, while Title V requirements are not generally included in SIPs.[4] The repeal and replace included in the November 6, 2012, SIP submittal more accurately represents the current fee structure than the previously approved SIP, which was approved by EPA on November 12, 1986. Based on EPA's evaluation of the fee assessment provisions submitted, EPA finds the submitted repeal and replace of, and subsequent revisions to Arkansas Regulation 9 establishing fee requirements for permits is consistent with sections 110(a)(2)(E)(i) and 110(a)(2)(L) of the CAA.

III. Final Action

For the reasons stated above and in the TSD, the EPA is taking direct final action to approve revisions to the Arkansas SIP pertaining to title I fees. Specifically, the EPA is deleting the current SIP-approved fee program and approving in its place the revised Arkansas fee program at Regulation 9, Chapters 1, 2,[5] 3, 5 and 9 effective on July 9, 2012, and submitted as revisions to the Arkansas SIP on November 6, 2012.

We are approving the revisions to the Arkansas SIP under section 110 of the Act. We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no relevant adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on June 29, 2015 without further notice unless we receive relevant adverse comment by June 1, 2015. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Incorporation by Reference

In this direct final rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Arkansas title I Permit Fees described in the Final Action section above. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. 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, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The 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).

[4] The Arkansas air permitting program is a one permit system (meaning that title I and title V are issued together for major sources) the fee regulations are combined in Regulation 9. The EPA has not evaluated the revised Regulation 9 Fee Provisions for sufficiency under 40 CFR 70.9 of the title V state operating permit program.

[5] Only the portions of Chapter 2 that relate to the Air program are included in the Arkansas SIP. The definitions to include are specified in ADEQ letter to the EPA dated December 11, 2014, which is available in our rulemaking docket and addressed in more detail in the TSD.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 29, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposed 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 17, 2015.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart E—Arkansas

■ 2. In § 52.170(c), the table titled ''EPA-Approved Regulations in the Arkansas SIP'' is amended by revising the heading and entries for ''Arkansas Regulation No. 9: Permit Fees,'' to read as follows:

§ 52.170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP

State citation	Title/ subject	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	* *
Regulation No. 9: Fee Regulation				
Chapter 1	Title	7/9/2012	4/30/2015 [Insert FR citation].	
Chapter 2	Definitions	7/9/2012	4/30/2015 [Insert FR citation].	The following definitions do not relate to the air program and are not being approved into the SIP: ''Category'', ''Certificate'', ''Confined Animal Operation'', ''Discretionary Major Facility'', ''Evaluation'', ''Laboratory'', ''Major Municipal Facility'', ''Non-Municipal Major Facility'', ''Parameter'', ''Program''.
Chapter 3	Permit Fee Payment	7/9/2012	4/30/2015 [Insert FR citation].	
Chapter 5	Air Permit Fees	7/9/2012	4/30/2015 [Insert FR citation].	
Chapter 9	Administrative Procedures.	7/9/2012	4/30/2015 [Insert FR citation].	

* * * * *

[FR Doc. 2015–09905 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2009–0234 and EPA–HQ–OAR–2011–0044; FRL–9926–74–OAR]

RIN 2060–AR62

Reconsideration on the Mercury and Air Toxics Standards (MATS) and the Utility New Source Performance Standards; Final Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action denying petitions for reconsideration.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is providing notice that it has responded to 23 petitions for reconsideration of the final rules titled National Emission Standards for Hazardous Air Pollutants (NESHAP) From Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance (NSPS) for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units, published in the **Federal Register** on February 16, 2012. The agency previously granted reconsideration on several discrete issues and took final action on reconsideration through documents published in the **Federal Register** on April 24, 2013, and November 19, 2014. The Administrator denied the remaining requests for reconsideration in separate letters to the petitioners dated April 21, 2015. A document providing a full explanation of the agency's rationale for each denial is in the docket for these rules.

DATES: Effective April 30, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Eddinger, Sector Policies and Programs Division (D243–01), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5426; fax number: (919) 541–5450; email address: *eddinger.jim@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. How can I get copies of this document and other related information?

This **Federal Register** document, the petitions for reconsideration, the letters denying the petitions for reconsideration, and the document titled ''Denial of Petitions for

Reconsideration of Certain Issues: MATS and Utility NSPS'' (Reconsideration Response Document) are available in the dockets the EPA established under Docket ID No. EPA–HQ–OAR–2009–0234 and Docket ID No. EPA–HQ–OAR–2011–0044. The Reconsideration Response Document is available in both the MATS and Utility NSPS dockets by conducting a search of the title ''Denial of Petitions for Reconsideration of Certain Issues: MATS and Utility NSPS.'' All documents in the dockets are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center (EPA/DC), Room 3334, EPA WJC West Building, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air Docket is (202) 566–1742. This **Federal Register** document and the Reconsideration Response Document denying the petitions can also be found on the EPA's Web site at *http://www.epa.gov/ttn/atw/utility/utilitypg.html.*

II. Judicial Review

Section 307(b)(1) of the Clean Air Act (CAA) indicates which Federal Courts of Appeals have venue for petitions for review of final EPA actions. This section provides, in part, that the petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit if: (i) The agency action consists of ''nationally applicable regulations promulgated, or final action taken, by the Administrator,'' or (ii) such actions are locally or regionally applicable, if ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator find and publishes that such action is based on such a determination.''

The EPA has determined that its actions denying the petitions for reconsideration are of nationwide scope and effect for purposes of section 307(d)(1) because the actions directly affect the ''National Emission Standards for Hazardous Air Pollutants (NESHAP) From Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance (NSPS) for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units,'' both of which were found to be of nationwide scope and effect. Thus, any petitions for review of the EPA's decisions denying petitioners' requests for reconsideration must be filed in the United States Court of Appeals for the District of Columbia Circuit by June 29, 2015.

III. Description of Action

On February 16, 2012, pursuant to sections 111 and 112 of the CAA, the EPA published the final rules titled ''National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units'' (77 FR 9304). The NESHAP rule issued pursuant to CAA section 112 is referred to as the Mercury and Air Toxics Standards (MATS), and the NSPS rule issued pursuant to CAA section 111 is referred to as the Utility NSPS. Following promulgation of the final rules, the Administrator received petitions for reconsideration of numerous provisions of both MATS and the Utility NSPS pursuant to CAA section 307(d)(7)(B).

The EPA received 20 petitions for reconsideration of the MATS rule and 3 petitions for reconsideration of the Utility NSPS. The EPA received petitions for reconsideration of the MATS rule from the following organizations: American Public Power Association, ARIPPA, Babcock & Wilcox, Basin Electric Power Cooperative, Climate Policy Group, Coal Utilization Research Council, Earthjustice, East Kentucky Power Cooperative, Edgecombe/Spruance Genco, Edison Mission Energy, FirstEnergy, Hawaiian Electric Company, Institute of Clean Air Companies, International Brotherhood of Boilermakers, Power4Georgians, Puerto Rico Electric Power Authority, Southern Company, State of Texas (Texas Commission on Environmental Quality, Texas Public Utility Commission, Railroad Commission of Texas), Utility Air Regulatory Group (UARG), and Wolverine Power Supply Cooperative. The EPA received petitions for reconsideration of the Utility NSPS from the following organizations: Air Products, State of Texas (Texas Commission on Environmental Quality, Texas Public Utility Commission, Railroad Commission of Texas), and UARG.

CAA section 307(d)(7)(B) states that ''[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b)).'' Thus, the EPA is only required to grant a CAA section 307(d)(7)(B) petition for reconsideration if the petitioner demonstrates both: (1) That it was impractical to raise the objection during the public comment period, or that the grounds for such objection arose after the public comment period but within the time specified for judicial review (*i.e.,* within 60 days after publication of the final rulemaking in the **Federal Register**); and (2) that the objection is of central relevance to the outcome of the rule.

On November 30, 2012, the EPA issued a proposed rule reconsidering certain new source MATS, the requirements applicable during periods of startup and shutdown for MATS and the Utility NSPS (for the PM standard only), certain definitional and monitoring issues in the Utility NSPS, and additional technical corrections to both MATS and the Utility NSPS (77 FR 71323). On April 24, 2013, the EPA issued the final action on reconsideration of the new source MATS, the definitional and monitoring provisions in the Utility NSPS, and the technical corrections in both rules (78 FR 24073). The EPA issued the final action on reconsideration of the startup and shutdown provisions in the MATS and Utility NSPS on November 19, 2014 (79 FR 68777). In addition, on February 17, 2015, the EPA proposed additional technical corrections to the final MATS rule and the Utility NSPS (80 FR 8442). These actions addressed many issues

raised in the petitions for reconsideration of the final MATS rule and the Utility NSPS.

On April 21, 2015, the Administrator, Gina McCarthy, signed letters to petitioners denying the remaining issues in the petitions for reconsideration. The EPA carefully reviewed the petitions and evaluated each issue raised in the petitions for reconsideration to determine if they meet the CAA section 307(d)(7)(B) criteria for reconsideration. The EPA denied the remaining issues in the petitions for reconsideration because they do not meet the criteria for reconsideration and/or are moot as explained in detail in the Reconsideration Response Document. That document articulates in detail the rationale for the EPA's final response to each of the remaining issues in the petitions for reconsideration received on the final MATS rule and the Utility NSPS.

As explained in the Reconsideration Response Document, a significant majority of the issues raised in the petitions for reconsideration were or could have been raised in comments on the proposed MATS and Utility NSPS. In addition, many of the parties that filed petitions for reconsideration of the final MATS and Utility NSPS also filed petitions for review of the final rules in the United States Court of Appeals for the District of Columbia Circuit (Court or D.C. Circuit). Many of the issues raised in the petitions for reconsideration were also raised in the D.C. Circuit litigation, and other reconsideration issues could have been raised in that litigation. On April 15, 2014, the Court denied all petitions for review of MATS and the Utility NSPS. *White Stallion Energy Center* v. *EPA,* 784 F.3d 1222 (D.C. Cir. 2014); cert. granted, *State of Michigan* v. *EPA,* No. 14–46 (and consolidated cases). As the Court may only consider issues raised during the period for public comment, issues raised in the litigation and addressed by the Court clearly do not meet the criteria for reconsideration in CAA section 307(d)(7)(B). Moreover, parties may not use this final action denying reconsideration as a basis to litigate issues that could have been raised in the initial litigation.

Dated: April 21, 2015.

Gina McCarthy,

Administrator.

[FR Doc. 2015–10118 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R06–OAR–2013–0763; FRL–9927–00–Region 6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico; Control of Emissions From Existing Sewage Sludge Incinerator Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve Clean Air Act (CAA) section 111(d)/129 negative declarations for the States of Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico, for existing sewage sludge incinerator (SSI) units. These negative declarations certify that existing SSI units subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdictions of Texas, Oklahoma, Arkansas, and New Mexico (including the City of Albuquerque). EPA is accepting the negative declarations in accordance with the requirements of the CAA.

DATES: This rule is effective on June 29, 2015 without further notice, unless EPA receives relevant adverse comment by June 1, 2015. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2013–0763, by one of the following methods:

- *www.regulations.gov.* Follow the online instructions.
- *Email:* Mr. Kenneth W. Boyce at *boyce.kenneth@epa.gov.*
- *Mail or delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket No. EPA–R06–OAR–2013–0763. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit 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.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Boyce, (214) 665–7259, email address *boyce.kenneth@epa.gov.* To inspect the hard copy materials please contact Mr. Boyce or Mr. Bill Deese at (214) 665–6645.

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

Outline

I. Background

EPA's statutory authority for the regulation of new and existing solid waste incineration units is outlined in CAA sections 129 and 111. Section 129 of the CAA is specific to solid waste combustion and requires EPA to establish performance standards for each category of solid waste incineration units. These standards include new source performance standards (NSPS), applicable to new units, and emissions guidelines and other requirements applicable to

existing units. Under CAA section 129, an NSPS or emissions guideline must contain numerical emissions limitations for particulate matter, opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans. While the NSPS is directly applicable to affected facilities, the emissions guidelines for existing units are intended for states to use in order to develop a state plan to submit to EPA. Once approved by EPA, the state plan becomes federally enforceable. If a State does not submit an approvable state plan to EPA, EPA is responsible for developing, implementing, and enforcing a federal plan.

While section 129 of the CAA is specific to the combustion of solid waste, it also relies on CAA section 111 in promulgating the NSPS and emissions guidelines. Section 111 of the CAA gives EPA the statutory authority to promulgate an NSPS and/or emissions guideline for certain categories of stationary sources, and describes the procedural requirements for the development and implementation of these standards. More specifically, CAA section 111(d) requires EPA to establish procedures for States to submit a state plan to EPA for the regulation of existing sources whenever emissions guidelines are promulgated. The general provisions for the submittal and approval of state plans are codified in 40 CFR part 60, subpart B and 40 CFR part 62, subpart A. States have options other than submitting a state plan in order to fulfill their obligations under CAA sections 111(d) and 129. If a State does not have any existing solid waste incineration units for the relevant emissions guidelines, 40 CFR 60.23(b) and 62.06 provide that a letter may be submitted certifying that no such units exist within the State (*i.e.,* negative declaration) in lieu of a state plan. The negative declaration exempts the State from the requirements of subpart B that would otherwise require the submittal of a CAA section 111(d)/129 plan.

On March 21, 2011 (76 FR 15372), EPA promulgated new source performance standards (40 CFR part 60, subpart LLLL) for new SSI units, and emission guidelines (40 CRF part 60, subpart MMMM), for existing SSI units. Existing SSI units are units that commenced construction on or before October 14, 2010. The Texas Commission on Environmental Quality (TCEQ), Oklahoma Department of Environmental Quality (ODEQ), Arkansas Department of Environmental Quality (ADEQ), New Mexico Environment Department (NMED) and the City of Albuquerque, New Mexico have each determined that there are no existing SSI units subject to CAA sections 111(d) and 129 requirements in their individual air pollution control jurisdictions. In order to fulfill obligations under CAA sections 111(d) and 129, TCEQ, ODEQ, ADEQ, NMED and the City of Albuquerque, New Mexico submitted negative declaration letters to EPA on January 28, 2013, November 14, 2011, May 21, 2012, October 6, 2011 and September 12, 2011, respectively. The submittal of these declarations exempts TCEQ, ODEQ, ADEQ, NMED and the City of Albuquerque, New Mexico from the requirement to submit a state plan for existing SSI units.

II. Final Action

In this Direct Final action, EPA is amending part 62 to reflect receipt of the negative declaration letters from the TCEQ, ODEQ, ADEQ, NMED and the City of Albuquerque, New Mexico, certifying that there are no existing SSI units subject to 40 CFR part 60, subpart MMMM, in their respective jurisdictions, in accordance with 40 CFR 60.5010, 40 CFR 62.06, and Section 111(d) of the CAA. If a designated facility (*i.e.,* existing SSI unit) is later found within any noted jurisdiction after publication of this **Federal Register** action, then the overlooked facility will become subject to the requirements of the Federal plan for that designated facility, including the compliance schedule. The Federal plan will no longer apply, if we subsequently receive and approve the 111(d) plan from the jurisdiction with the overlooked facility. EPA is publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the negative declarations if relevant adverse comments are received. This rule will be effective on June 29, 2015 without further notice unless we receive relevant adverse comment by June 1, 2015. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

III. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely notifies the public of EPA receipt of negative declarations from air pollution control agencies without any existing SSI units in their jurisdiction. This action imposes no requirements. Accordingly, EPA certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a negative declaration for SSI units, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

With regard to negative declarations for SSI units received by EPA from states, EPA's role is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority

to disapprove a 111(d)/129 plan negative declaration submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a 111(d)/129 plan negative declaration submission, to use VCS in place of a 111(d)/129 plan submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and advancement Act of 1995 (15 U.S.C. 272 note) do not apply. 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.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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 rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 29, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action approving a negative declaration for SSI units may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: April 16, 2015.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 62 is amended as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart E—Arkansas

■ 2. Subpart E is amended by adding an undesignated center heading and § 62.856 to read as follows:

Emissions From Existing Sewage Sludge Incinerator Units

§ 62.856 Identification of sources—negative declaration.

Letter from the Arkansas Department of Environmental Quality, dated May 21, 2012, certifying that there are no known existing sewage sludge incineration (SSI) units subject to 40 CFR part 60, subpart MMMM, within its jurisdiction.

Subpart GG—New Mexico

■ 3. Subpart GG is amended by adding an undesignated center heading and § 62.7892 to read as follows:

Emissions From Existing Sewage Sludge Incinerator Units

§ 62.7892 Identification of sources.

(a) *Negative declaration for the State of New Mexico excluding Bernalillo County.* Letter from the New Mexico Environment Department, dated October 6, 2011, certifying that there are no known existing sewage sludge incineration (SSI) units subject to 40 CFR part 60, subpart MMMM, within its jurisdiction, excluding Bernalillo County, New Mexico.

(b) *Negative declaration for Bernalillo County.* Letter from the City of Albuquerque Air Pollution Control Division, dated September 12, 2011, certifying that there are no known existing sewage sludge incineration (SSI) units subject to 40 CFR part 60, subpart MMMM, within the jurisdiction of the City of Albuquerque and Bernalillo County, New Mexico.

Subpart LL—Oklahoma

■ 4. Subpart LL is amended by adding an undesignated center heading and § 62.9121 to read as follows:

Emissions From Existing Sewage Sludge Incinerator Units

§ 62.9121 Identification of sources—negative declaration.

Letter from the Oklahoma Department of Environmental Quality, dated November 14, 2011, certifying that there are no known existing sewage sludge incineration (SSI) units subject to 40 CFR part 60, subpart MMMM, within its jurisdiction.

Subpart SS—Texas

■ 5. Subpart SS is amended by adding an undesignated center heading and § 62.10912 to read as follows:

Emissions From Existing Sewage Sludge Incinerator Units

§ 62.10912 Identification of sources—negative declaration.

Letter from the Texas Commission on Environmental Quality, dated January 28, 2013, certifying that there are no existing sewage sludge incineration (SSI) units subject to the requirements of 40 CFR part 60, subpart MMMM, within its jurisdiction.

[FR Doc. 2015–10043 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 418

[CMS–1609–CN]

RIN 0938–AS10

Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on August 22, 2014 entitled ''Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting

Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice.''

DATES: *Effective Date:* October 1, 2014.

FOR FURTHER INFORMATION CONTACT: Debra Dean-Whittaker, (410) 786–0848.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2014–18506 of August 22, 2014 (79 FR 50451), there were a number of technical errors that are identified and corrected in the Correction of Errors section below. The provisions in this correction document are effective as if they had been included in the document published on August 22, 2014. Accordingly, the corrections are effective October 1, 2014.

II. Summary of Errors

On page 50492, in Table 8, we omitted the description of a quality reporting measure ''Providing Support for Religious and Spiritual Beliefs''. We are adding the omitted measure to the table.

On Page 50493, in Table 9, we listed an incorrect deadline for the ''Monthly data collection April–June 2015 (Q2).'' We inadvertently provided November 1, 2015 as the deadline. We are correcting this error to reflect the correct monthly data collection deadline date of November 11, 2015.

III. Waiver of Proposed Rulemaking

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 in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. Rulemaking is unnecessary because this notice merely fixes errors and makes no policy changes.

IV. Correction of Errors

In FR Doc. 2014–18506 of August 22, 2014 (79 FR 50451), make the following corrections:

1. On page 50492, in Table 8—''Hospice Experience of Care Survey Quality Measures and Their Items'', after the quality measure description of ''Getting help for Symptoms'' and before the quality measure description of ''Information Continuity'' add the following quality measure description to read as follows:

Providing Support for Religious and Spiritual Beliefs

(Support for religious or spiritual beliefs includes talking, praying, quiet time, or other ways of meeting your religious or spiritual needs.)

While your family member was in hospice care, how much support for your religious or spiritual beliefs did you get from the hospice team?

2. On page 50493, in Table 9—Data Submission Dates 2015–1016 For CAHPS® Hospice Survey, under the quarterly data submission deadline column the date ''November 1, 2015'' is corrected to read ''November 11, 2015''.

Dated: April 24, 2015.

C'Reda Weeden,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2015–10169 Filed 4–29–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

CFR Correction

In Title 45 of the Code of Federal Regulations, Parts 1 to 199, revised as of October 1, 2014, on page 933, in § 156.285, reinstate paragraph (d)(2) after paragraph (d)(1)(iii)(B) to read as follows:

§ 156.285 Additional standards specific to SHOP. [Corrected]

* * * * *

(d) * * *

(2) If a qualified employer chooses to withdraw from participation in the SHOP, the QHP issuer must terminate coverage for all enrollees of the withdrawing qualified employer.

* * * * *

[FR Doc. 2015–09681 Filed 4–29–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 131021878–4158–02]

RIN 0648–XD921

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch 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; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the Western Aleutian district (WAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access fishery. This action is necessary to prevent exceeding the 2015 total allowable catch (TAC) of Pacific ocean perch in this area allocated to vessels participating in the BSAI trawl limited access fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), April 27, 2015, through 2400 hrs, A.l.t., December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

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 2015 TAC of Pacific ocean perch, in the WAI, allocated to vessels participating in the BSAI trawl limited access fishery was established as a directed fishing allowance of 164 metric tons by the final 2014 and 2015 harvest specifications for groundfish in the BSAI (79 FR 12108, March 4, 2014).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the WAI by vessels participating in the BSAI trawl limited access fishery.

After the effective dates of this closure, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

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) 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 closure of the Pacific ocean perch directed fishery in the WAI for vessels participating in the BSAI trawl limited access fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 24, 2015. 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.

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: April 27, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10120 Filed 4–27–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 83
Thursday, April 30, 2015

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–0758; Notice No. 25–15–05–SC]

Special Conditions: L–3 Communications Integrated Systems, Boeing Model 747–8 Series Airplanes; Therapeutic Oxygen for Medical Use

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Boeing Model 747–8 series airplanes. This airplane, as modified by L–3 Communications Integrated Systems (L–3), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is therapeutic oxygen for medical use installed in an executive-interior airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send your comments on or before May 20, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–0758 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 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: Robert Hettman, FAA, Propulsion and Mechanical Systems, ANM–112, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2683; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On May 10, 2011, L–3 applied for a supplemental type certificate (STC) for therapeutic oxygen for medical use in the Boeing Model 747–8 series airplanes equipped with executive interiors. The Boeing Model 747–8 series airplane, which is a derivative of the Boeing Model 747–400 airplane currently approved under Type Certificate No. A20WE, is a four-engine jet-transport airplane that will have a maximum takeoff weight of 970,000 lbs. The Model 747–8 airplane will have 153 seats approved for taxi, takeoff, and landing (19 crewmembers and 134 passengers).

Section 25.1445 includes standards for oxygen-distribution systems when oxygen is supplied to flightcrew and passengers. If a common source of supply is used, § 25.1445(a)(2) requires a means to separately reserve the minimum supply required by the flightcrew. This requirement was included in § 25.1445 when the regulations were codified, and was originally added to Civil Air Regulations 4b.831 at Amendment 4b–13, effective September 21, 1949.

It is apparent that the regulation is intended to protect the flightcrew by ensuring that an adequate supply of oxygen is available to complete a descent and landing following a loss of cabin pressure. When the regulation was written, the only passenger-oxygen system designs were supplemental-oxygen systems intended to protect passengers from hypoxia in the event of a decompression. Existing passenger-oxygen systems did not include design features that would allow the flightcrew to control oxygen to passengers during flight. There are no similar requirements when oxygen is supplied from the same source to passengers for use during a decompression and for discretionary/first-aid use any time during the flight. In the proposed design, the passenger and therapeutic-oxygen systems use the same source of oxygen. The flightcrew-oxygen emergency system uses a dedicated source of oxygen independent from the passenger-oxygen system. An oxygen-duration chart and operation procedures will be incorporated into the ''Flight Crew Operating Manual'' and ''Flight Manual Supplement,'' as part of the STC, to provide information to the flightcrew to determine when to cease operation of the therapeutic system as a

means by which to reserve the minimum supply of supplemental passenger oxygen.

Type Certification Basis

Under the provisions of § 21.101, L–3 must show that the Boeing Model 747–8 series airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A20WE, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* Title 14, Code of Federal Regulations (14 CFR) part 25) do not contain adequate or appropriate safety standards for the Boeing Model 747–8 series airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for an STC to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 747–8 series airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34; and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

L–3 is seeking certification of an interior modification to Boeing Model 747–8 series airplanes to include executive and medical-patient transport. As a part of the executive-interior installation, the airplane will be outfitted with a therapeutic-oxygen system. The therapeutic-oxygen system shares the same supply of oxygen with the existing passenger-oxygen system and consists of multiple constant-flow oxygen outlets located throughout the cabin. The flightcrew can turn the therapeutic-oxygen system on and off from the flight deck to allow use at any point during the flight, and to preserve a sufficient remaining oxygen reserve, in the event therapeutic oxygen is used for medical purposes, to accommodate the passengers in the event of an emergency-oxygen situation.

The gaseous passenger-oxygen system will be modified to accommodate additional supply cylinders and several therapeutic-oxygen outlets located throughout the cabin. Each therapeutic outlet will provide a constant flow of oxygen at either 2 or 4 liters per minute. The flightcrew will be able to control the flow of therapeutic oxygen at any time during flight. Therapeutic-oxygen systems previously have been certified, and were generally considered an extension of the passenger-oxygen system for the purpose of defining the applicable regulations. As a result, the applicable regulations included those that applied to oxygen systems in general, or supplemental-oxygen systems.

Discussion

No specific regulations address the design and installation of oxygen systems used specifically for therapeutic applications. Existing requirements, such as §§ 25.1309, 25.1441(b) and (c), 25.1451, and 24.1453, in the Boeing Model 747–8 airplane certification basis applicable to this STC project, provide some design standards appropriate for oxygen-system installations. However, additional design standards for systems supplementing the existing oxygen system are needed to complement the existing applicable requirements. The addition of equipment involved in this installation, and the unsafe conditions that can exist when the oxygen content of an enclosed area becomes too high because of system leaks, malfunction, or damage from external sources, make it necessary to ensure that adequate safety standards are applied to the design and installation of the oxygen system in Boeing Model 747–8 series airplanes. These potential hazards also necessitate development and application of appropriate additional design and installation standards.

These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these proposed special conditions are applicable to the Boeing Model 747–8 series airplanes. Should L–3 apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A20WE to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Certification of these Boeing Model 747–8 series airplanes is currently scheduled for June 2015. Therefore, because a delay would significantly affect the applicant's installation of the system and the certification of the airplane, we are shortening the public-comment period to 20 days.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability, and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type-certification basis for Boeing Model 747–8 series airplanes as modified by L–3 Communications Integrated Systems.

The distribution system for the therapeutic-oxygen system must be designed and installed as follows:

When oxygen is supplied to passengers for both supplemental and therapeutic purposes, the distribution system must be designed for either—

1. A source of supplemental supply for protection from hypoxia following a loss of cabin pressure, and a separate source for therapeutic purposes, or

2. A common source of supply, with means to separately reserve the minimum supply required by the passengers for supplemental use following a loss of cabin pressure.

Issued in Renton, Washington, on April 17, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–10103 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 005–2015]

Privacy Act of 1974; Implementation; Correction

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Department of Justice (the Department or DOJ) published a proposed rule in the **Federal Register** on March 26, 2015 (80 FR 15951), which added a new section to the Department's Privacy Act exemption regulations to exempt a DOJ-wide system of records from certain subsections of the Privacy Act. The heading of the document referenced ''CPCLO Order No. 004–2014'' when the Chief Privacy and Civil Liberties Order (CPCLO) number should read 004–2015. This document corrects the CPCLO number.

DATES: This correction is effective on April 30, 2015.

FOR FURTHER INFORMATION CONTACT: Robin Moss, Privacy Analyst, 202–514–8568.

Correction

In the **Federal Register** of March 26, 2015, in FR Doc. 2015–06938, on page 15951, in the heading, second line, correct the number to read:

[CPCLO Order No. 004–2015]

Dated: April 2, 2015.

Kristi Lane Scott,

Deputy Director, Office of Privacy and Civil Liberties, United States Department of Justice.

[FR Doc. 2015–10106 Filed 4–29–15; 8:45 am]

BILLING CODE 4410–FB–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0054; FRL–9926–90-Region 6]

Approval and Promulgation of Implementation Plans; State of Arkansas; Revisions to the State Implementation Plan; Fee Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Arkansas State Implementation Plan (SIP) related to the Fee Regulations section of the Arkansas SIP that were submitted by the State of Arkansas on November 6, 2012. The EPA has evaluated the SIP submittal from Arkansas and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under section 110 of the Act.

DATES: Written comments should be received on or before June 1, 2015.

ADDRESSES: Comments may be mailed to Ms. Tracie Donaldson, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Tracie Donaldson, (214) 665–6633; email address *donaldson.tracie@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: April 17, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–09903 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2014–0846; FRL–9927–09–Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Revisions to the State Implementation Plan; Stage I Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Texas State Implementation Plan (SIP) related to Stage I Regulations that were submitted by the State of Texas on November 12, 2014. The EPA evaluated the Texas SIP submittal and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under the federal CAA.

DATES: Written comments should be received on or before June 1, 2015.

ADDRESSES: Comments may be mailed to Ms. Mary Stanton, Chief, Air Grants Section (6PD–S), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tracie Donaldson, (214) 665–6633, *Donaldson.tracie@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: April 22, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–10121 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R06–OAR–2013–0763; FRL–9927–01-Region 6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico; Control of Emissions From Existing Sewage Sludge Incinerator Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Clean Air Act (CAA) section 111(d)/129 negative declarations for the States of Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico, for existing sewage sludge incinerator (SSI) units. These negative declarations certify that existing SSI units subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdictions of Texas, Oklahoma, Arkansas, and New Mexico (including the City of Albuquerque).

DATES: Written comments must be received on or before June 1, 2015.

ADDRESSES: Comments may be mailed to Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Boyce, (214) 665–7259, *boyce.kenneth@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the negative declarations submitted by the Texas Commission on Environmental Quality (TCEQ), the Oklahoma Department of Environmental Quality (ODEQ), the Arkansas Department of Environmental Quality (ADEQ), New Mexico Environment Department (NMED) and the City of Albuquerque, New Mexico, certifying that there are no existing sewage sludge incinerator (SSI) units within their respective jurisdictions. These negative declarations meet the requirements of 40 CFR 62.06. EPA is approving the negative declaration as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule, which is located in the rules section of this **Federal Register**.

Dated: April 16, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–10041 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting Rulemaking Proceedings

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa–14(c)(2)(B), notice is hereby given concerning the reasons for not conducting rulemaking proceedings to add diabetes mellitus as an injury associated with the measles-mumps-rubella vaccine to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Avril M. Houston, MD, MPH, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, Maryland 20857, or by telephone at (301) 443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99–660 (42 U.S.C. 300 aa–10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under the VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. *See* section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. 42 CFR 100.3(c)(8). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. *See* sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 300aa–14(e)(2). Finally, section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2), provides that:

''[a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

[w]hichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the **Federal Register** a statement of reasons for not conducting such proceeding.''

On April 9, 2014, a private citizen submitted an email inquiry to the Secretary of Health and Human Services (HHS) regarding the VICP. This email asked why the condition of diabetes mellitus (DM) is not a listed injury on the Vaccine Injury Table (Table) in association with the measles, mumps, and rubella (MMR) vaccination, explaining that it is identified by the manufacturer as a possible adverse result of the MMR vaccine. The email also asked whether the Secretary would consider amending the Table to add DM as an injury for MMR vaccines. As such, the email was considered to be a petition to the Secretary to propose regulations to amend the Table to add the injury of DM for the category of MMR vaccines. Accordingly, pursuant to the VICP statute, the petition was referred to the Commission on June 5, 2014. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table as requested in the petition.

DM is a chronic disease in which there is a high level of sugar in the blood. There are two types: Type 1 and Type 2. Type 1 Diabetes is one of the most common chronic diseases in childhood. It is caused by insulin deficiency following destruction of the insulin producing pancreatic beta cells, resulting in absolute insulin deficiency. Type 2 Diabetes is characterized by hyperglycemia and insulin resistance and relative impairment in insulin secretion. Through the years, there have been many studies evaluating the risk of Type 1 Diabetes after MMR vaccination. However, HRSA's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine. The Secretary notes that vaccine package inserts list adverse events reported to vaccine manufacturers during clinical trials even though they may not have been shown to have been caused by the vaccines.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP.[1] The IOM committee reviewed the relevant studies through 2011 and concluded that ''[t]he evidence favors rejection of a causal relationship between MMR vaccine and Type 1 Diabetes.'' Specifically, the epidemiologic studies consistently reported a null association, or no association between the MMR vaccine and Type 1 Diabetes. The IOM committee concluded that the mechanistic evidence regarding an association between MMR vaccine and Type 1 Diabetes was lacking.

In 2012, the Cochrane Collaboration reviewed and assessed studies in the Cochrane Central Register of Controlled Trials.[2] The specific conclusion was that MMR vaccine was unlikely associated with Type 1 Diabetes. A recent study by Duderstadt et al. (2012)[3] was not reviewed by the IOM Committee and the Cochrane Collaboration. This was a retrospective cohort study among U.S. military personnel, which evaluated whether vaccination increased the risk of Type 1 Diabetes. The result was that there was no increased risk of diagnosed Type 1 Diabetes after administration of any studied vaccines, including the MMR vaccine. Current scientific literature consistently shows that there is no causal association between MMR vaccination and Type 1 Diabetes. As noted above, the VICP's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine.

In light of the literature discussed above, I have determined that there is no reliable scientific evidence of a causal association between MMR vaccine and DM. Therefore, I will not amend the Table to add DM as an injury associated with the MMR vaccine.

Dated: April 23, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–10110 Filed 4–29–15; 8:45 am]

BILLING CODE 4165–15–P

[1] IOM, Adverse Effects of Vaccines: Evidence and Causality (Washington, DC: The National Academies Press, 2012):204–211.

[2] Demicheli, V., A. Rivetti, et al. ''Vaccines for Measles, Mumps and Rubella in Children.'' Cochrane Database System Rev 2: CD004407 (2012): 19.

[3] Duderstadt, S., C. Rose Jr., T. Real, J. Sabatier, B. Stewart, G. Ma, U. Yerubandi, A. Eick, J. Tokars, M. McNeil. ''Vaccination and Risk of Type 1 Diabetes Mellitus in Active Component U.S. Military, 2002–2008. Vaccine 30:813–819, (2012).

Notices

Federal Register
Vol. 80, No. 83
Thursday, April 30, 2015

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

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Tobacco Transition Program; Final Date To Request Payments; No Change to Final Assessment Procedures

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: The Farm Service Agency (FSA), on behalf of the Commodity Credit Corporation (CCC), is announcing that the final date for holders of Tobacco Transition Payment Program (TTPP) contracts to request payments on their existing contracts is July 1, 2015. Through TTPP, eligible former tobacco quota holders and producers of quota tobacco received annual payments from funds that CCC collected through quarterly assessments on domestic manufacturers and importers of tobacco products under the Tobacco Transition Assessment Program (TTAP), as required by the Fair and Equitable Tobacco Reform Act of 2004 (FETRA). The authority to issue TTAP assessments ended with fiscal year 2014.

DATES: Submit claims for payment by July 1, 2015; no claims will be accepted after this date.

ADDRESSES: Any USDA FSA county office.

FOR FURTHER INFORMATION CONTACT: Kelly Dawson; telephone: (202) 720–0448. Persons with disabilities who require alternative means for communications (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

On behalf of CCC, FSA administers the Tobacco Transition Program (TTP), which includes TTPP and TTAP. The TTP regulations are located in 7 CFR part 1463, subpart B; TTAP regulations are located in subpart A. This notice does not change the regulations. TTPP was authorized by Title VI of the American Jobs Creation Act of 2004 (Pub. L. 108–357). Title VI is also known as FETRA (7 U.S.C. 518–519a). FETRA repealed the tobacco marketing quota and related price support programs authorized by Title III of the Agricultural Adjustment Act of 1938 and by the Agricultural Act of 1949, and provided for payments to persons who were owners of farms with tobacco quotas, or who were producers of quota tobacco. As specified in FETRA, TTPP used funds from assessments collected quarterly from domestic tobacco manufacturers and importers to make TTPP contract payments; those payments ended with fiscal year 2014. There will be no new TTPP contracts issued; the July 1, 2015 deadline is only for claims for payment under existing contracts.

Final TTPP Contract Payments Procedures

FSA is clarifying a few final procedures and dates for both the orderly close-out of TTPP, and the effect of the former on the close-out of the TTAP. Accordingly, this notice clarifies how final payments will be handled after fiscal year 2014. Specifically, all claims for payments on existing contracts must be received in an FSA county office by July 1, 2015. This notice will also discuss the final ''true-up'' for TTAP.

FSA has already made every effort to pay in full existing TTPP contract holders. We believe that the only remaining pending payments are those that may be due to the surviving spouses, beneficiaries of an estate, or successors in interest of now-deceased contract holders.

In accordance with 7 CFR 1463.113, the TTPP payment can be transferred to the surviving spouse of a deceased TTPP contract holder upon presentation of a death certificate, without regard to any will or other document created on behalf of or by the deceased contract holder. If there is no surviving spouse of a deceased contract holder, the TTPP payment can be transferred to the estate of the deceased by any person authorized under State law to distribute assets of the deceased TTPP contract holder. The regulations for successor-in-interest contracts are found in 7 CFR 1463.112. This notice does not change those regulations. Evidence of authority to distribute assets of a deceased TTPP contract holder must be submitted to FSA by July 1, 2015.

Persons who are surviving spouses, beneficiaries of an estate, or successors in interest may not have received payment if contact information was not provided to FSA in a timely fashion, or if the right to receive such payments was not documented as required. Any such persons who wish to receive payments must provide contact information, present evidence of authority to distribute assets (if applicable), and submit a claim for payment, using form CCC–971, ''Transfer of Tobacco Transition Payment Program Contracts Exempt From Maximum Discount Rate,'' to a local FSA county office. The CCC–971 form must have an original signature. All of the above information and form CCC–971 must be submitted to any local FSA office either in person, or received by mail, no later than July 1, 2015. Form CCC–971 is available online at *http://forms.sc.egov.usda.gov/efcommon/eFileServices/eForms/CCC971-971-A.PDF.*

Final Assessment Procedures Will Not Change

This notice does not change the final dates or procedures for assessments that were specified in the most recent final rule for TTAP, published on April 9, 2014 (79 FR 19462–19464). As specified in the preamble of that final rule, FSA will make any necessary final ''trued up'' revisions to the assessments for all 10 fiscal years of the Tobacco Transition Program and issue revised assessments on or before December 1, 2015. The final ''trued up'' assessment will include any adjustments needed to cover payments made for final claims for payments on existing TTPP contracts received by July 1, 2015. After December 1, 2015, there will be no revised assessments issued for any fiscal years. The final date for appeals of assessments is January 16, 2016, as specified in 7 CFR 1463.11; that date is not changing with this notice.

Signed on April 27, 2015.

Val Dolcini,

Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2015–10056 Filed 4–29–15; 8:45 am]

BILLING CODE 3410–05–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska Advisory Committee for Members of the Committee To Receive Member Orientation and Discuss Civil Rights Issues in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held on Thursday, May 21, 2015, for the purpose of receiving an orientation on committee procedures and member responsibilities and to discuss possible civil rights issues in the state for examination by the Committee. The meeting will be held by teleconference.

This meeting is available to the public through the following toll-free call-in number: 888–430–8709 conference ID: 1833093. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments. The comments must be received in the Western Regional Office of the Commission by June 21, 2015. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments may do so by sending them to Angelica Trevino, Civil Rights Analyst, Western Regional Office, at *atrevino@usccr.gov.* Persons who desire additional information should contact the Western Regional Office, at (213) 894–3437, (or for hearing impaired TDD 913–551–1414), or by email to *atrevino@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 and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=234* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Western Regional Office at the above email or street address.

Agenda:

Introductions

Member orientation

Discussion of civil rights issues in the state

Adjournment

DATES: Thursday, May 21, 2015 from 2 p.m. to 3:00 p.m. AST

Public Call Information:

Dial: 888–430–8709

Conference ID: 1833093

FOR FURTHER INFORMATION CONTACT: Peter Minarik, DFO, at (213) 894–3437 or *pminarik@usccr.gov*.

Dated: April 27, 2015.

David Mussatt,

Chief, Regional Programs Coordination Unit.

[FR Doc. 2015–10099 Filed 4–29–15; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–25–2015]

Foreign-Trade Zone (FTZ) 122—Corpus Christi, Texas; Notification of Proposed Production Activity; M & G Resins, LLC, (Polyethylene Terephthalate and Terephthalic Acid); Corpus Christi, Texas

The Port of Corpus Christi Authority, grantee of FTZ 122, submitted a notification of proposed production activity to the FTZ Board on behalf of M & G Resins, LLC (M & G), located in Corpus Christi, Texas. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on April 17, 2015.

The M & G facility is located within Subzone 122S. The facility will be used for the manufacturing of polyethylene terephthalate and terephthalic acid. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt M & G from customs duty payments on the foreign status components used in export production. On its domestic sales, M & G would be able to choose the duty rates during customs entry procedures that apply to polyethylene terephthalate (PET) and terephthalic acid (PTA) (duty rate 6.5%) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: Ethylene glycol, para-xylene and acetic acid (duty rate ranges from duty-free to 5.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 9, 2015.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: April 24, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–10166 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–848 and C–533–849]

Commodity Matchbooks From India: Continuation of Antidumping Duty and Countervailing Duty Orders

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

SUMMARY: As a result of the determinations by the Department of Commerce (the Department) and the International Trade Commission (the ITC) in their five year (sunset) reviews that revocation of the antidumping duty (AD) and countervailing duty (CVD) orders on commodity matchbooks from India would likely lead to a continuation or recurrence of dumping and a countervailable subsidy, as well as material injury to an industry in the United States, the Department is publishing a notice of continuation for the AD and CVD orders.

DATES: Effective Date: April 30, 2015.

FOR FURTHER INFORMATION CONTACT: David Crespo (AD), Office II, and Jacqueline Arrowsmith (CVD), Office VII, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3693 and (202) 482–5255, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 2014, the Department initiated sunset reviews on the AD and CVD orders on commodity matchbooks from India pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] As a result of the reviews, the Department found that revocation of the AD order on commodity matchbooks from India would be likely to lead to the continuation or recurrence of dumping, and notified the ITC of the margins of dumping likely to prevail should the order be revoked.[2] The Department also found that revocation of the CVD order on commodity matchbooks from India would be likely to lead to the continuation or recurrence of a countervailable subsidy, and notified the ITC of the net countervailable subsidy that is likely to prevail should the order be revoked.[3]

On April 17, 2015, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the AD and CVD orders on commodity matchbooks from India would be likely to lead to the continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[4]

Scope of the Orders

The scope of the orders covers commodity matchbooks, also known as commodity book matches, paper matches or booklet matches.[5] Commodity matchbooks typically, but do not necessarily, consist of twenty match stems which are usually made from paperboard or similar material tipped with a match head composed of any chemical formula. The match stems may be stitched, stapled or otherwise fastened into a matchbook cover of any material, on which a striking strip composed of any chemical formula has been applied to assist in the ignition process.

Commodity matchbooks included in the scope of these orders may or may not contain printing. For example, they may have no printing other than the identification of the manufacturer or importer. Commodity matchbooks may also be printed with a generic message such as ''Thank You'' or a generic image such as the American Flag, with store brands (*e.g.,* Kroger, 7-Eleven, Shurfine or Giant); product brands for national or regional advertisers such as cigarettes or alcoholic beverages; or with corporate brands for national or regional distributors (*e.g.,* Penley Corp. or Diamond Brands). They all enter retail distribution channels. Regardless of the materials used for the stems of the matches and regardless of the way the match stems are fastened to the matchbook cover, all commodity matchbooks are included in the scope of these orders. All matchbooks, including commodity matchbooks, typically comply with the United States Consumer Product Safety Commission (CPSC) Safety Standard for Matchbooks, codified at 16 CFR 1202.1 *et seq.*

The scope of these orders excludes promotional matchbooks, often referred to as ''not for resale,'' or ''specialty advertising'' matchbooks, as they do not enter into retail channels and are sold to businesses that provide hospitality, dining, drinking or entertainment services to their customers, and are given away by these businesses as promotional items. Such promotional matchbooks are distinguished by the physical characteristic of having the name and/or logo of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue or individual establishment printed prominently on the matchbook cover. Promotional matchbook cover printing also typically includes the address and the phone number of the business or establishment being promoted.[6] Also excluded are all other matches that are not fastened into a matchbook cover such as wooden matches, stick matches, box matches, kitchen matches, pocket matches, penny matches, household matches, strike-anywhere matches (*aka* ''SAW'' matches), strike-on-box matches (*aka* ''SOB'' matches), fireplace matches, barbeque/grill matches, fire starters, and wax matches.

The merchandise subject to these orders is properly classified under subheading 3605.00.0060 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 3605.00.0030 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these orders is dispositive.[7]

Determination

As a result of the determinations by the Department and the ITC that revocation of these AD and CVD duty

[1] *See Initiation of Five-Year (''Sunset'') Review,* 79 FR 65186 (November 3, 2014).

[2] *See Commodity Matchbooks from India: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order,* 80 FR 12801 (March 11, 2015).

[3] *See Commodity Matchbooks from India: Final Results of Expedited Sunset Review of the Countervailing Duty Order,* 80 FR 12800 (March 11, 2015) (*CVD Final Results*).

[4] *See Commodity Matchbooks from India; Determinations,* 80 FR 21263 (April 17, 2015).

[5] Such commodity matchbooks are also referred to as ''for resale'' because they always enter into retail channels, meaning businesses that sell a general variety of tangible merchandise, *e.g.,* convenience stores, supermarkets, dollar stores, drug stores and mass merchandisers.

[6] The gross distinctions between commodity matchbooks and promotional matchbooks may be summarized as follows: (1) If it has no printing, or is printed with a generic message such as ''Thank You'' or a generic image such as the American Flag, or printed with national or regional store brands or corporate brands, it is commodity; (2) if it has printing, and the printing includes the name of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue, or individual establishment prominently displayed on the matchbook cover, it is promotional.

[7] The Department inadvertently omitted the HTSUS numbers for the merchandise subject to the CVD Order in the ''Scope of the Order'' section in the *CVD Final Results.* However, the complete description of the scope of the Orders is included in this notice, above.

orders would likely lead to the continuation or recurrence of dumping and a countervailable subsidy, as well as material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the AD and CVD orders on commodity matchbooks from India. U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of these orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next sunset review of these orders not later than 30 days prior to the fifth anniversary of the effective date of continuation.

These sunset reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act, and published pursuant to 777(i) of the Act and 19 CFR 351.218(f)(4).

Dated: April 24, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–10133 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

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

SUMMARY: The Department of Commerce (''the Department'') has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with March anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews.

DATES: Effective date April 30, 2015.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with March anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (''POR''), it must notify the Department within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (''the Act''). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the POR. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within seven days of publication of this initiation notice and to make our decision regarding respondent selection within 21 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the applicable review. Rebuttal comments will be due five days after submission of initial comments.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (''Q&V'') Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

deadline will be made on a case-by-case basis.

Separate Rates

In proceedings involving non-market economy (''NME'') countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994). In accordance with the separate rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name, [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than March 31, 2016.

	Period to be reviewed
Antidumping Duty Proceedings	
France: Brass Sheet and Strip A–427–602	3/1/14–2/28/15
Griset SA	
KME France	
Germany: Brass Sheet and Strip A–428–602	3/1/14–2/28/15
Aurubis Stolberg GmbH & Co. KG	
Carl Schreiber GmbH	
KME Germany AG & Co. KG	
Messingwerk Plettenberg Herfeld GmbH & Co. KG	
MKM Mansfelder Kupfer & Messing GmbH	
Schlenk Metallfolien GmbH & Co. KG (also known as ''Schlenk Metal Foils'')	
Schwermetall Halbzeugwerk GmbH & Co. KG	
Sundwiger Messingwerke GmbH & Co. KG	
ThyssenKrupp VDM GmbH	
Wieland-Werke AG	
Italy: Brass Sheet and Strip A–475–601	3/1/14–2/28/15
KME Italy SpA	
Spain: Stainless Steel Bar A–469–805	3/1/14–2/28/15
Gerdau Aceros Especiales Europa, S.L.	

[2] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[3] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Thailand: Circular Welded Carbon Steel Pipes and Tubes, A–549–502	3/1/14–2/28/15
Saha Thai Steel Pipe (Public) Company, Ltd.	
The People's Republic of China: Glycine A–570–836	3/1/14–2/28/15
Baoding Mantong Fine Chemistry Co., Ltd.	
Kumar Industries	
Nutracare International	
Ravi Industries	
Rudraa International	
Countervailing Duty Proceedings	
Republic of Korea: Large Residential Washers.[4]	
C–580–869	1/1/14–12/31/14
Samsung Electronics Co., Ltd.	
Suspension Agreements	
None	

[4] The company listed above was misspelled in the initiation notice that published on April 3, 2015 (80 FR 18202). The correct spelling of the company is listed in this notice.

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Revised Factual Information Requirements

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to antidumping and countervailing duty proceedings: the definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all segments initiated on or after May 10, 2013. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.[5] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[6] The Department intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation concerning the extension of time limits for submissions in antidumping and countervailing duty proceedings: *Final Rule,* 78 FR 57790 (September 20, 2013).

[5] *See* section 782(b) of the Act.

[6] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*''); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

The modification clarifies that parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: April 24, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–10134 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Harvard University, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Electron Microscope

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 3720, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 14–031. Applicant: Harvard University, Cambridge, MA 02138. Instrument: Electron Microscope.

Manufacturer: JEOL Ltd., Japan. Intended Use: See notice at 80 FR 2914–15, January 21, 2015.

Docket Number: 14–033. Applicant: University of South Carolina School of Medicine, Columbia, SC 29208. Instrument: Electron Microscope.

Manufacturer: JEOL Ltd., Japan. Intended Use: See notice at 80 FR 2914–15, January 21, 2015.

Docket Number: 14–036. Applicant: University of Michigan, Ann Arbor, MI 48109–2200. Instrument: Electron Microscope. Manufacturer: JEOL Ltd., Japan. Intended Use: See notice at 80 FR 2914–15, January 21, 2015.

Docket Number: 14–037. Applicant: University of Arizona, Tucson, AZ 85721. Instrument: Electron Microscope. Manufacturer: FEI Company, Czech Republic. Intended Use: See notice at 80 FR 2914–15, January 21, 2015.

Docket Number: 14–038. Applicant: University of North Dakota, Grand Forks, ND 58202–8153. Instrument: Electron Microscope. Manufacturer: FEI Company, Czech Republic.

Intended Use: See notice at 80 FR 2914–15, January 21, 2015.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is being manufactured in the United States at the time the instrument was ordered. Reasons: Each foreign instrument is an electron microscope and is intended for research or scientific educational uses requiring an electron microscope. We know of no electron microscope, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of each instrument.

Dated: April 24, 2015.

Gregory W. Campbell,

Director, Subsidies Enforcement Office, Enforcement and Compliance.

[FR Doc. 2015–10132 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

New Mexico Institute of Mining and Technology, et al.; Notice of Decision on Application for Duty-Free Entry of Scientific Instruments

This is a decision pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 3720, U.S. Department of Commerce, 14th and Constitution Ave. NW., Washington, DC.

Docket Number: 14–032. Applicant: New Mexico Institute of Mining and Technology, Socorro, NM 87801. Instrument: Delay Line Trolley (DLT). Manufacturer: University of Cambridge/Cavendish Lab, United Kingdom. Intended Use: See notice at 80 FR 2914–15, January 21, 2015. Comments: None received. Decision: Approved. We know of no instruments of equivalent scientific value to the foreign instruments described below, for such purposes as this is intended to be used, that was being manufactured in the United States at the time of order. Reasons: The instrument will be used within the Magdalena Ridge Observatory Interferometer (MROI) to equalize path lengths traveled by the light from a target object, via the telescopes, to the point where interference takes place, by acting as a continuously movable retro-reflector. Each trolley moves continuously within an evacuated pipe in order to introduce the optical path delay appropriate for the target, time of observation, and inter-telescope separations in use. For most of the sky to be accessible, a delay range approximately equal to the longest inter-telescope separation must be available, requiring an unprecedented monolithic delay line length of almost 200m. The instrument is essentially a cat's-eye assembly that is flexure-mounted and voice coil actuated on a motorized wheeled carriage, which runs directly on the inner surface of the delay line pipe, not on pre-installed rails. Its position is precisely measured by a laser metrology system and computer controlled so as to introduce the

appropriate optical path compensation as a function of time. The following specifications are required for the research: A focus on model-independent imaging as opposed to astrometric or precision phase or visibility measurement, a wavelength of operation that covers both the visible and near infrared, between 600 nm and 2400 nm, accommodation for baseline lengths as long as 250m, a concern for polarization fidelity in the image, and a requirement to reach a limiting group-delay tracking magnitude of H=14 to allow observations of extragalactic targets while tracking on the science object rather than a nearby reference star.

Docket Number: 14–034. Applicant: National Institutes of Health, Bethesda, MD 20892–8025. Instrument: Falcon II Direct Detection Camera. Manufacturer: FEI Company, the Netherlands. Intended Use: See notice at 80 FR 2914–15, January 21, 2015. Comments: None received. Decision: Approved. We know of no instruments of equivalent scientific value to the foreign instruments described below, for such purposes as this is intended to be used, that was being manufactured in the United States at the time of order. Reasons: The instrument will be used in cryo-electron microscopy experiments, to visualize biological specimens suspended in vitreous ice involving recording electron micrographs of the highest possible quality and subjecting them to digital image analysis to elicit the maximum amount of structural information and interpretation, taking into account all pertinent complimentary data. Sensor specifications required for this research include a pixel size of ~14 μm which predicates a magnification of ~100 kx, optimal performance as measured by Detective Quantum Efficiency at a typical dose rate of 10–20 e/pixel/second, and protection of the sensor against accidental high-dose exposures to the microscope's electron beam.

Dated: April 24, 2015.

Gregory W. Campbell,

Director, Subsidies Enforcement Office, Enforcement and Compliance.

[FR Doc. 2015–10146 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD810

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Russian River Estuary Management Activities

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the Sonoma County Water Agency (SCWA) to incidentally harass, by Level B harassment only, three species of marine mammals during estuary management activities conducted at the mouth of the Russian River, Sonoma County, California.

DATES: This IHA is effective for the period of one year, from April 21, 2015, through April 20, 2016.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability

Electronic copies of SCWA's application and any supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the Internet at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In the case of problems accessing these documents, please call the contact listed above. NMFS' Environmental Assessment (2010) and associated Finding of No Significant Impact, prepared pursuant to the National Environmental Policy Act, and NMFS' Biological Opinion (2008) on the effects of Russian River management activities on salmonids, prepared pursuant to the Endangered Species Act, are also available at the same site.

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 by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified area, the incidental, but not intentional, taking of small numbers of marine mammals, providing that certain findings are made and the necessary prescriptions are established.

The incidental taking of small numbers of marine mammals may be allowed only if NMFS (through authority delegated by the Secretary) finds that the total taking by the specified activity during the specified time period will (i) have a negligible impact on the species or stock(s) and (ii) not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). Further, the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking must be set forth.

The allowance of such incidental taking under section 101(a)(5)(A), by harassment, serious injury, death, or a combination thereof, requires that regulations be established. Subsequently, a Letter of Authorization may be issued pursuant to the prescriptions established in such regulations, providing that the level of taking will be consistent with the findings made for the total taking allowable under the specific regulations. Under section 101(a)(5)(D), NMFS may authorize such incidental taking by harassment only, for periods of not more than one year, pursuant to requirements and conditions contained within an IHA. The establishment of these prescriptions requires notice and opportunity for public comment.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' Except with respect to certain activities not pertinent here, section 3(18) of 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 January 21, 2015, we received an adequate and complete request from SCWA for authorization of the taking of marine mammals incidental to Russian River estuary management activities in

Sonoma County, California. SCWA plans to continue ongoing actions necessary to manage the naturally-formed barrier beach at the mouth of the Russian River in order to minimize potential for flooding adjacent to the estuary and to enhance habitat for juvenile salmonids, as well as to conduct biological and physical monitoring of the barrier beach and estuary. Flood control-related breaching of barrier beach at the mouth of the river may include artificial breaches, as well as construction and maintenance of a lagoon outlet channel. The latter activity, an alternative management technique conducted to mitigate impacts of flood control on rearing habitat for Endangered Species Act (ESA)-listed salmonids, occurs only from May 15 through October 15 (hereafter, the ''lagoon management period''). Artificial breaching and monitoring activities may occur at any time during the one-year period of validity of the IHA.

Breaching of naturally-formed barrier beach at the mouth of the Russian River requires the use of heavy equipment (*e.g.,* bulldozer, excavator) and increased human presence, and monitoring in the estuary requires the use of small boats. As a result, pinnipeds hauled out on the beach or at peripheral haul-outs in the estuary may exhibit behavioral responses that indicate incidental take by Level B harassment under the MMPA. Species known from the haul-out at the mouth of the Russian River or from peripheral haul-outs, and therefore anticipated to be taken incidental to the specified activity, include the harbor seal (*Phoca vitulina richardii*), California sea lion (*Zalophus californianus*), and northern elephant seal (*Mirounga angustirostris*).

This is the sixth such IHA issued to SCWA. SCWA was first issued an IHA, valid for a period of one year, effective on April 1, 2010 (75 FR 17382), and was subsequently issued one-year IHAs for incidental take associated with the same activities, effective on April 21, 2011 (76 FR 23306), April 21, 2012 (77 FR 24471), April 21, 2013 (78 FR 23746), and April 21, 2014 (79 FR 20180).

Description of the Specified Activity

Additional detail regarding the specified activity was provided in our **Federal Register** notice of proposed authorization (80 FR 14073; March 18, 2015) and in past notices cited herein; please see those documents or SCWA's application for more information.

Overview

The planned action involves management of the estuary to prevent flooding while preventing adverse modification to critical habitat for ESA-listed salmonids. Requirements related to the ESA are described in further detail below. During the lagoon management period, this involves construction and maintenance of a lagoon outlet channel that would facilitate formation of a perched lagoon. A perched lagoon, which is an estuary closed to tidal influence in which water surface elevation is above mean high tide, reduces flooding while maintaining beneficial conditions for juvenile salmonids. Additional breaches of barrier beach may be conducted for the sole purpose of reducing flood risk. SCWA's planned activity was described in detail in our notice of proposed authorization prior to the 2011 IHA (76 FR 14924; March 18, 2011); please see that document for a detailed description of SCWA's estuary management activities. Aside from minor additions to SCWA's biological and physical estuary monitoring measures, the specified activity remains the same as that described in the 2011 document.

Dates and Duration

The specified activity may occur at any time during the one-year timeframe (April 21, 2015, through April 20, 2016) of the IHA, although construction and maintenance of a lagoon outlet channel will occur only during the lagoon management period. In addition, there are certain restrictions placed on SCWA during the harbor seal pupping season. These, as well as periodicity and frequency of the specified activities, are described in further detail below.

Specific Geographic Region

The estuary is located about 97 km (60 mi) northwest of San Francisco in Sonoma County, near Jenner, California (see Figure 1 of SCWA's application). The Russian River watershed encompasses 3,847 km^2 (1,485 mi^2) in Sonoma, Mendocino, and Lake Counties. The mouth of the Russian River is located at Goat Rock State Beach (see Figure 2 of SCWA's application); the estuary extends from the mouth upstream approximately 10 to 11 km (6–7 mi) between Austin Creek and the community of Duncans Mills (Heckel and McIver, 1994).

Detailed Description of Activities

Within the Russian River watershed, the U.S. Army Corps of Engineers (Corps), SCWA and the Mendocino County Russian River Flood Control and Water Conservation Improvement District (District) operate and maintain federal facilities and conduct activities in addition to the estuary management, including flood control, water diversion and storage, instream flow releases, hydroelectric power generation, channel maintenance, and fish hatchery production. As described in the notice of proposed IHA, NMFS issued a 2008 Biological Opinion (BiOp) for Water Supply, Flood Control Operations, and Channel Maintenance conducted by the Corps, SCWA and the District in the Russian River watershed (NMFS, 2008). This BiOp found that the activities—including SCWA's estuary management activities prior to the BiOp—authorized by the Corps and undertaken by SCWA and the District, if continued in a manner similar to recent historic practices, were likely to jeopardize the continued existence of ESA-listed salmonids and were likely to adversely modify critical habitat. In part, therefore, the BiOp requires SCWA to collaborate with NMFS and modify their estuary water level management in order to reduce marine influence (*i.e.,* high salinity and tidal inflow) and promote a higher water surface elevation in the estuary in order to enhance the quality of rearing habitat for juvenile salmonids. SCWA is also required to monitor the response of water quality, invertebrate production, and salmonids in and near the estuary to water surface elevation management in the estuary-lagoon system.

There are three components to SCWA's ongoing estuary management activities: (1) Lagoon outlet channel management, during the lagoon management period only, required to accomplish the dual purposes of flood risk abatement and maintenance of juvenile salmonid habitat; (2) traditional artificial breaching, with the sole objective of flood risk abatement; and (3) physical and biological monitoring in and near the estuary, required under the terms of the BiOp, to understand response to water surface elevation management in the estuary-lagoon system. The latter category (physical and biological monitoring) includes all ancillary beach and/or estuary monitoring activities, including topographic and geophysical beach surveys and biological and physical habitat monitoring in the estuary. Please see the previously referenced **Federal Register** notice (76 FR 14924; March 18, 2011) for detailed discussion of lagoon outlet channel management, artificial breaching, and other physical and biological monitoring activities, as well as our in our **Federal Register** notice of proposed authorization for this authorization (80 FR 14073; March 18, 2015) for descriptions of minor changes

to physical and biological monitoring activities.

Comments and Responses

We published a notice of receipt of SCWA's application and proposed IHA in the **Federal Register** on March 18, 2015 (80 FR 14073). During the thirty-day comment period, we received a letter from the Marine Mammal Commission (Commission). The Commission recommends that we issue the requested authorization, subject to inclusion of the proposed mitigation and monitoring measures as described in our notice of proposed IHA and the application. All measures proposed in the initial **Federal Register** notice are included within the IHA.

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species that may be harassed incidental to estuary management activities are the harbor seal, California sea lion, and the northern elephant seal. We presented a detailed discussion of the status of these stocks and their occurrence in the action area in the notice of the proposed IHA (80 FR 14073; March 18, 2015).

Ongoing monthly harbor seal counts at the Jenner haul-out were begun by J. Mortenson in January 1987, with additional nearby haul-outs added to the counts thereafter. In addition, local resident E. Twohy began daily observations of seals and people at the Jenner haul-out in November 1989. These datasets note whether the mouth at the Jenner haul-out was opened or closed at each observation, as well as various other daily and annual patterns of haul-out usage (Mortenson and Twohy, 1994). Recently, SCWA began regular baseline monitoring of the haul-out as a component of its estuary management activity. In the notice of proposed IHA, we presented average daily numbers of seals observed at the mouth of the Russian River from 1993–2005 and from 2009–14 (see Table 1; 80 FR 14073; March 18, 2015).

Potential Effects of the Specified Activity on Marine Mammals

We provided a detailed discussion of the potential effects of the specified activity on marine mammals in the notice of the proposed IHA (79 FR 12472, March 5, 2013). A summary of anticipated effects is provided below.

A significant body of monitoring data exists for pinnipeds at the mouth of the Russian River. In addition, pinnipeds have co-existed with regular estuary management activity for decades as well as with regular human use activity at the beach, and are likely habituated to human presence and activity. Nevertheless, SCWA's estuary management activities have the potential to disturb pinnipeds present on the beach or at peripheral haul-outs in the estuary. During breaching operations, past monitoring has revealed that some or all of the seals present typically move or flush from the beach in response to the presence of crew and equipment, though some may remain hauled-out. No stampeding of seals—a potentially dangerous occurrence in which large numbers of animals succumb to mass panic and rush away from a stimulus—has been documented since SCWA developed protocols to prevent such events in 1999. While it is likely impossible to conduct required estuary management activities without provoking some response in hauled-out animals, precautionary mitigation measures, described later in this document, ensure that animals are gradually apprised of human approach. Under these conditions, seals typically exhibit a continuum of responses, beginning with alert movements (*e.g.,* raising the head), which may then escalate to movement away from the stimulus and possible flushing into the water. Flushed seals typically re-occupy the haul-out within minutes to hours of the stimulus. In addition, eight other haul-outs exist nearby that may accommodate flushed seals. In the absence of appropriate mitigation measures, it is possible that pinnipeds could be subject to injury, serious injury, or mortality, likely through stampeding or abandonment of pups.

California sea lions and northern elephant seals, which have been noted only infrequently in the action area, have been observed as less sensitive to stimulus than harbor seals during monitoring at numerous other sites. For example, monitoring of pinniped disturbance as a result of abalone research in the Channel Islands showed that while harbor seals flushed at a rate of 69 percent, California sea lions flushed at a rate of only 21 percent. The rate for elephant seals declined to 0.1 percent (VanBlaricom, 2011). In the event that either of these species is present during management activities, they would be expected to display a minimal reaction to maintenance activities—less than that expected of harbor seals.

Although the Jenner haul-out is not known as a primary pupping beach, harbor seal pups have been observed during the pupping season; therefore, we have evaluated the potential for injury, serious injury or mortality to pups. There is a lack of published data regarding pupping at the mouth of the Russian River, but SCWA monitors have observed pups on the beach. No births were observed during recent monitoring, but were inferred based on signs indicating pupping (*e.g.,* blood spots on the sand, birds consuming possible placental remains). Pup injury or mortality would be most likely to occur in the event of extended separation of a mother and pup, or trampling in a stampede. As discussed previously, no stampedes have been recorded since development of appropriate protocols in 1999. Any California sea lions or northern elephant seals present would be independent juveniles or adults; therefore, analysis of impacts on pups is not relevant for those species.

Similarly, the period of mother-pup bonding, critical time needed to ensure pup survival and maximize pup health, is not expected to be impacted by estuary management activities. Harbor seal pups are extremely precocious, swimming and diving immediately after birth and throughout the lactation period, unlike most other phocids which normally enter the sea only after weaning (Lawson and Renouf, 1985; Cottrell *et al.,* 2002; Burns *et al.,* 2005). Lawson and Renouf (1987) investigated harbor seal mother-pup bonding in response to natural and anthropogenic disturbance. In summary, they found that the most critical bonding time is within minutes after birth. Although pupping season is defined as March 15-June 30, the peak of pupping season is typically concluded by mid-May, when the lagoon management period begins. As such, it is expected that most mother-pup bonding would likely be concluded as well. The number of management events during the months of March and April has been relatively low in the past, and the breaching activities occur in a single day over several hours. In addition, mitigation measures described later in this document further reduce the likelihood of any impacts to pups, whether through injury or mortality or interruption of mother-pup bonding.

In summary, and based on extensive monitoring data, we believe that impacts to hauled-out pinnipeds during estuary management activities would be behavioral harassment of limited duration (*i.e.,* less than one day) and limited intensity (*i.e.,* temporary flushing at most). Stampeding, and therefore injury or mortality, is not expected—nor been documented—in the years since appropriate protocols were established (see Mitigation for more details). Further, the continued, and increasingly heavy (Figure 4; SCWA, 2015), use of the haul-out

despite decades of breaching events indicates that abandonment of the haul-out is unlikely.

Anticipated Effects on Habitat

We provided a detailed discussion of the potential effects of this action on marine mammal habitat in the notice of the proposed IHA (80 FR 14073; March 18, 2015). SCWA's estuary management activities will result in temporary physical alteration of the Jenner haul-out. With barrier beach closure, seal usage of the beach haul-out declines, and the three nearby river haul-outs may not be available for usage due to rising water surface elevations. Breaching of the barrier beach, subsequent to the temporary habitat disturbance, will likely increase suitability and availability of habitat for pinnipeds. Biological and water quality monitoring will not physically alter pinniped habitat.

In summary, there will be temporary physical alteration of the beach. However, natural opening and closure of the beach results in the same impacts to habitat; therefore, seals are likely adapted to this cycle. In addition, the increase in rearing habitat quality has the goal of increasing salmonid abundance, ultimately providing more food for seals present within the action area. Thus, any impacts to marine mammal habitat are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

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 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.

SCWA will continue the following mitigation measures, as implemented during the previous IHAs, designed to minimize impact to affected species and stocks:

- SCWA crews will cautiously approach the haul-out ahead of heavy equipment to minimize the potential for sudden flushes, which may result in a stampede—a particular concern during pupping season.
- SCWA staff will avoid walking or driving equipment through the seal haul-out.
- Crews on foot will make an effort to be seen by seals from a distance, if possible, rather than appearing suddenly at the top of the sandbar, again preventing sudden flushes.
- During breaching events, all monitoring will be conducted from the overlook on the bluff along Highway 1 adjacent to the haul-out in order to minimize potential for harassment.
- A water level management event may not occur for more than two consecutive days unless flooding threats cannot be controlled.

In addition, SCWA will continue mitigation measures specific to pupping season (March 15–June 30), as implemented in the previous IHA:

- SCWA will maintain a one-week no-work period between water level management events (unless flooding is an immediate threat) to allow for an adequate disturbance recovery period. During the no-work period, equipment must be removed from the beach.
- If a pup less than one week old is on the beach where heavy machinery will be used or on the path used to access the work location, the management action will be delayed until the pup has left the site or the latest day possible to prevent flooding while still maintaining suitable fish rearing habitat. In the event that a pup remains present on the beach in the presence of flood risk, SCWA will consult with NMFS to determine the appropriate course of action. SCWA will coordinate with the locally established seal monitoring program (Stewards' Seal Watch) to determine if pups less than one week old are on the beach prior to a breaching event.
- Physical and biological monitoring (including topographic and geophysical beach surveys) will not be conducted if a pup less than one week old is present at the monitoring site or on a path to the site.
- Any jetty study activities in the vicinity of the harbor seal haul-out will not occur during the pupping season.

Equipment will be driven slowly on the beach and care will be taken to minimize the number of shutdowns and start-ups when the equipment is on the beach. All work will be completed as efficiently as possible, with the smallest amount of heavy equipment possible, to minimize disturbance of seals at the haul-out. Boats operating near river haul-outs during monitoring will be kept within posted speed limits and driven as far from the haul-outs as safely possible to minimize flushing seals.

We have carefully evaluated SCWA's planned mitigation measures and considered their effectiveness in past implementation to determine whether they are likely to effect the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (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; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

- Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).
- A reduction in the number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).
- A reduction in the number (total number or number at biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).
- A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing the severity of behavioral harassment only).
- Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary disturbance of habitat during a biologically important time.
- For monitoring directly related to mitigation, an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of SCWA's planned measures and on SCWA's record of management at the mouth of the Russian River including information from monitoring of SCWA's implementation of the mitigation measures as prescribed under the previous IHAs, we have determined that the planned mitigation measures provide the means of effecting the least

practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Any monitoring requirement we prescribe should accomplish one or more of the following general goals:

1. An increase in the probability of detecting marine mammals, both within defined zones of effect (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

2. An increase in our understanding of how many marine mammals are likely to be exposed to stimuli that we associate with specific adverse effects, such as behavioral harassment or hearing threshold shifts;

3. An increase in our understanding of how marine mammals respond to stimuli expected to result in incidental take and how anticipated adverse effects on individuals may impact the population, stock, or species (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict pertinent information, *e.g.,* received level, distance from source);
- Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict pertinent information, *e.g.,* received level, distance from source);
- Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli;

4. An increased knowledge of the affected species; or

5. An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

SCWA submitted a marine mammal monitoring plan as part of the IHA application. It can be found on the Internet at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* The plan has been successfully implemented by SCWA under previous IHAs. The purpose of this monitoring plan, which is carried out collaboratively with the Stewards of the Coasts and Redwoods (Stewards) organization, is to detect the response of pinnipeds to estuary management activities at the Russian River estuary. SCWA has designed the plan both to satisfy the requirements of the IHA, and to address the following questions of interest:

1. Under what conditions do pinnipeds haul out at the Russian River estuary mouth at Jenner?

2. How do seals at the Jenner haul-out respond to activities associated with the construction and maintenance of the lagoon outlet channel and artificial breaching activities?

3. Does the number of seals at the Jenner haul-out significantly differ from historic averages with formation of a summer (May 15 to October 15) lagoon in the Russian River estuary?

4. Are seals at the Jenner haul-out displaced to nearby river and coastal haul-outs when the mouth remains closed in the summer?

Monitoring Measures

In summary, monitoring includes the following:

Baseline Monitoring—Seals at the Jenner haul-out are counted twice monthly for the term of the IHA. This baseline information will provide SCWA with details that may help to plan estuary management activities in the future to minimize pinniped interaction. This census begins at local dawn and continues for eight hours. All seals hauled out on the beach are counted every thirty minutes from the overlook on the bluff along Highway 1 adjacent to the haul-out using spotting scopes. Monitoring may conclude for the day if weather conditions affect visibility (*e.g.,* heavy fog in the afternoon). Counts are scheduled for two days out of each month, with the intention of capturing a low and high tide each in the morning and afternoon. Depending on how the sandbar is formed, seals may haul out in multiple groups at the mouth. At each thirty-minute count, the observer indicates where groups of seals are hauled out on the sandbar and provides a total count for each group. If possible, adults and pups are counted separately.

In addition to the census data, disturbances of the haul-out are recorded. The method for recording disturbances follows those in Mortenson (1996). Disturbances will be recorded on a three-point scale that represents an increasing seal response to the disturbance. The time, source, and duration of the disturbance, as well as an estimated distance between the source and haul-out, are recorded. It should be noted that only responses falling into Mortenson's Levels 2 and 3 (*i.e.,* movement or flight) will be considered as harassment under the MMPA under the terms of the IHA. Weather conditions are recorded at the beginning of each census. These include temperature, percent cloud cover, and wind speed (Beaufort scale). Tide levels and estuary water surface elevations are correlated to the monitoring start and end times.

In an effort towards understanding possible relationships between use of the Jenner haul-out and nearby coastal and river haul-outs, several other haul-outs on the coast and in the Russian River estuary are monitored as well (see Figure 4 of SCWA's application). The peripheral haul-outs are visited for ten-minute counts twice during each baseline monitoring day. All pinnipeds hauled out were counted from the same vantage point(s) at each haul-out using a spotting scope or binoculars.

Estuary Management Event Monitoring—Activities associated with artificial breaching or initial construction of the outlet channel, as well as the maintenance of the channel that may be required, will be monitored for disturbances to the seals at the Jenner haul-out. A one-day pre-event channel survey will be made within one to three days prior to constructing the outlet channel. The haul-out will be monitored on the day the outlet channel is constructed and daily for up to the maximum two days allowed for channel excavation activities. Monitoring will also occur on each day that the outlet channel is maintained using heavy equipment for the duration of the lagoon management period. Monitoring will correspond with that described under the ''Baseline'' section previously, with the exception that management activity monitoring duration is defined by event duration, rather than being set at eight hours. On the day of the management event, pinniped monitoring begins at least one hour prior to the crew and equipment accessing the beach work area and continues through the duration of the event, until at least one hour after the crew and equipment leave the beach.

In an attempt to understand whether seals from the Jenner haul-out are displaced to coastal and river haul-outs

nearby when management events occur, other nearby haul-outs are monitored concurrently with monitoring of outlet channel construction and maintenance activities. This provides an opportunity to qualitatively assess whether these haul-outs are being used by seals displaced from the Jenner haul-out. This monitoring will not provide definitive results regarding displacement to nearby coastal and river haul-outs, as individual seals are not marked, but is useful in tracking general trends in haul-out use during disturbance. As volunteers are required to monitor these peripheral haul-outs, haul-out locations may need to be prioritized if there are not enough volunteers available. In that case, priority will be assigned to the nearest haul-outs (North Jenner and Odin Cove), followed by the Russian River estuary haul-outs, and finally the more distant coastal haul-outs.

For all counts, the following information will be recorded in thirty-minute intervals: (1) Pinniped counts, by species; (2) behavior; (3) time, source and duration of any disturbance; (4) estimated distances between source of disturbance and pinnipeds; (5) weather conditions (*e.g.,* temperature, wind); and (5) tide levels and estuary water surface elevation.

Monitoring During Pupping Season—As described previously, the pupping season is defined as March 15 to June 30. Baseline, lagoon outlet channel, and artificial breaching monitoring during the pupping season will include records of neonate (pups less than one week old) observations. Characteristics of a neonate pup include: Body weight less than 15 kg; thin for their body length; an umbilicus or natal pelage present; wrinkled skin; and awkward or jerky movements on land. SCWA will coordinate with the Seal Watch monitoring program to determine if pups less than one week old are on the beach prior to a water level management event.

If, during monitoring, observers sight any pup that might be abandoned, SCWA will contact the NMFS stranding response network immediately and also report the incident to NMFS' West Coast Regional Office and Office of Protected Resources within 48 hours. Observers will not approach or move the pup. Potential indications that a pup may be abandoned are no observed contact with adult seals, no movement of the pup, and the pup's attempts to nurse are rebuffed.

Reporting

SCWA is required to submit a report on all activities and marine mammal monitoring results to the Office of Protected Resources, NMFS, and the West Coast Regional Administrator, NMFS, 90 days prior to the expiration of the IHA if a renewal is sought, or within 90 days of the expiration of the permit otherwise. This annual report will also be distributed to California State Parks and Stewards, and would be available to the public on SCWA's Web site. This report will contain the following information:

- The number of pinnipeds taken, by species and age class (if possible);
- Behavior prior to and during water level management events;
- Start and end time of activity;
- Estimated distances between source and pinnipeds when disturbance occurs;
- Weather conditions (*e.g.,* temperature, wind);
- Haul-out reoccupation time of any pinnipeds based on post-activity monitoring;
- Tide levels and estuary water surface elevation; and
- Seal census from bi-monthly and nearby haul-out monitoring.

The annual report includes descriptions of monitoring methodology, tabulation of estuary management events, summary of monitoring results, and discussion of problems noted and proposed remedial measures. SCWA will report any injured or dead marine mammals to NMFS' West Coast Regional Office and Office of Protected Resources.

Summary of Previous Monitoring

SCWA complied with the mitigation and monitoring required under all previous authorizations. In accordance with the 2014 IHA, SCWA submitted a Report of Activities and Monitoring Results, covering the period of January 1 through December 31, 2014. Previous monitoring reports (available at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm*) provided additional analysis of monitoring results from 2009–13. A barrier beach was formed eleven times during 2014, but SCWA was required to implement artificial breaching for only six of these closure events. The Russian River outlet was closed to the ocean for a total of 110 days in 2014, including extended closures totaling 29 days during the lagoon management period. However, these closures all culminated in natural breaches and no outlet channel management events were required. During 2013, five artificial breaching events occurred (SCWA, 2014). In January 2012, the barrier beach was artificially breached after two days of breaching activity. There were also several periods over the course of the year where the barrier beach closed or became naturally perched and then subsequently breached naturally (SCWA, 2013). In 2011, no water level management activities occurred (SCWA, 2012). In 2010, one lagoon management event and two artificial breaching events occurred (SCWA, 2011). Pinniped monitoring occurred no more than 3 days before, the day of, and the day after each water level management activity. In addition, SCWA conducted biological and physical monitoring as described previously. During the course of these activities, SCWA did not exceed the take levels authorized under the relevant IHAs. We provided a detailed description of previous monitoring results in the notice of the proposed IHA (80 FR 14073; March 18, 2015).

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of 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].''

We are authorizing SCWA to take harbor seals, California sea lions, and northern elephant seals, by Level B harassment only, incidental to estuary management activities. These activities, involving increased human presence and the use of heavy equipment and support vehicles, are expected to harass pinnipeds present at the haul-out through behavioral disturbance only. In addition, monitoring activities prescribed in the BiOp may result in harassment of additional individuals at the Jenner haul-out and at the three haul-outs located in the estuary. Estimates of the number of harbor seals, California sea lions, and northern elephant seals that may be harassed by the activities is based upon the number of potential events associated with Russian River estuary management activities and the average number of individuals of each species that are present during conditions appropriate to the activity. As described previously in this document, monitoring effort at the mouth of the Russian River has shown that the number of seals utilizing the haul-out declines during bar-closed conditions. Tables 1 and 2 detail the total number of authorized takes.

Methodology of take estimation was discussed in detail in our notice of proposed IHA (80 FR 14073; March 18, 2015).

TABLE 1—ESTIMATED NUMBER OF HARBOR SEAL TAKES RESULTING FROM RUSSIAN RIVER ESTUARY MANAGEMENT ACTIVITIES

Number of animals expected to occur [a]	Number of events [b c]	Potential total number of individual animals that may be taken
Lagoon Outlet Channel Management (May 15 to October 15)		
Implementation: 117 [d]	Implementation: 3	Implementation: 351.
Maintenance and Monitoring:	Maintenance:	Maintenance: 1,160.
May: 80	May: 1.	
June: 97	June–Sept: 4/month.	
July: 117	Oct: 1.	
Aug: 17	Monitoring:	Monitoring: 552.
Sept: 33	June–Sept: 2/month.	
Oct: 24	Oct: 1	Total: 2,063.
Artificial Breaching		
Oct: 24	Oct: 2	Oct: 48.
Nov: 36	Nov: 2	Nov: 72.
Dec: 51	Dec: 2	Dec: 102.
Jan: 41	Jan: 1	Jan: 41.
Feb: 90	Feb: 1	Feb: 90.
Mar: 130	Mar: 1	Mar: 130.
Apr: 80	Apr: 1	Apr: 80.
May: 80	May: 2	May: 160.
	12 events maximum	Total: 723.
Topographic and Geophysical Beach Surveys		
Jan: 89	1 topographic survey/month; 100 percent of animals present Jun–Feb; 10 percent of animals present Mar–May.	Jan: 89.
Feb: 131		Feb: 131.
Mar: 173		Mar: 17.
Apr: 137		Apr: 14.
May: 157		May: 16.
Jun: 154		Jun: 154.
Jul: 158		Jul: 158.
Aug: 146		Aug: 146.
Sep: 78		Sep: 78.
Oct: 50		Oct: 50.
Nov: 66		Nov: 66.
Dec: 106		Dec: 106.
		Total: 1,025.
Biological and Physical Habitat Monitoring in the Estuary		
1 [e]	165	165
Total		3,976

[a] For Lagoon Outlet Channel Management and Artificial Breaching, average daily number of animals corresponds with data from Table 2. For Topographic and Geophysical Beach Surveys, average daily number of animals corresponds with 2012–14 data from Table 1.

[b] For implementation of the lagoon outlet channel, an event is defined as a single, two-day episode. It is assumed that the same individual seals would be hauled out during a single event. For the remaining activities, an event is defined as a single day on which an activity occurs. Some events may include multiple activities.

[c] Number of events for artificial breaching derived from historical data. The average number of events for each month was rounded up to the nearest whole number; estimated number of events for December was increased from one to two because multiple closures resulting from storm events have occurred in recent years during that month. These numbers likely represent an overestimate, as the average annual number of events is six.

[d] Although implementation could occur at any time during the lagoon management period, the highest daily average per month from the lagoon management period was used.

[e] Based on past experience, SCWA expects that no more than one seal may be present, and thus have the potential to be disturbed, at each of the three river haul-outs. Number of events includes addition of acoustic telemetry surveys.

TABLE 2—ESTIMATED NUMBER OF CALIFORNIA SEA LION AND ELEPHANT SEAL TAKES RESULTING FROM RUSSIAN RIVER ESTUARY MANAGEMENT ACTIVITIES

Species	Number of animals expected to occur [a]	Number of events [a]	Potential total number of individual animals that may be taken
Lagoon Outlet Channel Management (May 15 to October 15)			
California sea lion (potential to encounter once per event)	1	6	6
Northern elephant seal (potential to encounter once per event)	1	6	6
Artificial Breaching			
California sea lion (potential to encounter once per month, Oct–May)	1	8	8
Northern elephant seal (potential to encounter once per month, Oct–May)	1	8	8
Topographic and Geophysical Beach Surveys			
California sea lion (potential to encounter once per month year-round for topographical surveys)	1	12	12
Northern elephant seal (potential to encounter once per month year-round for topographical surveys)	1	12	12
Biological and Physical Habitat Monitoring in the Estuary			
California sea lion (potential to encounter once per month, Jul–Feb)	1	8	8
Northern elephant seal (potential to encounter once per month, Jul–Feb)	1	8	8
Total			
California sea lion			34
Elephant seal			34

[a] SCWA expects that California sea lions and/or northern elephant seals could occur during any month of the year, but that any such occurrence would be infrequent and unlikely to occur more than once per month.

Analyses and Determinations

Negligible Impact Analysis

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.'' A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, we consider other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

Although SCWA's estuary management activities may disturb pinnipeds hauled out at the mouth of the Russian River, as well as those hauled out at several locations in the estuary during recurring monitoring activities, impacts are occurring to a small, localized group of animals. While these impacts can occur year-round, they occur sporadically and for limited duration (*e.g.,* a maximum of two consecutive days for water level management events). Seals will likely become alert or, at most, flush into the water in reaction to the presence of crews and equipment on the beach. While disturbance may occur during a sensitive time (during the March 15–June 30 pupping season), mitigation measures have been specifically designed to further minimize harm during this period and eliminate the possibility of pup injury or mother-pup separation.

No injury, serious injury, or mortality is anticipated, nor is the proposed action likely to result in long-term impacts such as permanent abandonment of the haul-out. Injury, serious injury, or mortality to pinnipeds would likely result from startling animals inhabiting the haul-out into a stampede reaction, or from extended mother-pup separation as a result of such a stampede. Long-term impacts to pinniped usage of the haul-out could result from significantly increased presence of humans and equipment on the beach. To avoid these possibilities, we have worked with SCWA to develop the previously described mitigation measures. These are designed to reduce the possibility of startling pinnipeds, by gradually apprising them of the presence of humans and equipment on the beach, and to reduce the possibility of impacts to pups by eliminating or altering management activities on the beach when pups are present and by setting limits on the frequency and duration of events during pupping season. During the past fifteen years of flood control management, implementation of similar mitigation measures has resulted in no known stampede events and no known injury, serious injury, or mortality. Over the course of that time period, management events have generally been infrequent and of limited duration.

No pinniped stocks for which incidental take is authorized 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; populations of California sea lions and northern elephant seals in California are

also considered healthy. In summary, and based on extensive monitoring data, we believe that impacts to hauled-out pinnipeds during estuary management activities would be behavioral harassment of limited duration (*i.e.,* less than one day) and limited intensity (*i.e.,* temporary flushing at most). Stampeding, and therefore injury or mortality, is not expected—nor been documented—in the years since appropriate protocols were established (see Mitigation for more details). Further, the continued, and increasingly heavy (Figure 4; SCWA, 2015), use of the haul-out despite decades of breaching events indicates that abandonment of the haul-out is unlikely. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the planned monitoring and mitigation measures, we find that the total marine mammal take from SCWA's estuary management activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers Analysis

The authorized number of animals taken for each species of pinniped can be considered small relative to the population size. There are an estimated 30,968 harbor seals in the California stock, 296,750 California sea lions, and 179,000 northern elephant seals in the California breeding population. Based on extensive monitoring effort specific to the affected haul-out and historical data on the frequency of the specified activity, we are proposing to authorize take, by Level B harassment only, of 3,976 harbor seals, 34 California sea lions, and 34 northern elephant seals, representing 12.8, 0.01, and 0.02 percent of the populations, respectively. However, this represents an overestimate of the number of individuals harassed over the duration of the IHA, because these totals represent much smaller numbers of individuals that may be harassed multiple times. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, we find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

No species listed under the ESA are expected to be affected by these activities. Therefore, we have determined that a section 7 consultation under the ESA is not required. As described elsewhere in this document, SCWA and the Corps consulted with NMFS under section 7 of the ESA regarding the potential effects of their operations and maintenance activities, including SCWA's estuary management program, on ESA-listed salmonids. As a result of this consultation, NMFS issued the Russian River Biological Opinion (NMFS, 2008), including Reasonable and Prudent Alternatives, which prescribes modifications to SCWA's estuary management activities. The effects of the proposed activities and authorized take would not cause additional effects for which section 7 consultation would be 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, we prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from issuance of the original IHA to SCWA for the specified activities and found that it would not result in any significant impacts to the human environment. We signed a Finding of No Significant Impact (FONSI) on March 30, 2010. We have reviewed SWCA's application for a renewed IHA for ongoing estuary management activities for 2015 and the 2014 monitoring report. Based on that review, we have determined that the proposed action follows closely the IHAs issued and implemented in 2010–13 and does not present any substantial changes, or significant new circumstances or information relevant to environmental concerns which would require a supplement to the 2010 EA or preparation of a new NEPA document. Therefore, we have determined that a new or supplemental EA or Environmental Impact Statement is unnecessary, and reaffirm the existing FONSI for this action. The 2010 EA and FONSI for this action are available for review at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.*

Authorization

As a result of these determinations, we have issued an IHA to SCWA to conduct estuary management activities in the Russian River from the period of April 21, 2015, through April 20, 2016, provided the previously mentioned mitigation, monitoring, and reporting requirements are implemented.

Dated: April 27, 2015.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–10115 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD881

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewal.

SUMMARY: The Assistant Administrator for Fisheries, NMFS, (Assistant Administrator) has issued an affirmative finding annual renewal for the Government of Spain under the Marine Mammal Protection Act (MMPA). This affirmative finding annual renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Spanish-flag purse seine vessels or purse seine vessels operating under Spanish jurisdiction to be imported into the United States. The affirmative finding annual renewal was based on review of documentary evidence submitted by the Government of Spain and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding annual renewal is effective from April 1, 2014, through March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264 Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows

for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Government of Spain and obtained from the IATTC and has determined that Spain has met the MMPA's requirements to receive an affirmative finding annual renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding annual renewal to Spain, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Spanish-flag purse seine vessels or purse seine vessels operating under Spanish jurisdiction through March 31, 2015. Spain's 5-year affirmative finding will remain valid through March 31, 2015.

Dated: April 24, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10167 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD903

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Endangered Species Workgroup will hold a meeting, which is open to the public.

DATES: The meeting will occur May 19–21, 2015. The meeting will begin at 1 p.m. Tuesday, May 19 and at 9 a.m. on Wednesday and Thursday, May 20–21.

ADDRESSES: The meeting will be held at the Regional Administrator's Conference Room, Building 1, National Oceanic and Atmospheric Administration, Western Regional Center, 7600 Sand Point Way NE., Seattle, WA 98115–6349, telephone: (206) 526–6150.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Sarah Williams, NMFS, *Sarah.Williams@noaa.gov;* telephone: (206) 526–4646.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is to review information on take of species listed under the Endangered Species Act (ESA) in the Pacific Coast groundfish fishery (other than salmonids) and provide recommendations to the Pacific Council on any additional mitigation measures needed, if any, to meet the requirements of the ESA as implemented through the terms and conditions in the most recent biological opinion for the fishery.

You may also join this meeting by conference line and webinar. To join by phone, participants should dial 888–790–6085, passcode 1730793. To join by webinar, each day of the meeting requires a different Web address. On May 19, participants can join Meeting ID: 544–685–613 at *https://global.gotomeeting.com/join/544685613.* On May 20, participants can join Meeting ID: 991–327–765 at *https://global.gotomeeting.com/join/991327765.* On May 21, participants can join Meeting ID: 845–869–013 at *https://global.gotomeeting.com/join/845869013.* Once you have joined the webinar, choose either your computer's audio or select ''Use Telephone.'' If you do not select ''Use Telephone'' you will be connected to audio using your computer's microphone and speakers (VolP). If you do not have a headset and speakers, you may use the conference line number by dialing 1–888–790–6085, and entering passcode 1730793 at the prompt.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2425 at least 5 days prior to the meeting date.

Dated: April 27, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10080 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD922

Presidential Task Force on Combating Illegal Unreported and Unregulated (IUU) Fishing and Seafood Fraud Action Plan Recommendations 14/15 Identifying Species ''At Risk'' of IUU Fishing and Seafood Fraud

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The National Ocean Council Committee on IUU Fishing and Seafood

Fraud (NOC Committee) is seeking public input on principles to be used in determining seafood species ''at risk'' for IUU fishing and seafood fraud.

DATES: Comments must be received by June 8, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2014–0090, by any of the following methods:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0090,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- Mail: Submit written comments to Danielle Rioux, 1315 East-West Highway; Silver Spring, Maryland 20910.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by the NOC Committee. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. The NOC Committee will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Danielle Rioux, 301–427–8516.

SUPPLEMENTARY INFORMATION: According to NOAA, in 2013, U.S. fishers landed 9.9 billion pounds of fish and shellfish worth $5.5 billion. Globally, illegal, unreported, and unregulated (IUU) fishing and seafood fraud undermine the sustainability of U.S. and global seafood stocks and negatively impact general ecosystem health. At the same time, IUU fishing and fraudulent seafood products distort legal markets and unfairly compete with the products of law-abiding fishers and seafood industries.

On March 15, 2015, the Presidential Task Force on Combating IUU Fishing and Seafood Fraud (Task Force), co-chaired by the Departments of Commerce and State, took an historic step to address these issues and published its action plan to implement Task Force recommendations (*http://www.nmfs.noaa.gov/ia/iuu/taskforce.html*).

This plan articulates the aggressive steps that Federal agencies will take to implement the recommendations the Task Force made to the President in December 2014 on a comprehensive framework of integrated programs to combat IUU fishing and seafood fraud. The plan identifies actions that will strengthen enforcement, create and expand partnerships with state and local governments, industry, and non-governmental organizations, and create a risk-based traceability program to track seafood from harvest to entry into U.S. commerce, including the use of existing traceability mechanisms. The work the Task Force began will continue under the oversight of the NOC Committee.

This notice is the first step in implementing Task Force Recommendations 14 and 15, ''Identifying current at risk species threatened by IUU fishing and seafood fraud.'' Once ''at-risk'' species have been determined, the NOC Committee will transmit the list to agencies for appropriate action. This list will form the basis for the species addressed in the first phase of the risk-based seafood traceability program, as described in the Task Force Action Plan.

With this notice, the NOC Committee is soliciting comment on what principles should be used to determine the seafood species ''at risk'' for IUU fishing and seafood fraud. Recommended principles should be measurable (*i.e.,* there should be a reasonable amount of existing data to assess), and be applicable to domestic and/or international fisheries.

For example, possible principles could include assessing the extent to which species are known to have:

- significant domestic or international enforcement-related concerns, such as substantial numbers of violations of relevant regulations or conservation and management measures, significant challenges or limitations in existing enforcement regimes, or repeated reports of IUU activity;
- catches that are mis-reported or not reported according to the reporting procedures of the relevant international regional fisheries management organizations or national authorities, particularly when they are of high economic value;
- a human health risk when substituted for other species; and
- instances of being substituted for other species in order to avoid tariffs or to sell a lower value fish at a higher price.

Following the public comment period, the NOC Committee will take the input received into consideration as it develops a draft list of principles to be used in determining species ''at risk'' for IUU fishing and seafood fraud. The draft list of principles will then be used to create a draft list of ''at-risk'' species. Both the draft list of principles and the draft list of ''at-risk'' species will be published in the **Federal Register** for public comment in July 2015.

Dated: April 27, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2015–10125 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD923

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Risk Policy Working Group to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, May 19, 2015 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Four Points by Sheraton, 407 Squire Road, Revere, MA 02151; Phone: (781) 284–7200; Fax: (781) 289–3176.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The items of discussion on the agenda are to discuss implementation of the Councils Risk Policy across all Council-managed species. The group will also continue work on development of the Risk Policy ''operational handbook'' to address the application of the Risk Policy. Additionally they will discuss the application of the Risk Policy in the Atlantic Herring FMP and develop related recommendations. The group

will also plan for future work. They will discuss as other business as necessary.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 27, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10081 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD879

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewal.

SUMMARY: The Assistant Administrator for Fisheries, NMFS, (Assistant Administrator) has issued an affirmative finding annual renewal for the Government of Guatemala under the Marine Mammal Protection Act (MMPA). This affirmative finding annual renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Guatemalan-flag purse seine vessels or purse seine vessels operating under Guatemalan jurisdiction to be imported into the United States. The affirmative finding annual renewal was based on review of documentary evidence submitted by the Government of Guatemala and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding annual renewal is effective from April 1, 2014, through March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264 Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Government of Guatemala and obtained from the IATTC and has determined that Guatemala has met the MMPA's requirements to receive an affirmative finding annual renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding annual renewal to Guatemala, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Guatemalan-flag purse seine vessels or purse seine vessels operating under Guatemalan jurisdiction through March 31, 2015. Guatemala's 5-year affirmative finding will remain valid through March 31, 2015.

Dated: April 24, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10162 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD878

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewal.

SUMMARY: The Assistant Administrator for Fisheries, NMFS, (Assistant Administrator) has issued an affirmative finding annual renewal for the Government of El Salvador under the Marine Mammal Protection Act (MMPA). This affirmative finding annual renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Salvadoran-flag purse seine vessels or purse seine vessels operating under Salvadoran jurisdiction to be imported into the United States. The affirmative finding annual renewal was based on review of documentary evidence submitted by the Government of El Salvador and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding annual renewal is effective from April 1, 2014, through March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264 Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Government of El Salvador and obtained from the IATTC and has determined that El Salvador has met the MMPA's requirements to receive an affirmative finding annual renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding annual renewal to El Salvador, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Salvadoran-flag purse seine vessels or purse seine vessels operating under Salvadoran jurisdiction through March 31, 2015. El Salvador's 5-year affirmative finding will remain valid through March 31, 2018, subject to subsequent annual reviews by NMFS.

Dated: April 24, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10153 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD880

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding 2-year renewal.

SUMMARY: The Assistant Administrator for Fisheries, NMFS, (Assistant Administrator) has issued an affirmative finding 2-year renewal for the Government of Mexico under the Marine Mammal Protection Act (MMPA). This affirmative finding 2-year renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Mexican-flag purse seine vessels or purse seine vessels operating under Mexican jurisdiction to be imported into the United States. The affirmative finding 2-year renewal was based on review of documentary evidence submitted by the Government of Mexico and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding 2-year renewal is effective for the 2-year period of April 1, 2013 (retroactive) through March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264. Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Government of Mexico and obtained from the IATTC and has determined that Mexico has met the MMPA's requirements to receive an affirmative finding 2-year renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding 2-year renewal to Mexico, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Mexican-flag purse seine vessels or purse seine vessels operating under Mexican jurisdiction for the 2-year period of April 1, 2013 (retroactive) through March 31, 2015. Mexico's 5-year affirmative finding will remain valid through March 31, 2015.

Dated: April 24, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10164 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD877

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding 2-year renewal.

SUMMARY: The Assistant Administrator for Fisheries, NMFS, (Assistant Administrator) has issued an affirmative finding 2-year renewal for the Government of Ecuador under the Marine Mammal Protection Act (MMPA). This affirmative finding 2-year renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Ecuadorian-flag purse seine vessels or purse seine vessels operating under Ecuadorian jurisdiction to be imported into the United States. The affirmative finding 2-year renewal was based on review of documentary evidence submitted by the Government of Ecuador and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding 2-year renewal is effective for the 2-year period of April 1, 2013 (retroactive) through March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264 Email: *justin.greenman@noaa.gov*.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Government of Ecuador and obtained from the IATTC and has determined that Ecuador has met the MMPA's requirements to receive an affirmative finding 2-year renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding 2-year renewal to Ecuador, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Ecuadorian-flag purse seine vessels or purse seine vessels operating under Ecuadorian jurisdiction for the 2-year period of April 1, 2013 (retroactive) through March 31, 2015. Ecuador's 5-year affirmative finding will remain valid through March 31, 2015.

Dated: April 24, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–10151 Filed 4–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Addendum to the 26 June 2014 Record of Decision for the Final Supplemental Environmental Impact Statement F–35 Beddown at Eglin Air Force Base, Florida

ACTION: Notice of Availability (NOA) of Addendum to 26 June 2014 Record of Decision (ROD).

SUMMARY: On April 23, 2015, the United States Air Force signed an Addendum to the 26 June 2014 ROD for the Final F–35 Beddown Supplemental Environmental Impact Statement (SEIS). The Addendum to the 26 June 2014 Record of Decision (AROD) documents the Air Force's decisions to: (1) Temporarily shift the primary runway to Runway 01/19 (RW 01/19) and allow a temporary increase in previously limited F–35 operations for construction-related closure of Runway 12/30 (RW 12/30), and (2) approve the Department of the Navy's (DoN's) request to add fifteen (15) Backup Aircraft Inventory (BAI) F–35C aircraft at Eglin AFB.

The AROD augments the 26 June 2014 ROD by allowing a one-time, temporary increase in certain F–35 operations on Runway 01/19 (RW 01/19) due to required construction-related closure of Runway 12/30 (RW 12/30) for up to four months from approximately 1 May 2015 through 31 August 2015. During this up to four-month period of construction partially closing RW 12/30, but only after all mitigations measures have first been implemented and/or exhausted, limited additional F–35 operations up to the number and type of average daily operations analyzed in Alternative 1A (predominantly departures/take-offs on RW 01 and approaches/landings on RW 19) of the SEIS and published in Table E–16 at pages E–84 and E–85 in Appendix E, will be allowed on RW 01/19. The additional Navy F–35C BAI will not alter the number or type of F–35C operations analyzed in the SEIS and approved in the 26 June 2014 ROD.

The Final SEIS was made available to the public on February 28, 2014 through a NOA in the **Federal Register** (Volume 79, Number 40, Page 11428) with a wait period that ended on March 31, 2014. The 26 June 2014 SEIS ROD was made available to the public, through a NOA in the **Federal Register** (Volume 79, Number 131, Page 38857), on July 9, 2014.

Authority: This NOA is published pursuant to the relevant subsection of the regulations (40 CFR part 1506.6(b)2))

implementing the provisions of the NEPA of 1969 (42 U.S.C. 4321, *et seq.*) and the relevant subsections of the Air Force's Environmental Impact Analysis Process (EIAP) (32 CFR parts 989.21(b) and 989.24(b)(7)).

FOR FURTHER INFORMATION CONTACT: Mr. Mike Spaits, 850–882–2836.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2015–10089 Filed 4–29–15; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0055]

Agency Information Collection Activities; Comment Request; Child Care Access Means Parents in School Program Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 29, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0055 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Josephine Hamilton, 202–502–7583.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Child Care Access Means Parents in School Program Annual Performance Report.

OMB Control Number: 1840–0763.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 89.

Total Estimated Number of Annual Burden Hours: 801.

Abstract: This is a revision of the Child Care Access Means Parent In School Program (CCAMPIS) Annual Performance Report (APR). This report provides the Department of Education with information needed to evaluate a grantee's performance and compliance with program requirements in accordance with the program authorizing statute. The data collected is aggregated to provide national information on project participants and the results demonstrated by program outcomes. The burden hours are increased due to additional queries that have been added to the APR that capture more specific data needed to enhance the understanding of results demonstrated by this program in accordance with OMB mandates.

Dated: April 27, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–10079 Filed 4–29–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

State Energy Advisory Board (STEAB)

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

ACTION: Notice of open teleconference.

SUMMARY: This notice announces a teleconference call of the State Energy Advisory Board (STEAB). The Federal Advisory Committee Act (Pub. L. 92–463; 86 Stat.770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, May 21, 2015 from 3:30 p.m. to 4:00 p.m. (EDT). To receive the call-in number and passcode, please contact the Board's Designated Federal Officer at the address or phone number listed below.

FOR FURTHER INFORMATION CONTACT: Monica Neukomm, Policy Advisor, Office of Energy Efficiency and Renewable Energy, US Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585. Phone number 202–287–5189, and email at: *monica.neukomm@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* To make recommendations to the Assistant Secretary for the Office of Energy Efficiency and Renewable Energy regarding goals and objectives, programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

Tentative Agenda: Receive STEAB Task Force updates on action items and revised objectives for FY 2015, discuss follow-up opportunities and engagement with EERE and other DOE staff as needed to keep Task Force work moving forward, continue engagement with DOE, EERE and EPSA staff regarding energy efficiency and renewable energy projects and initiatives, and receive updates on member activities within their states.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items

should contact Monica Neukomm at the address or telephone number listed above. Requests to make oral comments must be received five days prior to the meeting; reasonable provision will be made to include requested topic(s) on the agenda. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days on the STEAB Web site at: *www.steab.org.*

Issued at Washington, DC, on April 24, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–10086 Filed 4–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Biomass Research and Development Technical Advisory Committee

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

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Biomass Research and Development Technical Advisory Committee under Section 9008(d) of the Food, Conservation, and Energy Act of 2008 amended by the Agricultural Act of 2014. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that agencies publish these notices in the **Federal Register** to allow for public participation.

DATES:

May 20, 2015 8:30 a.m.–5:30 p.m.
May 21, 2015 8:30 a.m.–5:30 p.m.
May 22, 2015 8:30 a.m.–1:00 p.m.

ADDRESSES: Marriott Marquis, 901 Massachusetts Ave NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Elliott Levine, Designated Federal Officer for the Committee, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; (202) 586–1476; Email: *Elliott.Levine@ee.doe.gov* and Roy Tiley at (410) 997–7778 ext. 220; Email: *rtiley@bcs-hq.com.*

SUPPLEMENTARY INFORMATION: *Purpose of Meeting:* To provide advice and guidance that promotes research and development leading to the production of biobased fuels and biobased products.

Tentative Agenda: Agenda will include the following:

- Update on USDA Biomass R&D Activities
- Update on DOE Biomass R&D Activities
- Updated on the Biomass Research and Development Initiative
- Overview of the Biomass Interagency Working Groups
- Panel on International Bioenergy Activities

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the Biomass Research and Development Technical Advisory Committee. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, you must contact Elliott Levine at 202–586–1476; Email: *Elliott.Levine@ee.doe.gov* and Roy Tiley at (410) 997–7778 ext. 220; Email: *rtiley@bcs-hq.com* at least 5 business days prior to the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Co-chairs of the Committee will make every effort to hear the views of all interested parties. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. The Co-chairs will conduct the meeting to facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying at *http://biomassboard.gov/committee/meetings.html.*

Issued at Washington, DC, on April 24, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–10084 Filed 4–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Methane Hydrate Advisory Committee

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Methane Hydrate Advisory Committee. The Federal Advisory Committee Act (Public Law 92–463, 86 Stat.770) requires that notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, May 15, 2014, 10:45 a.m. to 11:00 a.m. (EDT)—Registration, 11:00 a.m. to 12:30 p.m. (EDT)—Meeting.

ADDRESSES: U.S. Department of Energy, Forrestal Building, Room 3G–043, 1000 Independence Ave. SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Lou Capitanio, U.S. Department of Energy, Office of Oil and Natural Gas, 1000 Independence Avenue SW., Washington, DC 20585. *Phone:* (202) 586–5098.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the Methane Hydrate Advisory Committee is to provide advice on potential applications of methane hydrate to the Secretary of Energy, and assist in developing recommendations and priorities for the Department of Energy's Methane Hydrate Research and Development Program.

Tentative Agenda: The agenda will include: Welcome and Introduction by the Designated Federal Officer; Discussion of Committee Comments on Draft Letter to the Secretary of Energy; Discussion of Committee Recommendations; and Public Comments, if any.

Public *Participation:* The meeting is open to the public. The Designated Federal Officer and the Chair of the Committee will conduct the meeting to facilitate the orderly conduct of business. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Lou Capitanio at the phone number listed above and provide your name, organization, citizenship, and contact information. Anyone attending the meeting will be required to present government issued identification. Space is limited. You must make your request for an oral statement at least five business days prior to the meeting, and reasonable provisions will be made to include the presentation on the agenda. Public comment will follow the three-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 60 days at the following Web site: *http://energy.gov/fe/services/advisory-committees/methane-hydrate-advisory-committee.*

Issued at Washington, DC, on April 24, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–10085 Filed 4–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Commission To Review the Effectiveness of the National Energy Laboratories

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Commission to Review the Effectiveness of the National Energy Laboratories (Commission). The Commission was created pursuant section 319 of the Consolidated Appropriations Act, 2014, Public Law 113–76, and in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2. This notice is provided in accordance with the Act.

DATES: Thursday, May 22, 2015—9:00 a.m.–2:00 p.m.

ADDRESSES: Stanford Linear Accelerator Laboratory (SLAC), Kavli Auditorium, Building 51 (Kavli Building), 2575 Sand Hill Road, Menlo Park, CA 94025–7015.

FOR FURTHER INFORMATION CONTACT: Karen Gibson, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; telephone (202) 586–3787; email *crenel@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

Background: The Commission was established to provide advice to the Secretary on the Department's national laboratories. The Commission will review the DOE national laboratories for alignment with the Department's strategic priorities, clear and balanced missions, unique capabilities to meet current energy and national security challenges, appropriate size to meet the Department's energy and national security missions, and support of other Federal agencies. The Commission will also look for opportunities to more effectively and efficiently use the capabilities of the national laboratories and review the use of laboratory directed research and development (LDRD) to meet the Department's science, energy, and national security goals.

Purpose of the Meeting: This meeting is the ninth meeting of the Commission.

Tentative Agenda: The meeting will start at 9:00 a.m. on May 22. The tentative meeting agenda include the impact of the National Laboratories on economic development and technology transfer, partnerships within the Bay Area, and the appropriate level of DOE oversight for its M&O contractor laboratories. Key presenters will address and discuss these topics with comments from the public. The meeting will conclude at 2:00 p.m. The agenda along with possible schedule adjustments will be posted when finalized and in advance of the meeting on the Lab Commission Web site (*http://energy.gov/labcommission/commission-review-effectiveness-national-energy-laboratories*).

Public Participation: The meeting is open to the public. Individuals who would like to attend must RSVP to Karen Gibson no later than 5:00 p.m. EDT on Tuesday, May 19, 2015 at email: *crenel@hq.doe.gov*. Please provide your name, citizenship, organization, and contact information. Individuals and representatives of organizations who would like to offer comments and suggestions may do so at the end of the meeting. Approximately 30 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but will not exceed 5 minutes. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Those wishing to speak should register to do so beginning at 9:00 a.m. on May 22.

Those not able to attend the meeting or who have insufficient time to address the committee are invited to send a written statement to Karen Gibson, U.S. Department of Energy, 1000 Independence Avenue SW., Washington DC 20585, or to email: *crenel@hq.doe.gov*.

Minutes: The minutes of the meeting will be available on the Commission Web site at: *http://energy.gov/labcommission*.

Issued in Washington, DC, on April 24, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–10083 Filed 4–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3316–PN]

Medicare and Medicaid Programs; Application by the American Diabetes Association for Continued Deeming Authority for Diabetes Self-Management Training

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the American Diabetes Association for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 1, 2015.

ADDRESSES: In commenting, refer to file code CMS–3316–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3316–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

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–3316–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written ONLY to 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, call

telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Kristin Shifflett, (410) 786–4133.
Jacqueline Leach, (410) 786–4282.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient Diabetes Self-Management Training (DSMT) when ordered by the physician (or qualified non-physician practitioner) treating the beneficiary's diabetes, provided certain requirements are met. Pursuant to our regulations at 42 CFR 410.141(e)(3), we use national accrediting organizations to assess whether provider entities meet Medicare requirements when providing services for which Medicare payment is made. If a provider entity is accredited by an approved accrediting organization, it is ''deemed'' to meet applicable Medicare requirements.

Under section 1865(a)(1)(B) of the Social Security Act (the Act), a national accrediting organization must have an agreement in effect with the Secretary of the Department of Health and Human Services (the Secretary) and meet the standards and requirements specified by the Secretary in 42 CFR part 410, subpart H, to qualify for deeming authority. The regulations pertaining to application procedures for the national accreditation organizations for DSMT are specified at § 410.142 (CMS process for approving national accreditation organizations).

A national accreditation organization applying for deeming authority must provide us with reasonable assurance that the accrediting organization requires accredited entities to meet requirements that are at least as stringent as our requirements.

We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training. The accreditation organization, after being approved and recognized by us, may accredit an entity to meet one of the sets of quality standards in § 410.144 (Quality standards for deemed entities).

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act further requires that we review the applying accreditation organization's requirements for accreditation, as follows:

- Survey procedures;
- Ability to provide adequate resources for conducting required surveys;
- Ability to supply information for use in enforcement activities;
- Monitoring procedures for providers found out of compliance with the conditions or requirements; and
- Ability to provide us with necessary data for validation.

We then examine the national accreditation organization's accreditation requirements to determine if they meet or exceed the Medicare conditions as we would have applied them. Section 1865(a)(3)(A) of the Act requires that we publish a notice identifying the national accreditation organization that is making the request for approval or renewal within 60 days of receipt of a completed application. The notice must describe the nature of the request and provide at least a 30-day public comment period. We have 210 days from receipt of the request to publish a finding of approval or denial of the application. If CMS recognizes an accreditation organization in this manner, any entity accredited by the national accreditation organization's program for that service will be ''deemed'' to meet the Medicare conditions for coverage.

III. Evaluation of Deeming Authority Request

The purpose of this notice is to notify the public of the American Diabetes Association (ADA) request for the Secretary's approval of its accreditation program for outpatient DSMT services. The ADA submitted all the necessary materials to enable us to make a determination concerning its request for re-approval as a deeming organization for DSMTs. ADA was initially accredited on October 27, 2009 for a period of 6 years. This application was determined to be complete on March 13, 2015. This notice also solicits public comments on the ability of the ADA to continue to develop standards that meet or exceed the Medicare conditions for coverage, and apply them to entities furnishing outpatient services.

The regulations specifying the Medicare conditions for coverage for outpatient diabetes self-management training services are located in 42 CFR parts 410, subpart H. These conditions implement section 1861(qq) of the Act, which provides for Medicare Part B coverage of outpatient DSMT services specified by the Secretary.

Under section 1865(a)(2) of the Act and our regulations at § 410.142 (CMS process for approving accreditation organizations) and § 410.143 (Requirements for approved accreditation organizations), we review and evaluate a national accreditation organization based on (but not necessarily limited to) the criteria set forth in § 410.142(b).

We may conduct on-site inspections of a national accreditation organization's operations and office to verify information in the organization's application and assess the organization's compliance with its own policies and procedures. The on-site inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. 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. Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation.

Dated: April 21, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–10171 Filed 4–29–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10336]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 1, 2015.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of the currently approved collection; Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Electronic Health Record Incentive Program; *Use:* The American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111–5) was enacted on February 17, 2009. The Recovery Act includes many measures to modernize our nation's infrastructure, and improve affordable health care. Expanded use of health information technology (HIT) and certified electronic health record (EHR) technology will improve the quality and value of America's health care. Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the ''Health Information Technology for Economic and Clinical Health Act'' or the ''HITECH Act.''

The HITECH Act creates incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for payment adjustments in the Medicare FFS and MA programs starting in FY 2015 for EPs and eligible hospitals participating in Medicare that are not meaningful users of certified EHR technology. These payment adjustments do not pertain to Medicaid providers.

The first final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the **Federal Register** on July 28, 2010 (CMS–0033–F), specified the initial criteria EPs, eligible hospitals and CAHs, and MA organizations must meet in order to qualify for incentive payments; calculation of incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. On the same date, the Office of the National Coordinator of Health Information Technology (ONC) issued a closely related final rule (45 CFR part 170, RIN 0991–AB58) that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the

establishment of certification programs for health information technology (HIT) (45 CFR part 170, RIN 0991–AB59). The functionality of certified EHR technology should facilitate the implementation of meaningful use. Subsequently, final rules have been issued by CMS (77 FR 53968) and ONC (77 FR 72985) to create a Stage 2 of meaningful use criteria and other changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

The information collection requirements contained in this information collection request are needed to implement the HITECH Act. In order to avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), while all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider's tax identification number and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. *Form Number:* CMS–10336 (OMB control number: 0938–1158); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 214,694; *Total Annual Responses:* 214,694; *Total Annual Hours:* 2,034,740. (For policy questions regarding this collection contact Elisabeth Myers at 410–786–4751.)

Dated: April 28, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–10197 Filed 4–29–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 June 9, 2015, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Parkway, Gaithersburg, MD 20877. The hotel telephone number is 301–977–8900.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application 125559, proposed trade name PRALUENT (established name: Alirocumab) for injection, submitted by Sanofi Aventis, U.S., as an adjunct to diet, for long-term treatment of adult patients with primary hypercholesterolemia (non-familial and heterozygous familial) or mixed dyslipidemia including patients with type 2 diabetes mellitus, to reduce low-density lipoprotein cholesterol, total cholesterol, non-high-density lipoprotein cholesterol, apolipoprotein B, tryglyceride, and lipoprotein A, and to increase high-density lipoprotein cholesterol and apolipoprotein A–1 either in combination with a statin or as monotherapy including in patients who cannot tolerate statins.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 26, 2015. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 15, 2015. 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 May 18, 2015.

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 Philip Bautista 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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10023 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0602]

Guidance for Industry on Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product.'' This guidance is intended to provide sponsors with an overview of analytical factors that are relevant to assessing whether a proposed product and the reference product are highly similar for the purpose of submitting a marketing application through an abbreviated licensure pathway. This guidance finalizes the draft guidance issued in February 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product.'' This guidance is intended to provide sponsors with an overview of analytical factors that are relevant to assessing whether a proposed product and the reference product are highly similar for the purpose of submitting a marketing application through the abbreviated licensure pathway under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)). Although the 351(k) pathway applies generally to biological products, this guidance focuses on therapeutic protein products.

The Biologics Price Competition and Innovation Act of 2009 was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the PHS Act for biological products demonstrated to be biosimilar to or interchangeable with a reference product. Under this abbreviated licensure pathway, FDA will license a proposed biological product submitted under section 351(k) of the PHS Act if FDA ''determines that the information submitted in the application . . . is sufficient to show that the biological product . . . is biosimilar to the reference product . . .'' and the 351(k) applicant (or other appropriate person) consents to an inspection of the facility that is the subject of the application (*i.e.,* a facility in which the proposed biological product is manufactured, processed, packed, or held).[1]

All product applications should contain a complete and thorough chemistry, manufacturing, and controls section that provides the necessary and appropriate information, including, but not limited to, characterization, adventitious agent safety, process controls, and specifications, for the product to be adequately reviewed.[2] This guidance describes important factors for consideration when assessing whether a proposed product and the reference product are highly similar, including:

- Expression System
- Manufacturing Process
- Assessment of Physiochemical Properties
- Functional Activities
- Receptor Binding and Immunochemical Properties
- Impurities
- Reference Product and Reference Standards
- Finished Drug Product
- Stability

In the **Federal Register** of February 15, 2012 (77 FR 8884), FDA announced the availability of the draft guidance entitled ''Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product'' dated February 2012. FDA received a number of comments on the draft guidance. In response to these comments, this guidance provides further clarification on general principles on topics including, but not limited to, the use of comparative analytical data to provide the foundation for a biosimilar development program, the timing of submission of analytical similarity data, the appropriate number of lots needed, and the type of bridging data needed when sponsors use a non-U.S.-licensed comparator product in certain studies. The guidance provides additional clarification on the factors for consideration in assessing whether a proposed product is highly similar to the reference product. This guidance finalizes the draft guidance issued in February 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on quality considerations in demonstrating biosimilarity of a therapeutic protein product to a reference product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It

[1] Section 7002(a)(2) of the Affordable Care Act, adding section 351(k)(3) of the PHS Act (citing section 351(a)(2)(C) of the PHS Act).

[2] For CMC requirements for submission of a marketing application, applicants should consult current regulations, the guidance for industry for the ''Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In-Vivo Use,'' and other applicable FDA guidance documents.

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations, which are not expected to change as a result of the guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application (BLA) under section 351(a) of the PHS Act, which is covered under part 601 (21 CFR part 601) and approved under OMB control number 0910–0338; and (4) a BLA under section 351(k), which is covered under part 601 and approved under OMB control number 0910–0719.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10063 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0605]

Scientific Considerations in Demonstrating Biosimilarity to a Reference Product; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting a marketing application through an abbreviated licensure pathway. This guidance gives an overview of FDA's approach to determining biosimilarity.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product is ''biosimilar'' [1] to a reference product for the purpose of submitting a marketing application through the abbreviated licensure pathway under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)).

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted as part of the Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the PHS Act for biological products demonstrated to be biosimilar to, or interchangeable with, a reference product. Under this abbreviated licensure pathway, FDA will license a proposed biological product submitted under section 351(k) of the PHS Act if FDA ''determines that the information submitted in the application . . . is sufficient to show that the biological product is biosimilar to the reference product. . . .'' and the 351(k) applicant (or other appropriate person) consents to an inspection of the facility that is the subject of the application (*i.e.,* a facility in which the proposed biological product is manufactured, processed, packed, or held).[2] The guidance gives an overview of FDA's approach to determining biosimilarity. FDA intends to consider the totality of the evidence submitted in a 351(k) application and is recommending that sponsors use a stepwise approach in their development of biosimilar products. The guidance discusses important scientific considerations in demonstrating biosimilarity, including:

- A stepwise approach to demonstrating biosimilarity, which can include a comparison of the proposed product and the reference product with

[1] In section 7002(b)(3) of the Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. 111–148, ''biosimilar'' or ''biosimilarity'' means ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components,'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.''

[2] Section 7002(a)(2) of the Affordable Care Act, adding section 351(k)(3) of the PHS Act (citing section 351(a)(2)(C) of the PHS Act).

respect to structure, function, animal toxicity, human pharmacokinetics (PK) and pharmacodynamics (PD), clinical immunogenicity, and clinical safety and effectiveness;

- The *totality-of-the-evidence* approach that FDA will use to review applications for biosimilar products, consistent with a longstanding Agency approach to evaluation of scientific evidence; and
- General scientific principles in conducting comparative structural analyses, functional assays, animal testing, human PK and PD studies, clinical immunogenicity assessment, and comparative clinical trials (including clinical study design issues).

In the **Federal Register** of February 15, 2012 (77 FR 8883), FDA announced the availability of the draft guidance of the same title dated February 2012. FDA received a number of comments on the draft guidance. In response to these comments, FDA provides further clarification of the scientific considerations applicable to the conduct of comparative structural analysis, functional assays, animal studies, and clinical testing. The final guidance also provides additional information on clinical trial design and selection of study endpoint and population. It also explains FDA's current thinking on when a comparative clinical trial may not be needed. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes and replaces the draft guidance dated February 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on scientific considerations in demonstrating biosimilarity to a reference product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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

III. The Paperwork Reduction Act of 1995

This guidance describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). This guidance references information collections that are already approved by OMB and are not expected to change as a result of the guidance. This includes information collections related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB Control No. 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application under section 351(a) of the PHS Act, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0338; and (4) a biologics license application under section 351(k) of the PHS Act, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0719.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10062 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0611]

Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' This guidance is intended to provide answers to common questions from sponsors interested in developing proposed biosimilar products, biologics license application (BLA) holders, and other interested parties regarding FDA's interpretation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). This guidance finalizes several questions and answers (Q&As) from the draft guidance entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009'' issued February 15, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the

Biologics Price Competition and Innovation Act of 2009.'' This guidance provides answers to common questions from sponsors interested in developing proposed biosimilar products, BLA holders, and other interested parties regarding FDA's interpretation of the BPCI Act.

The BPCI Act, enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010, created an abbreviated licensure pathway under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)) for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed reference product. This guidance describes FDA's current interpretation of certain statutory requirements added by the BPCI Act and includes Q&As in the following categories:

- Biosimilarity or Interchangeability
- Provisions Related to Requirement to Submit a BLA for a ''Biological Product''
- Exclusivity

The Q&A format is intended to promote transparency and facilitate development programs for proposed biosimilar products by addressing questions that may arise in the early stages of development. In addition, these Q&As respond to questions the Agency has received from prospective BLA and new drug application (NDA) applicants regarding the appropriate statutory authority under which certain products will be regulated.

In the **Federal Register** of February 15, 2012 (77 FR 8885), FDA published a notice announcing the availability of a draft guidance entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' Although interested parties can comment on any guidance at any time, to ensure that the Agency considered comments on the draft guidance before beginning work on the final version of the guidance, FDA requested that interested parties submit comments by April 16, 2012. FDA's consideration of these comments, among other things, is reflected in a revised draft guidance and this final guidance. This guidance describes the status of the draft guidance Q&As provided in Revision 1 of the draft guidance entitled ''Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' and the status of the final guidance Q&As that are included in this guidance. FDA intends to update these guidances to include additional Q&As as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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

III. The Paperwork Reduction Act of 1995

This guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). The submission of an investigational new drug application is covered under 21 CFR part 312 and approved under OMB control number 0910–0014. The submission of an NDA is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001. The submission of a BLA under section 351(a) of the PHS Act is covered under part 601 (21 CFR part 601) and approved under OMB control number 0910–0338. The submission of a BLA under section 351(k) of the PHS Act is covered under part 601 and approved under OMB control number 0910–0719. In the **Federal Register** of April 1, 2013 (78 FR 19492), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' The notice contained an analysis of the information collection burden resulting from the draft guidance, and will be submitted to OMB for approval before issuance of the final guidance.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10064 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1305]

Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or ''we'') is announcing the availability of a risk assessment entitled ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products.'' The risk assessment is a tool to assist with reevaluating which animal drug residues should be included in milk testing programs. We undertook this project in response to a request from the National Conference on Interstate Milk Shipments (NCIMS).

DATES: Submit either electronic or written comments on the risk assessment by July 29, 2015.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the risk assessment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION:

I. Background

The NCIMS is a voluntary coalition that includes representatives from

Federal and State governments, the dairy industry, academia, and consumer groups. FDA collaborates with the NCIMS under a memorandum of understanding between the two entities. The NCIMS requested that we conduct an assessment of animal drug residues in the milk supply to inform potential changes to milk testing program requirements. In response, we developed a multicriteria-based ranking model of selected animal drugs used in dairy cows. The risk assessment provides a science-based, analytical approach to collate and incorporate relevant available data and information (Ref. 1). It provides a decision-support tool to assist with reevaluating which animal drug residues should be included in milk testing programs. The risk assessment also may be used to identify and prioritize research needs. The risk assessment model approach has undergone an independent external peer review. FDA's response to the peer review is available electronically on the FDA Web site (Ref. 2).

The muticriteria-based ranking model is based on four overarching criteria that collectively contribute to a drug's score and rank within the group of drugs evaluated: (1) The likelihood that the drug will be administered to lactating dairy cows; (2) the likelihood that, following administration, drug residues would be present in milk (bulk tank or bulk milk pickup tanker); (3) the relative extent to which consumers could be exposed to the drug residue via consumption of milk and milk products; and (4) the potential for a human health hazard given exposure to the drug residue. The risk assessment describes the ranking model structure, the scientific data and assumptions used to inform scoring in the model, and the ranking results. The risk assessment also identifies data gaps and research needs.

FDA invites comments that can help improve:

- The ranking model approach, including the specific criteria, scoring, and weighting scheme;
- the scientific data and assumptions used to inform scoring used in the model;
- the selection of animal drugs evaluated; and
- the clarity and the transparency of the risk assessment.

II. Comments

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

III. Electronic Access

Persons with access to the Internet may obtain the risk assessment at either *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm* or *http://www.regulations.gov.*

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products.'' Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm.*

2. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products: Peer Review Report.'' Accessible at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm.*

Dated: April 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10000 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Risk Communications 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: Risk Communications 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 June 8, 2015, from 9 a.m. to 5 p.m. and June 9, 2015, from 9 a.m. to 12 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503) Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3367, 240–402–5274, FAX: 301–847–3540, *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees.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.

If you are unable to join us in person, we encourage you to watch the free Webcast. Visit the Risk Communication Advisory Committee Web site at *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm.* The link will become active shortly before the open session begins at 9 a.m.

Agenda: On June 8 and 9, 2015, the Committee will discuss approaches to communicating information about fetal effects in product labeling for methadone or buprenorphine maintenance therapy for opioid addiction, and about the maternal benefits and risks of treatment, to best enable patients and health care providers to make informed decisions about the use of these drugs during pregnancy.

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/RiskCommunicationAdvisoryCommittee.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 1, 2015. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3:30 p.m. on June 8, 2015. 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 May 22, 2015. 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 May 26, 2015. Interested persons can also log on to *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm* to see and hear the proceedings.

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 Luis G. Bravo 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.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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10024 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 June 10, 2015, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 301–977–8900.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application (BLA) 125522, proposed trade name REPATHA (established name: Evolocumab) for injection, submitted by Amgen Inc., as adjunct to diet to reduce low-density lipoprotein cholesterol (LDL–C), total cholesterol (TC), apolipoprotein B (ApoB), non-high-density lipoprotein cholesterol (non-HDL–C), TC/HDL–C, ApoB/ApoA1, very low-density lipoprotein cholesterol, triglyceride, and lipoprotein A, and to increase HDL–C and ApoA1, in adults with hyperlipidemia or mixed dyslipidemia, either in combination with a statin or statin with other lipid-lowering therapies (*e.g.,* ezetimibe), or alone, or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or alone or in combination with other lipid-lowering therapies in patients for whom a statin is not considered clinically appropriate. In addition, the committee will discuss the safety and efficacy of evolocumab to reduce LDL–C, TC, ApoB, and non-HDL–C, in combination with other lipid-lowering therapies (*e.g.* statins, LDL apheresis) in patients at least 12 years of age with homozygous familial hypercholesterolemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 27, 2015. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 18,

2015. 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 May 19, 2015.

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 Philip Bautista 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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10022 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel T Cell Therapy Against Patient-Specific Cancer Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify T cells that specifically recognize immunogenic mutations expressed only by cancer cells. Human cancers contain genetic mutations that are unique to each patient. Some of the mutated peptides are immunogenic, can be recognized by T cells, and therefore, may serve as therapeutic targets. The inventors identified cancer-specific mutations from a patient with widely metastatic cholangiocarcinoma by sequencing tumor samples and comparing with normal cells. Using tandem minigene constructs encoding all of the mutations expressed by a patient's tumor, the inventors identified T cells that recognized the immunogenic mutations from the same patient. These mutation-reactive T cells have the potential to eliminate the cancer cells while sparing normal tissues since normal tissues do not express the mutations. The inventors expanded these mutation-reactive T cells in vitro, and infused a highly pure population of these T cells back into the same patient. The patient experienced tumor regression when she was treated with this approach.

Potential Commercial Applications

- Personalized immunotherapy with mutation-reactive T cells for mediating tumor regression in patients with immunogenic mutations.
- Mutation-reactive T cell therapy especially beneficial for cancer patients refractory to other therapies.
- A research tool to identify patient-specific immunogenic mutations in the tumor.

Competitive Advantages

- This patient-specific therapy has the potential application to most epithelial cancers, which account for about 90% of cancer deaths in the United States.
- Personalized mutation-specific T cells recognize mutations harboring tumor cells only and spare normal tissues. This therapy has no tissue toxicities comparing to traditional chemotherapy and radiotherapy.
- The infusion of a highly pure population of these mutation-specific T cells may maximize therapy and result in regression of all target lesions.

Development Stage

- Early-stage
- *In vitro* data available
- *In vivo* data available (human)
- *Ex vivo* data available

Inventors: Eric Tran, Yong-Chen W. Lu, Paul F. Robbins, Steven A. Rosenberg (all of NCI).

Publications

1. Tran E, et al. Cancer immunotherapy based on mutation-specific CD4+ T cells in a patient with epithelial cancer. Science. 2014 May 9; 344(6184):641–5. [PMID 24812403]

2. Robbins P, et al. Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. Nat Med. 2013 Jun;19(6):747–52. [PMID 23644516]

3. Tran E, et al. T-cell therapy against cancer mutations. Oncotarget. 2014 Jul 15;5(13):4579–80. [PMID 25046408]

Intellectual Property: HHS Reference No. E–229–2014/0—PCT Application No. PCT/US2014/058805 filed October 2, 2014.

Related Technology: HHS Reference No. E–233–2014/0—PCT Application No. PCT/US2014/058796 filed October 2, 2014.

Licensing Contact: Whitney A. Hastings, Ph.D.; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize T-cell therapy against cancer mutations. For collaboration opportunities, please contact Steven A. Rosenberg, M.D., Ph.D. at *sar@nih.gov.*

A Novel, Personalized T Cell Therapy: T-Cell Receptor Engineered T Cells Targeting Tumor Specific Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify and generate T-cell receptor (TCR) engineered T cells for personalized cancer therapy. The TCR is a complex of integral membrane proteins that recognizes antigens and activates T cells. Human cancers

contain genetic mutations that are unique in each patient. The inventors found cancer-specific mutations by sequencing tumors and comparing with normal cells. Using tandem minigene constructs encoding all of the patient's tumor mutations, they first identified T cells that were reactive with the unique mutated antigens expressed only in the patient's tumors. Next, they isolated the mutation-reactive TCRs and engineered peripheral blood T cells from the same patient to express these mutation-reactive TCRs. These personalized TCR engineered T cells can be expanded and infused back into the same patient with the potential to induce tumor regression.

Potential Commercial Applications

- Personalized immunotherapy to treat primary and recurrent epithelial cancer.
- A research tool to identify patient-specific immunogenic mutations in tumors.
- A research tool to identify and isolate mutation-specific T cell receptors.

Competitive Advantages

- This patient-specific therapy has the potential application to most epithelial cancers, which account for about 90% of cancer deaths in the United States.
- Personalized TCR engineered T cells target tumor cells and spare normal tissues. This therapy has no tissue toxicities comparing to traditional chemotherapy and radiotherapy.
- The infusion of a highly pure population of these T cells expressing mutation-specific TCRs may maximize therapy and result in regression of all target lesions.

Development Stage

- Early-stage
- *In vitro* data available
- *Ex vivo* data available

Inventors: Eric Tran, Yong-Chen W. Lu, Paul F. Robbins, Steven A. Rosenberg (all of NCI).

Publications

1. Tran E, et al. Cancer immunotherapy based on mutation-specific CD4+ T cells in a patient with epithelial cancer. Science. 2014 May 9;344 (6184):641–5. [PMID 24812403].

2. Robbins P, et al. Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. Nat Med. 2013 Jun;19(6):747–52. [PMID 23644516].

3. Tran E, et al. T-cell therapy against cancer mutations. Oncotarget. 2014 Jul 15;5(13):4579–80. [PMID 25046408].

4. Gros A, et al. PD–1 identifies the patient-specific CD8+ tumor-reactive repertoire infiltrating human tumors. J Clin Invest. 2014 May 1;124(5):2246–59. [PMID 24667641].

Intellectual Property: HHS Reference No. E–233–2014/0—PCT Application No. PCT/US2014/058796 filed October 2, 2014.

Related Technology: HHS Reference No. E–229–2014/0—PCT Application No. PCT/US2014/058805 filed October 2, 2014.

Licensing Contact: Whitney A. Hastings, Ph.D.; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize TCRs reactive with tumor associated antigens. For collaboration opportunities, please contact Steven A. Rosenberg, M.D., Ph.D. at *sar@nih.gov.*

Recombinant Paramyxoviruses Expressing Optimized Heterologous Antigens

Description of Technology: The invention pertains to recombinant paramyxoviruses that express one or more heterologous antigens, such as the human respiratory syncytial virus (RSV) F protein, that have been optimized for increased expression and immunogenicity. The recombinant constructs induce a bivalent immune response to the paramyxovirus vectors and the heterologous antigen. Potential vectors include parainfluenza virus (PIV) serotype 1 and 3, Sendai virus, Newcastle disease virus, PIV2, and PIV5. An exemplary modified heterologous antigen includes the ectodomain of RSV F protein linked to the transmembrane and cytoplasmic domains of the F protein from the PIV vector, which results in efficient incorporation into the vector particle. The RSV F ectodomain can be engineered to be stabilized in an optimal conformation, such as the highly immunogenic prefusion conformation. Additionally, the exemplary heterologous RSV F ectodomain can include one or more amino acid substitutions to modify ectodomain expression, conformation, phenotype, or stability.

Potential Commercial Applications

- RSV vaccine
- Paramyxovirus vaccines
- Prophylactic vaccines

Competitive Advantages

- Multi-valence
- Immunogenicity

Development Stage

- Early-stage
- *In vitro* data available

Inventors: Peter Collins, Bo Liang Shirin Munir, Anne Schaap-Nutt, Ursula Buchholz, Natalie Mackow, Peter Kwong, Barney Graham, Jason McLellan (all of NIAID).

Intellectual Property: HHS Reference No. E–241–2014/0—US Provisional Patent Application 62/105,667 filed January 20, 2015.

Related Technologies: HHS Reference No. E–081–2013/0–/5—US Patent Application 14/207,372 filed March 12, 2014; International Patent Application PCT/US2014/026714 filed March 13, 2014. Priority documents as follows:

(1) US Provisional Application 61/780,910 filed March 13, 2013;

(2) US Provisional Application 61/798,389 filed March 15, 2013;

(3) US Provisional Application 61/857,613 filed July 23, 2013; and

(4) US Provisional Application 61/863,909 filed August 9, 2013.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Jenish Patel at *jenish.patel@nih.gov.*

Adaptor for Suspending a Cryovial Over a Centrifuge Tube

Description of Technology: The invention pertains to a device and system for expediting the thawing of frozen specimens (*e.g.,* cryopreserved cells) contained in cryo-vials. An adaptor support suspends cryo-vials over a centrifuge tube containing culture medium in an inverted position. The adaptor has an elongated tubular body. While relatively basic, the adaptor dramatically expedites the process of recovering viable cells from frozen specimens. It reduces the labor time for thawing from several minutes to a few seconds. There is virtually no labor involved and enables a single person to load hundreds of samples within minutes. The cells, once thawed, spend essentially no time in liquid cryopreservative, since they are diluted instantly into growth medium contained in the centrifuge tubes. This process ensures the highest viability as well as recovery from each specimen while dramatically increasing throughput. Importantly, the elimination of multiple labor-intensive steps minimizes variation in viability and yield.

Potential Commercial Applications

- Sample preparation
- Cell culturing

Competitive Advantages

- High throughput
- Low labor
- Speed
- Reduced variability

Development Stage: Prototype.

Inventors: Mario Roederer, Margaret Beddall, Pratip Chattopadhyay (all of NIAID).

Intellectual Property: HHS Reference No. E–080–2015/0—US Patent Application No. 14/661,449 filed March 18, 2015.

Licensing Contact: Vince Contreras, Ph.D.; 301–435–4711; *contrerasv@mail.nih.gov*.

Collaborative Research Opportunity: The National Institutes of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Barry Buchbinder at *BBuchbinder@niaid.nih.gov* or 240–627–3678.

Dated: April 24, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–10013 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB 2015–10 U01 Quantum Review.

Date: June 23, 2015.

Time: 10 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov*.

Dated: April 24, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10006 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Novel Treatment for Drug-Induced Respiratory Depression (2239).

Date: May 12, 2015.

Time: 10 a.m. to 12 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, Scientific Review Officer, 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*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA Blending Initiative (2244).

Date: June 4, 2015.

Time: 10 a.m. to 12 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, Scientific Review Officer, 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: April 24, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10003 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 4, 2015.

Open: June 4, 2015, 8:00 a.m. to 12:10 p.m.

Agenda: Report of the Director, NICHD; Report of the Acting Director, Division of Extramural Research, NICHD; Division of Intramural Research, NICHD DIR Reorganization and Discussion; NIH BRAIN Initiative Update and New Business of the Council.

Closed: June 4, 2015, 1:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Caroline Signore, M.D., MPH., Acting Director, Division of Extramural Research, *Eunice Kenney Shriver* National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd. Room 4A05, MSC 7510, Bethesda, MD 20892, (301) 496–5577.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus.

All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

In order to facilitate public attendance at the open session of Council in the main meeting room, Conference Room 6, please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation, additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: *http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS).

Dated: April 24, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10005 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed 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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Biochemistry and Biophysics of Membranes Study Section.

Date: May 28–29, 2015.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel Fisherman's Wharf, 2620 Jones St., San Francisco, CA 94133.

Contact Person: Nuria E Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group, Clinical, Integrative and Molecular Gastroenterology Study Section.

Date: June 1, 2015.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Mushtaq A Khan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301–435–1778, *khanm@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Bioengineering, Technology and Surgical Sciences Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Chronic Dysfunction and Integrative Neurodegeneration Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Convention Center, 900 10th Street, Washington, DC 20001.

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group, Biodata Management and Analysis Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group, Behavioral Medicine, Interventions and Outcomes Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Grand, 2350 M Street NW., Washington, DC 20037.

Contact Person: Lee S Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, (301) 435–0677, *mannl@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Auditory System Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group, Development—2 Study Section.

Date: June 1–2, 2015.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Rass M Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Mechanisms of Sensory, Perceptual, and Cognitive Processes Study Section.

Date: June 1–2, 2015.

Time: 8 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 24, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10007 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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: Fogarty International Center Advisory Board.

Date: May 11–12, 2015.

Closed: May 11, 2015, 1 p.m. to 5 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, Building 31, B2C03, Bethesda, MD 20892.

Open: May 12, 2015, 9 p.m. to 3 p.m.

Agenda: Update and discussion of current and planned FIC activities an overview and future directions for the Center for Global Health Studies as well as an overview of the current Non-communicable diseases training program.

Place: National Institutes of Health, John Edward Porter Neuroscience Center, Building 35, Conference Room, Bethesda, MD 20892.

Contact Person: Robert Eiss, Public Health Advisor, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496–1415, *EISSR@MAIL.NIH.GOV*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nih.gov/fic/about/advisory.html,* where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health HHS)

Dated: April 24, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10004 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc., has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of November 19, 2014.

DATES: The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on November 19, 2014. The next triennial inspection date will be scheduled for November 2017.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 900 Milik St., Carteret, NJ 07008, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API Chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

SGS North America, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–08	ASTM D–86	Standard Test Method for Distillation of Petroleum Products.

CBPL No.	ASTM	Title
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity).
27–13	ASTM D–4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–14	ASTM D–2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry.
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–50	ASTM D–93	Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester.
27–54	ASTM D–1796	Standard test method for water and sediment in fuel oils by the centrifuge method (Laboratory procedure).
27–57	ASTM D–7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-ray Fluorescence Spectrometry.
27–58	ASTM D–5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf*

Dated: April 23, 2015.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2015–10082 Filed 4–29–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0018]

Agency Information Collection Activities: Ship's Store Declaration

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

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Ship's Stores Declaration (CBP Form 1303). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected on Form 1303. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before June 29, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Ship's Stores Declaration.

OMB Number: 1651–0018.

Form Number: CBP Form 1303.

Abstract: CBP Form 1303, Ship's Stores Declaration, is used by the carriers to declare articles to be retained on board the vessel, such as sea stores, ship's stores (*e.g.* alcohol and tobacco products), controlled narcotic drugs or bunker fuel in a format that can be readily audited and checked by CBP. This form collects information about the ship, the ports of arrival and departure, and the articles on the ship. CBP Form 1303 form is provided for by 19 CFR 4.7, 4.7a, 4.81, 4.85 and 4.87 and is accessible at: *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%201303.pdf.*

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Form 1303.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 8,000.

Estimated Number of Responses per Respondent: 13.

Estimated Number of Total Annual Responses: 104,000.

Estimated Total Annual Burden Hours: 26,000.

Dated: April 22, 2015.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015–10058 Filed 4–29–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2015–0016]

Privacy Act of 1974; Department of Homeland Security United States Immigration Customs and Enforcement—011 Immigration and Enforcement Operational Records System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of amendment of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security U.S. Immigration and Customs Enforcement is updating and reissuing an existing system of records titled, ''Department of Homeland Security/Immigration and Customs Enforcement—011 Immigration and Enforcement Operational Records System of Records (ENFORCE).'' This system of records is being modified to propose a new routine use that supports ICE's sharing of information with domestic law enforcement agencies when an alien who has been convicted of a violent or serious crime is released from ICE custody or removed from the United States. The exemptions for the existing system of records notice will continue to be unchanged. This updated system will continue to be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before June 1, 2015. This amended system will be effective June 1, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS–2015–0016 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, 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 go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lyn Rahilly, Privacy Officer, U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, phone: 202–732–3300, email: *ICEPrivacy@ice.dhs.gov;* or Karen Neuman, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528, phone: 202–343–1717.

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. Immigration and Customs Enforcement (ICE) is updating and reissuing a current DHS system of records titled ''DHS/ICE—011 Immigration and Enforcement Operational Records (ENFORCE) System of Records.'' With this update, ICE is proposing new routine use II that will authorize disclosure of information from this system of records ''to a domestic law enforcement agency for the purpose of providing notice of an individual's release from DHS custody or removal from the United States, when the individual has a conviction(s) for a violent or serious crime(s) and the agency receiving the notification has an interest in the individual due to: (1) A pending investigation or prosecution, (2) parole or other forms of supervision, or (3) the individual's intended residence or location of release falling within the agency's jurisdiction.''

ICE will share biographic and criminal history information as well as release conditions or restrictions with other domestic law enforcement agencies when an alien who has been convicted of a violent or serious crime is released from ICE custody or removed from the United States. Violent and serious crimes include certain firearms, national security, sex, and drug-related crimes that ICE has determined are most relevant to the safety of the community. For example, ICE will notify a local law enforcement agency of the release from ICE custody of an alien who has been convicted of aggravated assault with a deadly weapon and has parole requirements in the local jurisdiction. ICE will also notify a law enforcement agency when an alien who has been convicted of, for example, armed robbery and assault is released, to assist agency decisions concerning the allocation of public safety resources in the jurisdiction.

These notifications are intended as situational awareness messages to help inform agencies that have an interest in an alien for investigation, supervision, or public/officer safety purposes of the alien's whereabouts from the time the alien is released until the alien reaches his or her intended jurisdiction of residence or country of removal. Notifications also assist law enforcement agencies in narrowing the pool of potential suspects when a violent or serious crime is committed in their jurisdiction and there are few leads in the investigation, or if the particulars of a crime being investigated are similar to circumstances surrounding the violent or serious crime for which the individual was previously convicted. Notifications of removal of an alien from the United States will help ensure that law enforcement agencies with an interest in the alien do not deploy resources in an attempt to locate the alien.

The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will continue to be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the federal government agencies collect, maintain, use, and disseminate 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 from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the amended DHS/ICE–011 Immigration and Enforcement Operational Records (ENFORCE) System of Records.

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

DHS/ICE–011

SYSTEM NAME:

Immigration and Enforcement Operational Records (ENFORCE).

SECURITY CLASSIFICATION:

Unclassified; Controlled Unclassified Information (CUI).

SYSTEM LOCATION:

Records are maintained at the U.S. Immigration Customs and Enforcement (ICE) Headquarters in Washington, DC, ICE field and attaché offices, and detention facilities operated by or on behalf of ICE, or that otherwise house individuals detained by ICE.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

1. Individuals arrested, detained, and/or removed for criminal and/or administrative violations of the Immigration and Nationality Act, or individuals who are the subject of an ICE immigration detainer issued to another custodial agency;

2. Individuals arrested by ICE law enforcement personnel for violations of federal criminal laws enforced by ICE or DHS;

3. Individuals who fail to leave the United States after receiving a final order of removal, deportation, or exclusion, or who fail to report to ICE for removal after receiving notice to do so (fugitive aliens);

4. Individuals who are granted parole into the United States under section 212(d)(5) of the Immigration and Nationality Act (parolees);

5. Other individuals whose information may be collected or obtained during the course of an immigration enforcement or criminal matter, such as witnesses, associates, and relatives;

6. Attorneys or representatives who represent individuals listed in categories (1)–(4) above;

7. Persons who post or arrange bond for the release of an individual from ICE detention, or receive custodial property of a detained alien;

8. Personnel of other agencies who assisted or participated in the arrest or investigation of an alien, or who are maintaining custody of an alien; and

9. Prisoners of the U.S. Marshals Service held in ICE detention facilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

1. Biographic, descriptive, historical and other identifying data, including but not limited to: Names; aliases; fingerprint identification number (FIN); date and place of birth; passport and other travel document information; nationality; aliases; Alien Registration Number (A-Number); Social Security number; contact or location information (*e.g.,* known or possible addresses, phone numbers); visa information; employment, educational, immigration, and criminal history; height, weight, eye color, hair color, and other unique physical characteristics (*e.g.,* scars and tattoos).

2. Biometric data: Fingerprints and photographs. DNA samples required by Department of Justice regulation (see 28 CFR part 28) to be collected and sent to the Federal Bureau of Investigation (FBI). DNA samples are not retained or analyzed by DHS.

3. Information pertaining to ICE's collection of DNA samples, limited to the date and time of a successful collection and confirmation from the FBI that the sample was able to be sequenced. ICE does not receive or maintain the results of the FBI's DNA analysis (*i.e.,* DNA sequences).

4. Case-related data, including: Case number, record number, and other data describing an event involving alleged violations of criminal or immigration law (location, date, time, event category, types of criminal or immigration law violations alleged, types of property involved, use of violence, weapons, or assault against DHS personnel or third parties, attempted escape and other related information; event categories describe broad categories of criminal law enforcement, such as immigration worksite enforcement, contraband smuggling, and human trafficking). ICE case management information, including: Case category, case agent, date initiated, and date completed.

5. Birth, marriage, education, employment, travel, and other information derived from affidavits, certificates, manifests, and other documents presented to or collected by ICE during immigration and law enforcement proceedings or activities. This data typically pertains to subjects, relatives, and witnesses.

6. Detention data on aliens, including immigration detainers issued; transportation information; detention-related identification numbers; custodial property; information about an alien's release from custody on bond, recognizance, or supervision; detention facility; security classification; book-in/book-out date and time; mandatory detention and criminal flags; aggravated felon status; and other alerts.

7. Detention data for U.S. Marshals Service prisoners, including: Prisoner's name, date of birth, country of birth, detainee identification number, FBI identification number, state identification number, book-in date, book-out date, and security classification;

8. Limited health information relevant to an individual's placement in an ICE detention facility or transportation requirements (*e.g.,* general information on physical disabilities or other special needs to ensure that an individual is placed in a facility or bed that can accommodate his or her requirements). Medical records about individuals in ICE custody (*i.e.,* records relating to the diagnosis or treatment of individuals) are maintained in DHS/ICE—013 Alien Medical Records System of Records;

9. Progress, status, and final result of removal, prosecution, and other DHS processes and relating appeals, including: Information relating to criminal convictions, incarceration, travel documents, and other information pertaining to the actual removal of aliens from the United States.

10. Contact, biographical, and identifying data of relatives, attorneys or representatives, associates, or witnesses of an alien in proceedings initiated and/or conducted by DHS including, but not limited to: Name, date of birth, place of birth, telephone number, and business or agency name.

11. Data concerning personnel of other agencies that arrested, or assisted or participated in the arrest or investigation of, or are maintaining custody of an individual whose arrest record is contained in this system of records. This can include: Name, title, agency name, address, telephone number, and other information.

12. Data about persons who post or arrange an immigration bond for the release of an individual from ICE custody, or receive custodial property of an individual in ICE custody. This data may include: Name, address, telephone number, Social Security number, and other information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

8 U.S.C. 1103, 1225, 1226, 1324, 1357, 1360, and 1365(a)(b); Justice for All Act of 2004 (Pub. L. 108–405); DNA Fingerprint Act of 2005 (Public Law 109–162); Adam Walsh Child Protection and Safety Act of 2006 (Pub. L. 109–248); and 28 CFR part 28, ''DNA-Sample Collection and Biological Evidence Preservation in the Federal Jurisdiction.''

Purpose(s):

The purposes of this system are:

1. To support the identification, apprehension, and removal of individuals unlawfully entering or present in the United States in violation of the Immigration and Nationality Act, including fugitive aliens.

2. To support the identification and arrest of individuals (both citizens and non-citizens) who commit violations of federal criminal laws enforced by DHS.

3. To track the process and results of administrative and criminal proceedings

against individuals who are alleged to have violated the Immigration and Nationality Act or other laws enforced by DHS.

4. To support the grant, denial, and tracking of individuals who seek or receive parole into the United States.

5. To provide criminal and immigration history information during DHS enforcement encounters, and background checks on applicants for DHS immigration benefits (*e.g.,* employment authorization and petitions).

6. To identify potential criminal activity, immigration violations, and threats to homeland security; to uphold and enforce the law; and to ensure public safety.

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) as follows:

A. To the Department of Justice (DOJ) or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, or to a court, magistrate, administrative tribunal, opposing counsel, parties, and witnesses, in the course of a civil or criminal proceeding before a court or adjudicative body when it is 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 when DOJ or DHS has agreed to represent the employee; or

4. the U.S. or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual 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 individual who relies 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, when 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 and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. 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, including to an actual or potential party or his or her attorney, or in connection with criminal law proceedings.

I. To other federal, state, local, or foreign government agencies, individuals, and organizations during the course of an investigation, proceeding, or activity within the purview of immigration and nationality laws to elicit information required by DHS/ICE to carry out its functions and statutory mandates.

J. To the appropriate foreign government agency charged with enforcing or implementing laws when there is an indication of a violation or potential violation of the law of another nation (whether civil or criminal), and to international organizations engaged in the collection and dissemination of intelligence concerning criminal activity.

K. To other federal agencies for the purpose of conducting national intelligence and security investigations.

L. To any federal agency, when appropriate, to enable such agency to make determinations regarding the payment of federal benefits to the record subject in accordance with that agency's statutory responsibilities.

M. To foreign governments for the purpose of coordinating and conducting the removal of aliens to other nations; and to international, foreign, and intergovernmental agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

N. To family members and attorneys or other agents acting on behalf of an alien, to assist those individuals in determining whether: (1) The alien has been arrested by DHS for immigration violations; (2) the location of the alien if in DHS custody; or (3) the alien has been removed from the United States, provided however, that the requesting individuals are able to verify the alien's date of birth or Alien Registration Number (A-Number), or can otherwise present adequate verification of a familial or agency relationship with the alien.

O. To the DOJ Executive Office of Immigration Review (EOIR) or their contractors, consultants, or others performing or working on a contract for EOIR, for the purpose of providing information about aliens who are or may be placed in removal proceedings so that EOIR may arrange for the provision of educational services to those aliens under EOIR's Legal Orientation Program.

P. To attorneys or legal representatives for the purpose of facilitating group presentations to aliens in detention that will provide the aliens with information about their rights under U.S. immigration law and procedures.

Q. To a federal, state, tribal, or local government agency to assist such agencies in collecting the repayment of

recovery of loans, benefits, grants, fines, bonds, civil penalties, judgments or other debts owed to them or to the U.S. Government, and/or to obtain information that may assist DHS in collecting debts owed to the U.S. Government.

R. To the State Department in the processing of petitions or applications for immigration benefits and non-immigrant visas under the Immigration and Nationality Act, and all other immigration and nationality laws including treaties and reciprocal agreements; or when the State Department requires information to consider and/or provide an informed response to a request for information from a foreign, international, or intergovernmental agency, authority, or organization about an alien or an enforcement operation with transnational implications.

S. To the Office of Management and Budget (OMB) in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process as set forth in the Circular.

T. To the U.S. Senate Committee on the Judiciary or the U.S. House of Representatives Committee on the Judiciary when necessary to inform members of Congress about an alien who is being considered for private immigration relief.

U. To a criminal, civil, or regulatory law enforcement authority (whether federal, state, local, territorial, tribal, international, or foreign) when the information is necessary for collaboration, coordination, and de-confliction of investigative matters, to avoid duplicative or disruptive efforts, and for the safety of law enforcement officers who may be working on related investigations.

V. To the U.S. Marshals Service concerning Marshals Service prisoners that are or will be held in detention facilities operated by or on behalf of ICE in order to coordinate the transportation, custody, and care of these individuals.

W. To third parties to facilitate placement or release of an alien (*e.g.,* at a group home, homeless shelter) who has been or is about to be released from ICE custody but only such information that is relevant and necessary to arrange housing or continuing medical care for the alien.

X. To an appropriate domestic government agency or other appropriate authority for the purpose of providing information about an alien who has been or is about to be released from ICE custody who, due to a condition such as mental illness, may pose a health or safety risk to himself/herself or to the community. ICE will only disclose information about the individual that is relevant to the health or safety risk they may pose and/or the means to mitigate that risk (*e.g.,* the alien's need to remain on certain medication for a serious mental health condition).

Y. To the DOJ Federal Bureau of Prisons (BOP) and other federal, state, local, territorial, tribal, and foreign law enforcement or custodial agencies for the purpose of placing an immigration detainer on an individual in that agency's custody, or to facilitate the transfer of custody of an individual from ICE to the other agency. This will include the transfer of information about unaccompanied minor children to the U.S. Department of Health and Human Services (HHS) to facilitate the custodial transfer of such children from ICE to HHS.

Z. To DOJ, disclosure of DNA samples and related information as required by 28 CFR part 28.

AA. To DOJ, disclosure of arrest and removal information for inclusion in relevant DOJ law enforcement databases and for use in the enforcement federal firearms laws (*e.g.,* Brady Act).

BB. To federal, state, local, tribal, territorial, or foreign governmental or quasi-governmental agencies or courts to confirm the location, custodial status, removal, or voluntary departure of an alien from the United States, in order to facilitate the recipient agencies' exercise of responsibilities pertaining to the custody, care, or legal rights (including issuance of a U.S. passport) of the removed individual's minor children, or the adjudication or collection of child support payments or other debts owed by the removed individual.

CC. Disclosure to victims regarding custodial information, such as release on bond, order of supervision, removal from the United States, or death in custody, about an individual who is the subject of a criminal or immigration investigation, proceeding, or prosecution.

DD. To any person or entity to the extent necessary to prevent immediate loss of life or serious bodily injury, (*e.g.,* disclosure of custodial release information to witnesses who have received threats from individuals in custody.)

EE. To an individual or entity seeking to post or arrange, or who has already posted or arranged, an immigration bond for an alien to aid the individual or entity in (1) identifying the location of the alien, or (2) posting the bond, obtaining payments related to the bond, or conducting other administrative or financial management activities related to the bond.

FF. To appropriate federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations when DHS is aware of a need to utilize relevant data for purposes of testing new technology and systems designed to enhance national security or identify other violations of law.

GG. To members of the public, disclosure of limited detainee biographical information for the purpose of (1) identifying whether the detainee is in ICE custody and the custodial location, and (2) facilitating the deposit of monies into detainees' accounts for telephone or commissary services in a detention facility.

HH. To a domestic law enforcement agency or other agency operating a sex offender registry for the purpose of providing notice of an individual's release from DHS custody or removal from the United States, when the individual is required to register as a sex offender, in order to assist those agencies in updating sex offender registries and otherwise carrying out the sex offender registration requirements within their jurisdictions.

II. To a domestic law enforcement agency for the purpose of providing notice of an individual's release from DHS custody or removal from the United States, when the individual has a conviction(s) for a violent or serious crime(s) and the agency receiving the notification has an interest in the individual due to: (1) A pending investigation or prosecution, (2) parole or other forms of supervision, or (3) the individual's intended residence or location of release falling within the agency's jurisdiction.

JJ. To federal, state, local, tribal, territorial, or foreign governmental agencies; multilateral governmental organizations; or other public health entities, for the purposes of protecting the vital interests of a data subject or other persons, including to assist such agencies or organizations during an epidemiological investigation, in facilitating continuity of care, preventing exposure to or transmission of a communicable or quarantinable disease of public health significance, or to combat other significant public health threats.

KK. 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:

Information can be stored in case file folders, cabinets, safes, or a variety of electronic or computer databases and storage media.

RETRIEVABILITY:

Records may be retrieved by name, identification numbers including, but not limited to, A-Number, fingerprint identification number, Social Security number, case or record number if applicable, case related data, and/or combination of other personal identifiers including, but not limited to, date of birth and nationality.

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 that is being stored. Access to the computer system containing the records in this system 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:

ICE is in the process of drafting a proposed record retention schedule for the information maintained in the Enforcement Integrated Database (EID). ICE anticipates retaining records of arrests, detentions, and removals in EID for one-hundred (100) years; records concerning U.S. Marshals Service prisoners for ten (10) years; fingerprints and photographs collected using Mobile IDENT for up to seven (7) days in the cache of an encrypted government laptop; Enforcement Integrated Database Data Mart (EID–DM), ENFORCE Alien Removal Module Data Mart (EARM–DM), and ICE Integrated Decision Support (IIDS) records for seventy-five (75) years; user account management records (UAM) for ten (10) years following an individual's separation of employment from federal service; statistical records for ten (10) years; audit files for fifteen (15) years; and backup files for up to one (1) month.

ICE anticipates retaining records from the Fugitive Case Management System (FCMS) for ten (10) years after a fugitive alien has been arrested and removed from the United States; 75 years from the creation of the record for a criminal fugitive alien that has not been arrested and removed; ten (10) years after a fugitive alien reaches 70 years of age, provided the alien has not been arrested and removed and does not have a criminal history in the United States; ten (10) years after a fugitive alien has obtained legal status; ten (10) years after arrest and/or removal from the United States for a non-fugitive alien's information, whichever is later; audit files for 90 days; backup files for 30 days; and reports for ten (10) years or when no longer needed for administrative, legal, audit, or other operations purposes.

SYSTEM MANAGER AND ADDRESS:

Unit Chief, Law Enforcement Systems/Data Management, U.S. Immigration and Customs Enforcement, Office of Investigations Law Enforcement Support and Information Management Division, Potomac Center North, 500 12th Street SW., Washington, DC 20536.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, ICE will consider individual requests to determine whether or not information may be released. Thus, 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 ICE's FOIA Officer, whose contact information can be found at *www.dhs.gov/foia* under ''contacts.''

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 provide the following:

- An explanation of 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 this bulleted 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:

Records in the system are supplied by several sources. In general, information is obtained from individuals covered by this system, and other federal, state, local, tribal, or foreign governments. More specifically, DHS/ICE–011 records derive from the following sources:

(a) Individuals covered by the system and other individuals (*e.g.,* witnesses, family members);

(b) Other federal, state, local, tribal, or foreign governments and government information systems;

(c) Business records;

(d) Evidence, contraband, and other seized material; and

(e) Public and commercial sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security has exempted portions of this system of records from subsections (c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), and (e)(8); and (g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2). In addition, the Secretary of Homeland Security has exempted portions of this system of records from subsections (c)(3); (d); (e)(1), (e)(4)(G), and (e)(4)(H) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). These exemptions apply only to the extent that records in the system are subject to

exemption pursuant to 5 U.S.C. 552a(j)(2) and (k)(2).

In addition, to the extent a record contains information from other exempt systems of records, DHS will rely on the exemptions claimed for those systems.

Dated: April 17, 2015.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015–09615 Filed 4–29–15; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2015–N078; FXES11130100000–156–FF01E00000]

Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications for recovery permits to conduct activities with the purpose of enhancing the survival of an endangered species. The Endangered Species Act of 1973, as amended (Act), prohibits certain activities with endangered species unless a Federal permit allows such activity. The Act also requires that we invite public comment before issuing such permits.

DATES: To ensure consideration, please send your written comments by June 1, 2015.

ADDRESSES: Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Pacific Regional Office, 911 NE. 11th Avenue, Portland, OR 97232–4181. Please refer to the permit number for the application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Colleen Henson, Fish and Wildlife Biologist, at the above address, or by telephone (503–231–6131) or fax (503–231–6243).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits certain activities with respect to endangered and threatened species unless a Federal permit allows such activity. Along with our implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17, the Act provides for certain permits, and requires that we invite public comment before issuing these permits for endangered species.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittee to conduct activities (including take or interstate commerce) with respect to U.S. endangered or threatened species for scientific purposes or enhancement of propagation or survival. Our regulations implementing section 10(a)(1)(A) of the Act for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following applications. Please refer to the permit number for the application when submitting comments.

Documents and other information submitted with these applications are available for review by request from the Program Manager for Restoration and Endangered Species Classification at the address listed in the **ADDRESSES** section of this notice, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and the Freedom of Information Act (5 U.S.C. 552).

Permit Number: TE–050644

Applicant: Washington Department of Fish and Wildlife, Ephrata, Washington

The permittee requests a permit amendment to take (harass through captive propagation at two additional enclosure sites) the Columbia Basin distinct population segment of the pygmy rabbit (*Brachylagus idahoensis*) in Oregon and Washington, in conjunction with scientific research and recovery actions, for the purpose of enhancing the species' survival.

Permit Number: TE–63598B

Applicant: American Museum of Natural History, New York, New York

The applicant requests a new permit to take (survey, capture, handle, measure, mark, tag, weigh, collect biological samples, attach transmitters and accelerometers, photograph, release, monitor nests, inventory nests, excavate nests, and salvage) the green sea turtle (*Chelonia mydas*) and the hawksbill sea turtle (*Eretmochelys imbricata*), in conjunction with scientific research to characterize and monitor sea turtle nesting on Palmyra Atoll, for the purpose of enhancing the species' survival.

Public Availability of Comments

All comments and materials we receive in response to this request will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Dated: April 22, 2015.

Richard R. Hannan,

Acting Regional Director, Pacific Region, U.S. Fish and Wildlife Service.

[FR Doc. 2015–10077 Filed 4–29–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/A0A501010.999900 253G]

Renewal of Agency Information Collection for Data Elements for Student Enrollment in Bureau-funded Schools

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Education (BIE) is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for Data Elements for Student Enrollment in Bureau-funded Schools, authorized by OMB Control Number 1076–0122. This information collection expires August 31, 2015.

DATES: Submit comments on or before June 29, 2015.

ADDRESSES: You may submit comments on the information collection to: Ms. Jacquelyn Cheek, Special Assistant to the Director, Bureau of Indian Education, 1849 C Street NW., Mailstop 4657–MIB, Washington, DC 20240; facsimile: (202) 208–3312; or email to: *Jacklyn.Cheek@bia.edu.*

FOR FURTHER INFORMATION CONTACT: Ms. Jacquelyn Cheek, phone: (202) 208–6983.

SUPPLEMENTARY INFORMATION:

I. Abstract

The BIE is requesting renewal of OMB approval for the admission forms for the Student Enrollment Application in Bureau-funded Schools. School registrars collect information on this form to determine the student's eligibility for enrollment in a Bureau-funded school, and if eligible, is shared with appropriate school officials to identify the student's base and supplemental educational and/or residential program needs. The BIE compiles the information into a national database to facilitate budget requests and the allocation of congressionally appropriated funds.

II. Request for Comments

The BIE requests your comments on this collection concerning: (a) The necessity of this information collection 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 (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0122.

Title: Data Elements for Student Enrollment in Bureau-funded Schools.

Brief Description of Collection: This annual collection provides Bureau-funded schools with data about students that impacts placement, special needs assessments, and funding for individuals and assists schools in developing a plan for the school year. The information is collected on a Student Enrollment Application form.

Type of Review: Extension without change of currently approved collection.

Respondents: Contract and Grant schools; Bureau-operated schools.

Number of Respondents: 48,000 per year, on average.

Frequency of Response: Once per year.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Hour Burden: 12,000 hours.

Estimated Total Annual Non-Hour Dollar Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2015–10095 Filed 4–29–15; 8:45 am]

BILLING CODE 4437–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVC02000 L16200000.HP0000 241A MO# 4500074361 TAS: 15X]

Notice of Temporary Closure of Public Land in Storey County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: As authorized under the provisions of the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, the Bureau of Land Management (BLM) Carson City District Office will temporarily close certain public land surrounding and including the abandoned man-made structures and features, known as the American Flat Mill, in Storey County, Nevada, to all public use. This action would provide for public safety during demolition and reclamation activities occurring at the site.

DATES: The temporary closure will go into effect upon publication in the **Federal Register**, not to exceed a period of 24 months.

FOR FURTHER INFORMATION CONTACT: Leon Thomas, 775–885–6000, email: *l70thoma@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The American Flat Mill is an abandoned mining feature located within the Virginia City National Historic Landmark. At the time of its completion in 1922, it was the largest concrete mill structure in the world utilizing cyanide extraction to process silver ore. Following a substantial decrease in silver prices in 1924, the operation never recovered and the mill was dismantled in 1927. Only the deteriorated concrete skeleton of the mill remains today. The BLM plans on abating the substantial physical safety hazard posed by the American Flat Mill by demolishing the remaining buildings. Public land surrounding and including the American Flat Mill will be closed to public entry for the duration of demolition and reclamation activities. The public land affected by this closure is described as follows:

Mount Diablo Meridian

T. 16 N., R. 21 E.,
Sec. 6, E½SE¼SE¼, SE¼NE¼SE¼;
Sec. 7, NE¼.

The area described contains 190 acres, more or less, in Storey County, Nevada.

The closure notice, communications plan and map of the closure area will be posted at the BLM Carson City District Office, 5665 Morgan Mill Road, Carson City, Nevada and on the BLM Web site: *http://www.blm.gov/nv/st/en/fo/carson_city_field.html.* Roads leading into the public lands under the closure will be posted to notify the public of the closure. Under the authority of Section 303(a) of the FLPMA (43 U.S.C. 1733(a)), 43 CFR 8360.0–7 and 43 CFR 8364.1, the BLM will enforce the following rules in the area described above: All public use, whether motorized, on foot, or otherwise, is prohibited.

Exceptions: Closure restrictions do not apply to demolition activities conducted under contract with the BLM; agency personnel monitoring the demolition; or mining activities conducted under an approved plan of operation. Authorized users must have in their possession, a written permit or contract from BLM signed by the authorized officer.

Penalties: Any person who fails to comply with the closure orders is subject to arrest and, upon conviction, may be fined not more than $1,000 and/or imprisonment for not more than 12 months under 43 CFR 8360.0–7. Violations may also be subject to the

provisions of Title 18, U.S.C. 3571 and 3581.

Leon Thomas,

Field Manager, Sierra Front Field Office.

(Authority: 43 CFR 8360.0–7 and 8364.1)

[FR Doc. 2015–09821 Filed 4–29–15; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–955]

Certain Protective Cases for Electronic Devices and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on March 11, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Otter Products, LLC of Fort Collins, Colorado. An amended complaint was filed on March 25, 2015. The complaint, as amended, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain protective cases for electronic devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 8,792,232 (''the '232 patent'') and U.S. Patent No. 8,976,512 (''the '512 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION: *Authority:* The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 23, 2015, ORDERED THAT—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain protective cases for electronic devices and components thereof by reason of infringement of one or more of claims 9, 12, and 13 of the '232 patent and claims 17 and 28 of the '512 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Otter Products, LLC, 209 S. Meldrum Street, Fort Collins, CO 80521.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Speculative Product Design, LLC, 177 Bovet Road, Suite 200, San Mateo, CA 94402.

Tech21 UK Limited, Syd's Quay, Eel Pie Island, Twickenham, TWI 3DY, United Kingdom.

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 24, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–10002 Filed 4–29–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–531–533 and 731–TA–1270–1273 (Preliminary)]

Certain Polyethylene Terephthalate Resin From Canada, China, India, and Oman

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain polyethylene terephthalate resin from Canada, China, India, and Oman, provided for in subheading 3907.60.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV''), and

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

that are allegedly subsidized by the governments of China, India, and Oman.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On March 10, 2015, DAK Americas, LLC, Charlotte, NC; M&G Chemicals, Houston, TX; and Nan Ya Plastics Corporation, America, Lake City, SC, filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV and subsidized imports of certain polyethylene terephthalate resin from China, India, and Oman and LTFV imports of certain polyethylene terephthalate resin from Canada. Accordingly, effective March 10, 2015, the Commission, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation Nos. 701–TA–531–533 and antidumping duty investigation Nos. 731–TA–1270–1273 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 17, 2015 (80 FR 13889). The conference was held in Washington, DC, on March 31, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on April 24, 2015. The views of the Commission are contained in USITC Publication 4531 (May 2015), entitled *Certain Polyethylene Terephthalate Resin from Canada, China, India, and Oman: Investigation Nos. 701–TA–531–533 and 731–TA–1270–1273 (Preliminary)*.

By order of the Commission.

Dated: April 24, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–10045 Filed 4–29–15; 8:45 am]

BILLING CODE 7020–02–P

[2] Commissioner F. Scott Kieff did not participate in these investigations.

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Sematech, Inc. D/B/A International Sematech

Notice is hereby given that, on March 31, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Sematech, Inc. d/b/a International Sematech (''SEMATECH'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Qorvo Inc., Hillsboro, OR; Infineon Technologies Dresden GmbH, Dresden, GERMANY; Jusung Engineering Co., Ltd., Seoul, REPUBLIC OF KOREA; Texas Instruments, Inc., Dallas, TX; and Winbond Electronics Corporation, Taichung City, TAIWAN, have been added as parties to this venture.

Also, Matheson Tri-Gas, Basking Ridge, NJ; Centrotherm Photovoltaics, Blaubeuren, GERMANY; Fujifilm Electronic Materials, Shizuoka, JAPAN; Solid State Equipment LLC (SSEC), Horsham, PA; Intermolecular, San Jose, CA; Morgan Advance Materials, Southampton, UNITED KINGDOM; TriQuint Semiconductors Inc., Richardson, TX; Disco, Tokyo, JAPAN; Cimetrix, Hingham, MA; SUSS, Microtec Photomask Equipment GmbH & Co. kg., Garching, GERMANY; and University College of London, London, UNITED KINGDOM, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and SEMATECH intends to file additional written notifications disclosing all changes in membership.

On April 22, 1988, SEMATECH filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on May 19, 1988 (53 FR 17987).

The last notification was filed with the Department on January 6, 2015. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on February 10, 2015 (80 FR 7499).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10032 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Advanced Combustion Catalyst and Aftertreatment Technologies

Notice is hereby given that, on March 20, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Advanced Combustion Catalyst and Aftertreatment Technologies (''AC^{2}AT'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust

plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the identities of the parties to the venture are: Cummins, Inc., Columbus, IN; Denso Corporation, Aichi-ken, JAPAN; John Deere, Waterloo, IA; Komatsu Ltd., Tochigi-ken, JAPAN; and Tenneco Automotive Operating Co., Inc., Grass Lake, MI. The general area of AC^{2}AT's planned activity is to develop the most cost effective solutions for future engine systems by identifying and addressing the opportunities and challenges for integration of catalysts and aftertreatment systems to engines with advanced combustion technologies. The focus of the program will be to develop the tools and technologies necessary for the synergistic application of catalysts to advance engine technologies. The proposed program incorporates projects focused in four distinct areas: (1) Detailed characterization of emissions for advanced SI and CI engines; (2) alternative catalysts for use outside of the exhaust system; (3) development of simulation tools for streamlined aftertreatment analysis; and (4) evaluation of alternative emission control technologies.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10030 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on April 7, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, STAR-Dundee Ltd., Dundee, Scotland, UNITED KINGDOM, has been added as a party to this venture.

Also, Beijing HWA-Tech Information System Co., Beijing, PEOPLE'S REPUBLIC OF CHINA; and MagiQ Technologies, Somerville, MA, has withdrawn as a party to this venture.

In addition, Aeroflex, Inc. has changed its name to Cobham, Wireless, Wichita, KS.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems Alliance, Inc. filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on January 16, 2015. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on February 17, 2015 (80 FR 8348).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10021 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Heterogeneous System Architecture Foundation

Notice is hereby given that, on March 11, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Heterogeneous System Architecture Foundation (''HSA Foundation'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, University of West of England, Bristol, UNITED KINGDOM, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HSA Foundation intends to file additional written notifications disclosing all changes in membership.

On August 31, 2012, HSA Foundation filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on October 11, 2012 (77 FR 61786).

The last notification was filed with the Department on December 19, 2014. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on February 6, 2015 (80 FR 6768).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10033 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Halon Alternatives Research Corporation, Inc.

Notice is hereby given that, on March 2, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Halon Alternatives Research Corporation, Inc. (''HARC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, A-Gas RemTec, Bowling Green, OH; American Pacific Corporation, Las Vegas, NV; BP Exploration Alaska Inc., Anchorage, AK; ConocoPhillips Co., Anchorage, AK; Chemours Company LLC, Wilmington, DE; Fire Suppression System Association, Baltimore, MD; Haven Fire and Safety LLC, Dubai, UNITED ARAB EMIRATES; Meggitt PLC, Dorset, UNITED KINGDOM; Orient Corporation, Cranford, NJ; SEVO Systems, Lenexa, KS; Tyco Fire Protection Products, Marinette, WI; UTC Aerospace Systems, Arlington, VA; Waysmos USA Inc., Austin, TX; and Wesco, Metuchen, NJ, have been added as parties to this venture.

Also, British Airways, Harmondsworth, UNITED KINGDOM; Chemtura Corporation, Middlebury, CT; DuPont Chemicals & Fluoroproducts, Wilmington, DE; Eurotunnel PLC, London, UNITED KINGDOM; Fire Protection Systems, Inc., Washington Crossing, PA; Gielli di Luigi Galantucci,

Altarnura, ITALY; Global Safety Labs, Tulsa, OK; Great Lakes Chemical Corporation, West Lafayette, IN; Halon Banking System, St. Paul, MN; Heien-Larssen AS, Spikkestad, NORWAY; Honeywell, Buffalo, NY; Hughes Aircraft Company, Los Angeles, CA; Metalcraft, Inc., Baltimore, MD; Minimax USA, Inc., Mesa, AZ; Modular Protection Group, Lenexa, KS; NAFED, Chicago, IL; Powsus, Inc., Fort Pierce, FL; and Superior Safety Inc., Ontario, CANADA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HARC intends to file additional written notifications disclosing all changes in membership.

On February 7, 1990, HARC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 7, 1990 (55 FR 8204).

The last notification was filed with the Department on January 18, 2011. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on February 22, 2011 (76 FR 9812).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10031 Filed 4–29–15; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Automotive Consortium for Embedded Security™

Notice is hereby given that, on March 20, 2015, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Automotive Consortium for Embedded Security™,(''ACES'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Delphi Automotive Systems, LLC, Kokomo, IN; Denso International America, Inc., Southfield, MI; Ford Motor Company, Dearborn, MI; GM Global Technology Operations LLC, Detroit, MI; Honda R&D Americas, Inc., Raymond, OH; and Robert Bosch LLC, Farmington Hills, MI. The general area of ACES's planned activity is to provide pre-competitive and non-competitive research in automotive embedded systems security to protect the safety, reliability, brand image, trade secrets, and to provide privacy of members' future products. The objectives of ACES are to perform high-risk/high-reward pre-competitive and non-competitive research and development; serve as an independent verification and validation entity; develop understanding of industry problems and associated risk; monitor and share threats and industry research; keep abreast of and provide input for emerging safety and security regulations and standards; and provide members with relevant solutions and actionable results.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10028 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Platform for NFV Project, Inc.

Notice is hereby given that, on April 2, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Platform for NFV Project, Inc. (''Open Platform for NFV Project'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ADVA Optical Networking SE., Martinsried, GERMANY; Canonical Group Limited, London, UNITED KINGDOM; Dialogic Corporation, Montreal, Quebec, CANADA; Hangzhou H3C Technologies, Co., Ltd., Hangzhou, PEOPLE'S REPUBLIC OF CHINA; Qosmos, Paris, FRANCE; SK Telecom, Seoul, REPUBLIC OF KOREA; Spirent Communications, Inc., Sunnyvale, CA; and Stratus Technologies, Inc., Maynard, MA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Open Platform for NFV Project intends to file additional written notifications disclosing all changes in membership.

On October 17, 2014, Open Platform for NFV Project filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on November 14, 2014 (79 FR 68301).

The last notification was filed with the Department on January 12, 2015. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on February 6, 2015 (80 FR 6767).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–10027 Filed 4–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 007–2015]

Privacy Act of 1974; Systems of Records; Correction

AGENCY: Office of Legal Counsel, Department of Justice.

ACTION: Notice; correction.

SUMMARY: The United States Department of Justice, Office of Legal Counsel, published a notice document in the **Federal Register** on January 23, 2015, terminating the systems of records entitled ''Office of Legal Counsel Attorney Assignment Reports, JUSTICE/OLC–001'' and ''Office of Legal Counsel Central File, JUSTICE/OLC–003.'' The system notice title for the ''Office of Legal Counsel Central File'' system should read JUSTICE/OLC–002.

FOR FURTHER INFORMATION CONTACT: Robin Moss, 202–514–8568.

Correction

In the **Federal Register** January 23, 2015, in FR Doc. 2015–01211, on page 3624, first column, correct the ''SUMMARY'' caption to read:

Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), the United States Department of Justice, Office of Legal Counsel, is terminating the systems of records entitled ''Office of Legal Counsel Attorney Assignment Reports,

JUSTICE/OLC–001'' and ''Office of Legal Counsel Central File, JUSTICE/OLC–002.''

Dated: April 2, 2015.

Kristi Lane Scott,

Deputy Director, Office of Privacy and Civil Liberties, United States Department of Justice.

[FR Doc. 2015–10109 Filed 4–29–15; 8:45 am]

BILLING CODE 4410–23–P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 006–2015]

Privacy Act of 1974; System of Records

AGENCY: Department of Justice.

ACTION: Notice; correction.

SUMMARY: The Department of Justice (the Department or DOJ) published a system of records notice in the **Federal Register** on March 26, 2015 (80 FR 16025), which added a new system of records. The notice text did not reference the correct number to the accompanying proposed rule in the preamble portion of the notice. This document corrects the notice by revising the citation in the preamble to remove reference to 28 CFR 16.135.

DATES: This correction is effective on April 30, 2015.

FOR FURTHER INFORMATION CONTACT: Robin Moss, Privacy Analyst, 202–514–8568.

Correction

In the **Federal Register** of March 26, 2015, in FR Doc. 2015–06934, on page 16025, in the **SUPPLEMENTARY INFORMATION** section, second column, line 16, and third column, line one, correct the reference to the Code of Federal Regulation to read:

28 CFR 16.136

Dated: April 2, 2015.

Kristi Lane Scott,

Deputy Director, Office of Privacy and Civil Liberties, United States Department of Justice.

[FR Doc. 2015–10107 Filed 4–29–15; 8:45 am]

BILLING CODE 4410–FB–P

DEPARTMENT OF LABOR

Public Availability of Department of Labor FY 2014 Service Contract Inventory

AGENCY: Office of the Assistant Secretary for Administration and Management, Labor.

ACTION: Notice of public availability of FY 2014 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the Department of Labor (DOL) is publishing this notice to advise the public of the availability of its FY 2014 Service Contract Inventory. This inventory provides information on service contract actions over $25,000 made in FY 2014. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010, by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* The Department of Labor has posted its inventory and a summary of the inventory on the agency's Web site at the following link: *http://www.dol.gov/dol/aboutdol/main.htm#inventory.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Ngozi Ofili in the DOL/Office of Acquisition Management Services at (202) 693–7247 or *ofili.ngozi.e@dol.gov.*

Dated: April 17, 2015.

Edward C. Hugler,

Deputy Assistant Secretary for Administration and Management.

[FR Doc. 2015–10054 Filed 4–29–15; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations, 30 CFR part 44, govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by the Office of Standards, Regulations, and Variances on or before June 1, 2015.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, Attention: Sheila McConnell, Acting Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk on the 21st floor. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2015–007–C.

Petitioner: White Oak Resources, LLC, P.O. Box 339, McLeansboro, Illinois 62859.

Mine: White Oak Mine No. 1, MSHA I.D. No. 11–03203, located in Hamilton County, Illinois.

Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

Modification Request: The petitioner requests a modification of the existing standard to permit mining within a 300 foot diameter of abandoned oil and gas wells, and to allow mining through abandoned oil and gas wells.

1. A safety barrier of 300 feet diameter (150 feet between any mined area and a well) will be maintained around all oil and gas wells, to include all active, inactive, abandoned, shut-in, and previously plugged wells and including water injection wells until approval to proceed has been obtained from the District Manager (DM).

2. The petitioner proposes, prior to mining through any oil or gas well at its White Oak Mine No. 1, to provide the DM a sworn affidavit or declaration stating that all mandatory procedures for cleaning out, preparing, and plugging each gas or oil well have been completed. The declaration will be accompanied by down-hole logs and any other information that the DM may request.

(a) The petitioner proposes to use the following procedures when cleaning out and preparing oil and gas wells prior to plugging or replugging:

(1) Clean out the well from the surface to at least 200 feet below the base of the lowest mineable coal seam. The DM will be provided with all information it possesses concerning the geological nature of the strata and the pressure of the well. All material will be removed from the entire diameter of the well, wall to wall.

(2) Prepare down-hole logs for each well. The logs will consist of a caliper survey and be suitable for determining the top, bottom, and thickness of all coal seams and potential hydrocarbon-producing strata and the location for the bridge plug. In addition a journal will be maintained describing the depth and nature of each material encountered; bit size and type used to drill each portion of the hole; length and type of each material used to plug the well; length of casing(s) removed, perforated, or ripped, or left in place, any sections where casing was cut or milled; and other pertinent information concerning cleaning and sealing the well. Invoices, work-orders, and other records relating to all work on the well will be maintained as part of this journal and provided to MSHA on request.

(3) When cleaning out the well, a diligent effort will be made to remove all of the casing in the well or, if it is not possible to remove all of the casing, fill the annulus between the casings and the well walls with expanding cement (minimum 0.5 percent expansion on setting) and ensure that these areas contain no voids. If the casing cannot be removed it will be cut or milled at all mineable coal seam levels. Any remaining casings will be perforated or ripped at least every 50 feet from at least 200 feet below the base of the lowest mineable coal seam up to 100 feet above the uppermost mineable coal seam. When multiple casing and tubing strings are present in the coal horizon(s), perforate or rip any casing that remains and fill with expanding cement. Keep an acceptable casing bond log for each casing and tubing string used in lieu of ripping or perforating multiple strings.

(4) Place a mechanical bridge plug in the well, if a cleaned-out well emits excessive amounts of gas. Place the mechanical bridge plug in a competent stratum at least 200 feet below the base of the lowest mineable coal seam, but above the top of the uppermost hydrocarbon-producing stratum.

(5) If the uppermost hydrocarbon-producing stratum is within 300 feet of the base of the lowest mineable coal seam, properly place mechanical bridge plugs to isolate the hydrocarbon-producing stratum from the expanding cement plug. Place a minimum of 200 feet of expanding cement below the lowest mineable coal seam.

(b) The petitioner proposes to use the following procedures for plugging or replugging oil or gas wells to the surface:

(1) Pump expanding cement slurry down the well to form a plug that runs from at least 200 feet below the base of the lowest mineable coal seam to the surface. Place the expanding cement in the well under a pressure of at least 200 pounds per square inch. Portland cement or a lightweight cement mixture may be used to fill the area from 100 feet above the top of the uppermost mineable coal seam.

(2) Embed steel turnings or other small magnetic particles in the top of the cement near the surface to serve as a permanent magnetic monument of the well. In the alternative, extend a 4½-inch or larger casing, set in cement, at least 36 inches above the ground level with the American Petroleum Institute (API) well number either engraved or welded on the casing. When the hole cannot be marked with a physical monument (*i.e.,* prime farmland), use high-resolution GPS coordinates (one-half meter resolution) to locate the hole.

c. The petitioner proposes to use the following procedures for plugging or replugging oil and gas wells for subsequent use as degasification boreholes:

(1) Set a cement plug in the well by pumping expanding cement slurry down the tubing to provide at least 200 feet of expanding cement below the lowest mineable coal seam. Place the expanding cement in the well under a pressure of at least 200 pounds per square inch. Extend the top of the expanding cement at least 30 feet above the top of the coal seam being mined.

(2) Securely grout a suitable casing into the bedrock of the upper portion of the degasification well to protect it. The remainder of this well may be cased or uncased.

(3) Fit the top of the degasification casing with a wellhead, equipped as required by the DM in the approved ventilation plan. Such equipment may include check valves, shut-in valves, sampling ports, flame arrestor equipment, and security fencing.

(4) Operation of the degasification well will be addressed in the approved ventilation plan. This may include periodic tests of methane levels and limits on the minimum concentrations that may be extracted.

(5) After the area of the coal mine that is degassed by a well is sealed or the coal mine is abandoned, seal the degas holes using the following procedures:

(i) Insert a tube to the bottom of the drill hole or, if not possible, to at least 100 feet above the Herrin No. 6 coal seam. Remove any blockage to ensure that the tube is inserted to this depth.

(ii) Set a cement plug in the well by pumping Portland cement or a lightweight cement mixture down the tubing until the well is filled to the surface.

(iii) Embed steel turnings or other small magnetic particles in the top of the cement near the surface to serve as a permanent magnetic monument of the well. In the alternative, extend a 4½-inch or larger casing, set in cement, at least 36 inches above the ground level with the API well number engraved or welded on the casing.

d. The petitioner proposes to use the following mandatory alternative procedures for preparing and plugging or replugging oil or gas wells that cannot be cleaned out:

(1) Drill a hole adjacent and parallel to the well to a depth of at least 200 feet below the lowest mineable coal seam.

(2) Locate any casing that may remain in the well using a geophysical sensing device.

(3) If the well contains casings, drill into the well from the parallel hole and perforate or rip all casings at intervals of at least 5 feet from 10 feet below the coal seam to 10 feet above the coal seam. Beyond that distance, perforate or rip all casings at least every 50 feet from at least 200 feet below the base of the lowest mineable coal seam up to 100 feet above the seam being mined. Fill the annulus between the casings and

between the casings and the well wall with expanding cement (minimum of 0.5 percent expansion on setting), and ensure that these areas contain no voids. When multiple casing and tubing strings are present in the coal horizons, rip or perforate any casing that remains and fill with expanding cement. Provide an acceptable casing bond log for each casing and tubing used in lieu of ripping or perforating multiple strings.

(4) Use a horizontal hydraulic fracturing technique to intercept the original well. Fracture the original well in at least six places from at least 200 feet below the base of the lowest mineable coal seam to a point at least 50 feet above the seam being mined, at intervals to be agreed on by the petitioner and the DM after considering the geological strata and the pressure within the well. Pump expanding cement into the fractured well in sufficient quantities and in a manner that fills all intercepted voids.

(5) Prepare down-hole logs for each well. The logs will consist of a caliper survey and be suitable for determining the top, bottom, and thickness of all coal seams and potential hydrocarbon-producing strata and the location for the bridge plug. The operator may obtain the logs from the adjacent hole rather than the well if the condition of the well makes it impractical to insert the equipment necessary to obtain the log. Maintain a journal describing the depth of each material encountered; the nature of each material encountered; bit size and type used to drill each portion of the hole; length and type of each material used to plug the well; length of casing(s) removed, perforated, ripped, or left in place; and other pertinent information concerning sealing the well. Invoices, work orders, and other records relating to all work on the well will be maintained as part of the journal and provided to MSHA on request.

(6) After plugging the well, plug the open portions of both holes from the bottom to the surface with Portland cement or a lightweight cement mixture.

(7) Embed steel turnings or other small magnetic particles in the top of the cement near the surface to serve as a permanent magnetic monument of the well. In the alternative, extend a 4½-inch or larger casing, set in cement, at least 36 inches above the ground level.

(8) A combination of the methods outlined in subparagraphs (d)(3) and (d)(4) may have to be used in a single well depending on the conditions of the hole and the presence of casings. The petitioner and DM would discuss the nature of each hole. The DM may require that more than one method be used.

e. The petitioner proposes to use the following procedures after approval has been granted by the DM to mine through a plugged or replugged well:

(1) Prior to cutting-through a plugged well, notify the DM or designee, representative of the miners, and the appropriate State agency in sufficient time for them to have a representative present.

(2) When using continuous mining machines, install drivage sites at the last open crosscut near the place to be mined to ensure intersection of the well. The drivage sites will not be more than 50 feet from the well. When using longwall mining methods, install drivage sites on 10-foot centers for a distance of 50 feet in advance of the well. The drivage sites will be installed in the headgate and tailgate.

(3) Firefighting equipment, including fire extinguishers, rock dust, and sufficient fire hose to reach the working face area of the mine-through (when either the conventional or continuous mining method is used), will be available and operable during each well mine-through. Locate the fire hose in the last open crosscut of the entry or room. Maintain the water line to the belt conveyor tailpiece along with a sufficient amount of fire hose to reach the farthest point of penetration on the section. When the longwall mining method is used, a hose to the longwall water supply is sufficient. All fire hoses will be connected and ready for use, but do not have to be charged with water during the cut-through.

(4) Keep available at the last open crosscut a supply of roof support and ventilation materials sufficient to ventilate and support around the well on cut-through. In addition, keep emergency plugs and suitable sealing materials available in the immediate area of the well intersection.

(5) Maintain minimum air quantities in the working face during the period from when mining within 50 feet of the well location until the post cut-through inspection, or mining progresses at least 50 feet past the well location will be specified in the approved ventilation plan.

(6) On the shift prior to mining through the well, service all equipment and check for permissibility.

(7) Calibrate the methane monitors on the longwall, continuous mining machine, or cutting machine and loading machine on the shift prior to mining through the well.

(8) When mining is in progress, test methane levels with a hand-held methane detector at least every 10 minutes from the time that mining with the continuous mining machine is within 30 feet of the well until the well is intersected and immediately prior to mining through it. No individual is allowed on the return side during the actual cutting process until the mine-through has been completed and the area examined and declared safe. All workplace examinations will be conducted on the return side of the shearer while the shearer is idle.

(9) Keep the working place free from accumulations of coal dust and coal spillages, and place rock dust on the roof, rib, and floor to within 20 feet of the face when mining through the well when using continuous or conventional mining methods. Conduct rock dusting on longwall sections on the roof, rib, and floor up to both the headgate and tailgate gob.

(10) Deenergize all equipment when the wellbore is intersected and thoroughly examine the place and determine it safe before resuming mining. After a well has been intersected and the working place determined safe, mining will continue inby the well a sufficient distance to permit adequate ventilation around the area of the well.

(11) In rare instances, torches may be used for inadequately or inaccurately cut or milled casings at the coal seam level. No open flame is permitted in the area until adequate ventilation has been established around the wellbore and methane levels are less than 1.0 percent in all areas that will be exposed to flames and sparks from the torch. Apply a thick layer of rock dust to the roof, face, floor, ribs, and any exposed coal within 20 feet of the casing prior to any use of torches.

(12) Non-sparkling (brass) tools will be located on the working section and will be used to expose and examine cased wells.

(13) No person will be permitted in the area of the cut-through operation except those actually engaged in the mining operation, including mine management, representatives of miners, personnel from MSHA, and personnel from the appropriate State agency.

(14) A certified official will directly supervise the cut-through operation and only the certified official in charge will issue instructions concerning the cut-through operation.

(15) Within 60 days after this petition becomes final, the petitioner will submit proposed revisions for its approved part 48 training plan to the DM. These proposed revisions will include initial and refresher training regarding compliance with the terms and conditions stated in the Order. The operator will provide all miners involved in the mine-through of a well

with training regarding the requirements of this Order prior to mining within 150 feet of the next well intended to be mined through.

(16) The responsible person required in 30 CFR 75.1501 will be responsible for well intersection emergencies. The responsible person will review the well intersection procedures prior to any planned intersection.

(17) Within 60 days after this petition becomes final, the petitioner will submit proposed revisions for its approved mine emergency evacuation and firefighting plan required in 30 CFR 75.1501. The plan will include the hazards and evacuation procedures to be used for well intersections. All underground miners will be trained in this revised plan within 60 days of submittal of the revised evacuation plan.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure or protection afforded by the existing standard.

Docket Number: M–2015–008–C.

Petitioner: Consolidation Coal Company, RD #1 Box 62A, Dallas, West Virginia 26036.

Mine: Shoemaker Mine, MSHA I.D. No. 46–01436, located in Marshall County, West Virginia.

Regulation Affected: 30 CFR 75.311(b)(2) and (3) (Main mine fan operation).

Modification Request: The petitioner requests a modification of the existing standard to allow the refuse belt to continue to operate during a fan outage other than the Dupont Fan. Management will monitor and prohibit the entrance of any miners or personnel underground at any time during the fan outages. The mine will follow the re-entry requirements in 30 CFR for examinations and re-entry by mine personnel once all fans are operational. The petitioner states that:

(1) The Shoemaker Mine operates in the Pittsburgh #8 coal seam. The seam thickness averages 84 inches. The overburden averages 850 feet. The continuous miner and longwall sections are used to mine this coal seam. The mine currently has 730 employees.

(2) Coal extraction from the mine is transported via conveyor belt to the coal processing plant located on the surface. Rock and other impurities are separated from the coal at this location. The separated rock and impurities are termed ''refuse or refuse material''.

(3) The refuse material which has been separated from the coal is then loaded onto another conveyor belt, hereinafter known as the refuse belt, which carries the refuse material back into and through a small portion of the mine, before exiting to the surface again. The refuse is then trans-loaded onto rubber tired vehicles which distribute the refuse throughout the approved refuse disposal site.

(4) The belt consists of a 30-inch flame resistant material required in 30 CFR part 14. The belt travels from the preparation plant to the refuse site. The distance underground is approximately 4,000 feet.

(5) Removing the refuse belt from service due to a fan outage also prevents the coal processing plant from operating.

(6) The mine is ventilated with multiple main ventilation fans and the primary source of ventilation of the ''refuse'' belt is the Dupont main blowing fan. In the event of an outage of any or all ventilation fans, the Dupont fan will remain in operation to provide adequate ventilation to the petitioned area.

(7) The procedures below will be used to monitor the belt on the surface at manned locations.

(a) The following procedures will be used for operating the refuse belt during a fan outage:

(1) The refuse belt is ventilated by the Dupont main blowing fan. The air enters the mine and splits on the belt and exits the mine at the River Portal and top of the Refuse Slope at Browns Run. The blowing system provides positive pressure on the beltline and surrounding areas. Air measurements recorded at the two belt openings where air exits the mine will be monitored with a velometer. If at any time the Dupont main blowing fan becomes inoperative then the refuse belt will be deenergized by a remote system from a surface location.

(2) The beltline will be monitored on the surface at manned locations where audible and visual signals can be heard or seen. An intrinsically safe monitoring system capable of detection and monitoring of carbon monoxide, oxygen, methane and velocity will be installed and maintained along the refuse belt as indicated below:

(i) Carbon monoxide sensors will be installed near the center in the upper third of the entry, in a location that does not expose personnel working on the system to unsafe conditions. Sensors will not be located in abnormally high areas or in other locations where airflow patterns do not permit products of combustion to be carried to the sensors.

(ii) The carbon monoxide sensor location intervals will not exceed 1,000 feet along the belt entry and not more than 100 feet downwind of the belt tailpiece transfer.

(iii) Oxygen and methane sensors will be installed near the center of the entry, at least 12 inches from the roof, ribs, and floor, in a location that would not expose personnel working on the system to unsafe conditions. The sensor will be located where the ventilating current enters the refuse belt entry at Survey Station 12+50.

(iv) Velometers will be installed at the two locations where air used to ventilate the Refuse Belt exits the mine.

(v) The sensors will automatically provide visual and audible signals at the surface locations for any interruption of circuit continuity and any electrical malfunction of the system. These signals must be of sufficient magnitude to be seen or heard by the designated person at the surface locations.

(vi) The sensors will automatically provide visual and audible signals at the designated surface locations when carbon monoxide concentration levels reach alarm (10 PPM), (the Ambient CO Level for the entry will be zero); methane concentration levels reach alarm at 1.0 percent at any sensor; oxygen concentration levels drop below and reach alarm at 19.5 percent; or velocities drop under 50 FPM and reach alarm.

(vii) If at any time any segment of the monitoring system reaches alarm status the belt will be deenergized.

(8) The sensors will be installed and maintained by personnel trained in the installation and maintenance of the system. The system will be maintained in proper operating condition.

(9) Sensors used to monitor for carbon monoxide and methane will be of a type listed and installed in accordance with the recommendations of a nationally recognized testing laboratory approved by the Secretary, or will be of a type, and installed in a manner approved by the Secretary.

(10) At least once each shift when belts are operated as part of a production shift, sensors used to detect carbon monoxide will be visually examined.

(11) At least once every seven days alarms for the installed monitoring system will be functionally tested for proper operation.

(12) At intervals not to exceed 31 days, each carbon monoxide sensor will be calibrated in accordance with the manufacturer's calibration specifications. Calibration will be done with a known concentration of carbon monoxide in air sufficient to activate the alarm.

(13) Each methane sensor installed will be calibrated in accordance with

the manufacturer's calibration specifications. Calibration will be done with a known concentration of methane in air sufficient to activate an alarm.

(14) If the alarm signals are activated during calibration of sensors, the designated person will be notified prior to and upon completion of calibration.

(15) Gases used for the testing and calibration of sensors will be traceable to the National Institute of Standards and Technology reference standard for the specific gas. When these reference standards are not available for a specific gas, calibration gases will be traceable to an analytical standard which is prepared using a method traceable to the National Institute of Standards and Technology. Calibration gases must be within ±2.0 percent of the indicated gas concentration.

(16) A record of the date, time, location and type of sensor, and the cause for the activation will be recorded if an alarm occurs.

(17) If a sensor malfunctions, the date, the extent and cause of the malfunction, and the corrective action taken to return the system to proper operation will be recorded.

(18) A record of the seven-day tests of alert and alarm signals, calibrations, and maintenance of the sensors will be made by the person(s) performing these tests.

(19) The person(s) entering the recordings will include their name, date, and signature in the record.

(20) The records required by this section will be kept either in a secure book that is not susceptible to alteration, or electronically in a computer system that is secure and not susceptible to alteration. These records will be maintained separately from other records and identifiable by a title, such as the ''Sensor Log''.

(21) Records will be retained for at least one year at a surface location at the mine and made available for inspection by miners and authorized representatives of the Secretary.

(22) The Intrinsically Safe Fire Sensor and Warning System will be comprised of components from Conspec Controls, Inc., or equivalent parts or manufacture.

(23) The system will consist of intrinsically safe components. The following components will be the only electrical components present underground on the refuse belt:

(a) Belt Conveyor On/Off switches every 1,000 feet with an intrinsically safe system. A total of 6 switches are present along the beltline.

(b) The belt controls including belt switches and chute plug switch will be controlled by SMC C1570 IS Relays with diodes. The sequence switch will go through an IS barrier (BWI EAGLE 10–7072 IS Zenner Barrier) to an IS proximity switch (BWI EAGLE 10–7039 IS Prox Sensor).

(c) The refuse and slope belt drives and associated electrical components are located outside on the surface at Browns Run and the River Portal.

Within 60 days after this Petition is granted, the petitioner will submit proposed revisions for its approved part 48 training plan to the District Manager. The proposed revisions will specify initial and refresher training regarding the alternative method outlined in this petition and the terms and conditions stated in the Proposed Decision and Order.

Docket Number: M–2015–009–C.

Petitioner: Consolidation Coal Company, RD #1 Box 62A, Dallas, West Virginia 26036.

Mine: Shoemaker Mine, MSHA I.D. No. 46–01436, located in Marshall County, West Virginia.

Regulation Affected: 30 CFR 75.313(c)(2) and (3) (Main mine fan stoppage with persons underground).

Modification Request: The petitioner requests a modification of the existing standard to allow the refuse belt to continue to operate during a fan outage, other than the Dupont Fan. Management will monitor and prohibit the entrance of any miners or personnel underground at any time during the fan outages. The mine will follow the re-entry requirements in 30 CFR for examinations and re-entry by mine personnel once all fans are operational. The petitioner states that:

(1) The Shoemaker Mine operates in the Pittsburgh #8 coal seam. The seam thickness averages 84 inches. The overburden averages 850 feet. The continuous miner and longwall sections are used to mine this coal seam. The mine currently has 730 employees.

(2) Coal extraction from the mine is transported via conveyor belt to the coal processing plant located on the surface. Rock and other impurities are separated from the coal at this location. The separated rock and impurities and termed ''refuse or refuse material''.

(3) The refuse material which has been separated from the coal is them loaded onto another conveyor belt, hereinafter known as the refuse belt, which carries the refuse material back into and through a small portion of the mine, before exiting to the surface again. The refuse is then trans-loaded onto rubber tired vehicles which distribute the refuse throughout the approved refuse disposal site.

(4) The belt consists of a 30-inch flame resistant material required in 30 CFR part 14. The belt travels from the preparation plant to the refuse site. The distance underground is approximately 4,000 feet.

(5) Removing the refuse belt from service due to a fan outage also prevents the coal processing plant from operating.

(6) The mine is ventilated with multiple main ventilation fans and the primary source of ventilation of the ''refuse'' belt is the Dupont main blowing fan. In the event of an outage of any or all ventilation fans, the Dupont fan will remain in operation to provide adequate ventilation to the petitioned area.

(7) The procedures below will be used to monitor the belt on the surface at manned locations.

(a) The following procedures will be used for operating the refuse belt during a fan outage:

(1) The refuse belt is ventilated by the Dupont main blowing fan. The air enters the mine and splits on the belt and exits the mine at the River Portal and top of the refuse slope at Browns Run. The blowing system provides positive pressure on the beltline and surrounding areas. Air measurements recorded at the two belt openings where air exits the mine will be monitored with a velometer. If at any time the Dupont main blowing fan becomes inoperative then the refuse belt will be deenergized by a remote system from a surface location.

(2) The beltline will be monitored on the surface at manned locations where audible and visual signals can be heard or seen. An intrinsically safe monitoring system capable of detection and monitoring of carbon monoxide, oxygen, methane and velocity will be installed and maintained along the refuse belt as indicated below:

(i) Carbon monoxide sensors will be installed near the center in the upper third of the entry, in a location that does not expose personnel working on the system to unsafe conditions. Sensors will not be located in abnormally high areas or in other locations where airflow patterns do not permit products of combustion to be carried to the sensors.

(ii) The carbon monoxide sensor location intervals will not exceed 1,000 feet along the belt entry and not more than 100 feet downwind of the belt tailpiece transfer.

(iii) Oxygen and methane sensors will be installed near the center of the entry, at least 12 inches from the roof, ribs, and floor, in a location that would not expose personnel working on the system to unsafe conditions. The sensor will be located where the ventilating current enters the refuse belt entry at Survey Station 12+50.

(iv) Velometers will be installed at the two locations where air used to ventilate the refuse belt exits the mine.

(v) The sensors will automatically provide visual and audible signals at the surface locations for any interruption of circuit continuity and any electrical malfunction of the system. These signals must be of sufficient magnitude to be seen or heard by the designated person at the surface locations.

(vi) The sensors will automatically provide visual and audible signals at the designated surface locations when carbon monoxide concentration levels reach alarm (10 PPM), (the Ambient CO Level for the entry will be zero); methane concentration levels reach alarm at 1.0 percent at any sensor; oxygen concentration levels drop below and reach alarm at 19.5 percent; or velocities drop under 50 FPM and reach alarm.

(vii) If at any time any segment of the monitoring system reaches alarm status the belt will be deenergized.

(8) The sensors will be installed and maintained by personnel trained in the installation and maintenance of the system. The system will be maintained in proper operating condition.

(9) Sensors used to monitor for carbon monoxide and methane will be of a type listed and installed in accordance with the recommendations of a nationally recognized testing laboratory approved by the Secretary, or will be of a type, and installed in a manner approved by the Secretary.

(10) At least once each shift when belts are operated as part of a production shift, sensors used to detect carbon monoxide must be visually examined.

(11) At least once every seven days alarms for the installed monitoring system will be functionally tested for proper operation.

(12) At intervals not to exceed 31 days, each carbon monoxide sensor will be calibrated in accordance with the manufacturer's calibration specifications. Calibration will be done with a known concentration of carbon monoxide in air sufficient to activate the alarm.

(13) Each methane sensor installed will be calibrated in accordance with the manufacturer's calibration specifications. Calibration will be done with a known concentration of methane in air sufficient to activate an alarm.

(14) If the alarm signals are activated during calibration of sensors, the designated person will be notified prior to and upon completion of calibration.

(15) Gases used for the testing and calibration of sensors will be traceable to the National Institute of Standards and Technology reference standard for the specific gas. When these reference standards are not available for a specific gas, calibration gases will be traceable to an analytical standard which is prepared using a method traceable to the National Institute of Standards and Technology. Calibration gases must be within ±2.0 percent of the indicated gas concentration.

(16) A record of the date, time, location and type of sensor, and the cause for the activation will be recorded if an alarm occurs.

(17) If a sensor malfunctions, the date, the extent and cause of the malfunction, and the corrective action taken to return the system to proper operation will be recorded.

(18) A record of the seven-day tests of alert and alarm signals, calibrations, and maintenance of the sensors will be made by the person(s) performing these actions.

(19) The person(s) entering the record must include their name, date, and signature in the record.

(20) The records required by this section will be kept either in a secure book that is not susceptible to alteration, or electronically in a computer system that is secure and not susceptible to alteration. These records will be maintained separately from other records and identifiable by a title, such as the ''Sensor Log''.

(21) Records will be retained for at least one year at a surface location at the mine and made available for inspection by miners and authorized representatives of the Secretary.

(22) The Intrinsically Safe Fire Sensor and Warning System will be comprised of components from Conspec Controls, Inc., or equivalent parts or manufacture.

(23) The system will consist of intrinsically safe components. The following components will be the only electrical components present underground on the refuse belt:

(a) Belt conveyor on/off switches every 1,000 feet with an intrinsically safe system. A total of 6 switches are present along the beltline.

(b) The belt controls including belt switches and chute plug switch will be controlled by SMC C1570 IS Relays with diodes. The sequence switch will go through an IS barrier (BWI EAGLE 10–7072 IS Zenner Barrier) to an IS proximity switch (BWI EAGLE 10–7039 IS Prox Sensor).

(c) The refuse and slope belt drives and associated electrical components are located outside on the surface at Browns Run and the River Portal.

Within 60 days after this Petition is granted, the petitioner will submit proposed revisions for its approved part 48 training plan to the District Manager. The proposed revisions will specify initial and refresher training regarding the alternative method outlined in this petition and the terms and conditions stated in the Proposed Decision and Order.

Docket Number: M–2015–010–C.

Petitioner: Coyote Creek Mining Company, LLC, 6502 17th Street SW., Zap, North Dakota 58580.

Mine: Coyote Creek Mine, MSHA I.D. No. 32–01028, located in Mercer County, North Dakota.

Regulation Affected: 30 CFR 77.803 (Fail safe ground check circuits on high-voltage resistance grounded systems).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance when the boom/mast is raised or lowered during necessary repairs. The petitioner states that:

(1) Some stages of assembly/disassembly of draglines require special consideration when the boom/mast is raised/lowered into position.

(2) The boom is raised/lowered utilizing the on-board VFD hoist drive and AC drive motors. This process is critical because power to the machine must not be interrupted. Power loss conditions may result in the boom becoming uncontrolled, falling, and possible injuries to workers. To address this condition, the petitioner proposes to use the following guidelines to help prevent loss of power to the machine. This procedure only addresses raising/lowering the boom on draglines utilizing the machine's electrical onboard VFD hoist drive and AC drive motors. It does not replace other mechanical precautions or the requirements of 30 CFR 77.405(b) that are necessary to safely secure booms/masts during construction or maintenance procedures.

The petitioner proposes to use the following procedure for ''boom raising'' or ''boom lowering'' at the Coyote Creek Mine. During this period of construction and maintenance the machine will not be performing mining operations. This procedure will also be applicable in instances of disassembly or major maintenance that require the boom to be raised/lowered. The following guidelines will be used to minimize the potential for electrical power loss during this critical boom procedure:

(1) The petitioner proposes to initially use the procedure to raise the boom on the Marion 8400 dragline, which is currently being reconstructed, and would most likely only use this procedure during disassembly or major maintenance in the future.

(2) Major maintenance requiring the raising/lowering of the boom/mast would only be performed on an as needed basis, which could span long periods of time. Therefore, training and review of the procedure would only be conducted prior to this need. At such time, all persons involved in the process would be trained and retrained.

The petitioner states that:

(1) Coyote Creek employees, its contractors, and affected persons will be trained on the requirements of the procedure at the mine.

(2) The procedure will be coordinated by a Coyote Creek Mine maintenance supervisor and, if present, the contractor's representative will assist. At least two MSHA qualified electricians will be present at all times during the procedure.

(3) The number of persons required on board the machine will be limited. An MSHA qualified electrician, dragline operator, and the dragline oiler will be permitted on the machine. The Coyote Creek maintenance supervisor and contractor's representative may either be on board or at a location on the ground to assist in the coordination.

(4) The affected area under the boom will be secured to prevent persons from entering and/or contacting the frame of the machine during the ''boom raising/lowering''. The area will be secured and only those persons identified in Item #3 will be permitted inside the secured area. At no time will anyone be permitted under the boom or close to the boom.

(5) Communication between the dragline operator, the MSHA qualified electrician at the dragline, the MSHA qualified electrician at the substation, the Coyote Creek maintenance supervisor, and the contractor's representative, if present, will be a dedicated channel on the company's two-way radio.

(6) An MSHA qualified electrician will complete an examination of all electrical components that will be energized. The examination will be done within two hours prior to the boom raising/lowering process. A record of this examination will be made available to interested parties. The machine will be deenergized to perform this examination.

(7) After the examination is completed, the electrical components necessary to complete the boom raising/lowering process will be energized to assure they are operating properly as determined by an MSHA qualified electrician. When completed, the machine will be deenergized and locked out.

(8) The ground fault and ground check circuits will be disabled provided:

(a) The internal grounding conductor of the trailing cable has been tested and is continuous from the frame of the dragline to the grounding resistor located at the substation. Utilizing the ground check circuit and disconnecting the pilot circuit at the machine frame, and verifying the circuit breaker cannot be closed, will be an acceptable test. Resistance measurements will also be used to assure the ground conductor is continuous. The grounding resistor will be tested to assure it is properly connected, is not open, or is not shorted.

(b) Normal short circuit protection will be provided at all times. The over current relay setting may be increased up to 100 percent above its normal setting.

(9) During the boom raising/lowering procedure an MSHA qualified electrician will be positioned at the substation dedicated to monitor the grounding circuit. The MSHA qualified electrician will be able to detect a grounded phase condition or an open ground wire condition. The MSHA qualified electrician at the substation will at all times maintain communications with an MSHA qualified electrician at the dragline. If a grounded phase condition or an open ground wire should occur during the process, the MSHA qualified electrician at the substation will notify the MSHA qualified electrician at the dragline. All persons on board the machine must be aware of the condition and must remain on board the machine. The boom must be lowered to the ground or controlled and electrical circuit deenergized, locked and tagged out. The circuit must remain deenergized until the condition is corrected. The ground fault and ground check circuits will be reinstalled prior to reenergizing and testing the machine. Once circuits have been tested and no adverse conditions are present, the boom raising/lowering procedure, as outlined above, will be resumed.

(10) During the construction/maintenance procedure, persons cannot get on or off the dragline while the ground check ground fault circuits are disabled unless the circuit is deenergized, locked and tagged out as verified by the MSHA qualified electrician at the substation.

(11) After the boom raising/lowering is completed, the MSHA qualified electrician at the substation will restore all the protective devices to their normal state. When this has been completed, the MSHA qualified electrician at the substation will notify the dragline that all circuits are in their normal state. At this time normal work procedures can begin.

The petitioner asserts that this proposed alternative method of the existing standard will not result in a diminution of safety to the miners affected.

Dated: April 27, 2015.

Sheila McConnell,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2015–10093 Filed 4–29–15; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and 30 CFR part 44 govern the application, processing, and disposition of petitions for modification. This **Federal Register** Notice notifies the public that MSHA has investigated and issued a final decision on certain mine operator petitions to modify a safety standard.

ADDRESSES: Copies of the final decisions are posted on MSHA's Web site at *http://www.msha.gov/indexes/petition.htm.* The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2349, Arlington, Virginia 22209. All visitors must first stop at the receptionist desk on the 21st Floor to sign-in.

FOR FURTHER INFORMATION CONTACT: Roslyn B. Fontaine, Office of Standards, Regulations, and Variances at 202–693–9475 (Voice), *fontaine.roslyn@dol.gov* (Email), or 202–693–9441 (Telefax), or Barbara Barron at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Telefax). [These are not toll-free numbers].

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 101 of the Federal Mine Safety and Health Act of 1977, a mine operator may petition and the Secretary of Labor (Secretary) may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no

less protection for the miners affected than that provided by the standard; or (2) that the application of the standard will result in a diminution of safety to the affected miners.

MSHA bases the final decision on the petitioner's statements, any comments and information submitted by interested persons, and a field investigation of the conditions at the mine. In some instances, MSHA may approve a petition for modification on the condition that the mine operator complies with other requirements noted in the decision.

II. Granted Petitions for Modification

On the basis of the findings of MSHA's investigation, and as designee of the Secretary, MSHA has granted or partially granted the following petitions for modification:

- *Docket Number:* M–2014–026–C.
FR Notice: 79 FR 48256 (8/15/2014).
Petitioner: Covol Fuels No. 3, LLC, 10156 US Hwy 25 E, Pineville, Kentucky 40977.
Mine: Crockett, MSHA I.D. No. 15–12682, located in Bell County, Kentucky; Coarse Coal Refuse Fill #5, Site I.D. No. KY07–12682–05.
Regulation Affected: 30 CFR 77.214(a) (Refuse piles; general).

- *Docket Number:* M–2014–031–C.
FR Notice: 79 FR 64623 (10/30/2014).
Petitioner: Sunrise Coal LLC, 12661 Agricare Road, Oaktown, Indiana 47561.
Mine: Oaktown Fuels Mine No. 1, MSHA I.D. No. 12–02394, located in Knox County, Indiana.
Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

- *Docket Number:* M–2014–032–C.
FR Notice: 79 FR 64623 (10/30/2014).
Petitioner: Sunrise Coal LLC, 12661 Agricare Road, Oaktown, Indiana 47561.
Mine: Oaktown Fuels Mine No. 2, MSHA I.D. No. 12–02418, located in Knox County, Indiana.
Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

Dated: April 27, 2015.

Sheila McConnell,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2015–10092 Filed 4–29–15; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of National Science Board business, as follows:

AGENCY: National Science Board, NSF.

DATE AND TIME: May 5, 2015 from 8:00 a.m. to 3:45 p.m. and May 6, 2015 from 8:00 a.m. to 3:00 p.m. (EDT).

PLACE: These meetings will be held at the National Science Foundation, 4201 Wilson Blvd., Rooms 1235, Arlington, VA 22230. All visitors must contact the Board Office (call 703–292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the meeting and provide name and organizational affiliation. Visitors must report to the NSF visitor desk located in the lobby at the 9th and N. Stuart Streets entrance to receive a visitor's badge.

WEBCAST INFORMATION: Public meetings and public portions of meetings will be webcast. To view the meetings, go to *http://www.nsf.gov/nsb/notices/* and follow the instructions.

UPDATES: Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/notices/.*

AGENCY CONTACT: Jennie L. Moehlmann, *jmoehlma@nsf.gov,* (703) 292–7000.

PUBLIC AFFAIRS CONTACT: Nadine Lymn, *nlymn@nsf.gov,* (703) 292–2490.

STATUS: Portions open; portions closed.

Open Sessions

May 5, 2015

8:00–8:05 a.m. (Chairman's introduction)
8:05–9:05 a.m. (AO)
10:30–10:45 a.m. (CSB)
10:45–11:15 a.m. (CPP)
11:15–11:55 a.m. (Plenary)

May 6, 2015

10:45–11:25 a.m. (Plenary)
12:30–1:15 p.m. (Plenary)
1:15–3:00 p.m. (SEI)

Closed Sessions

May 5, 2015

9:05–9:35 a.m. (AO)
9:35–10:20 a.m. (CSB)
1:00–3:45 p.m. (CPP)

May 6, 2015

8:00–8:30 a.m. (Plenary executive)
8:30–10:30 a.m. (Plenary)

MATTERS TO BE DISCUSSED:

Tuesday, May 5, 2015

Committee on Audit & Oversight (AO)

Open Session: 8:05–9:05 a.m.

- Approval of February 2015 open meeting minutes
- Committee Chairman's opening remarks
- Approval of OIG Semiannual Report materials
- NSF FY 2014 Merit Review Report
- Inspector General's update, including FY 2015 Financial Statement audit plans
- Chief Financial Officer's update
- Committee Chairman's closing remarks

Audit and Oversight Committee

Closed Session: 9:05–9:35 a.m.

- Approval of February 2015 closed meeting minutes
- Committee Chairman's opening remarks
- Discussion of two-month grantee salary policy
- Chairman's closing remarks

Committee on Strategy and Budget (CSB)

Closed Session: 9:35–10:20 a.m.

- Committee Chairman's remarks
- Approval of CSB closed minutes for the February 2015 meeting and March 2015 teleconference
- NSF FY 2017 budget development
- Performance Improvement Officer update on FY 2015–2017 strategic reviews

Committee on Strategy and Budget (CSB)

Open Session: 10:30–10:45 a.m.

- Approval of CSB open minutes for February 2015 meeting and open joint CPP/CSB minutes for February 2015
- NSF FY 2016 budget update

Committee on Programs and Plans (CPP)

Open Session: 10:45–11:15 a.m.

- Approval of open minutes of the February 2015 meeting
- Committee Chairman's remarks
- Information item: Cornell High Energy Synchrotron Source (CHESS)
- Information item: Advanced LIGO

Plenary Board Meeting

Open Session: 11:15–11:35 a.m.

- Presentation by the President of NSB's 2015 Public Service Award recipient, the American Museum of Natural History

Plenary Board Meeting

Open Session: 11:35–11:55 a.m.

- Presentation by the President of NSB's 2015 Public Service Award recipient, the Museum of Science, Boston's National Center for Technological Literacy

Committee on Programs and Plans (CPP)

Closed Session: 1:00–3:45 p.m.

- Approval of closed CPP minutes for February 2015 meeting and April 2015 teleconference
- Committee Chairman's remarks
- Information Item: MPS Advisory Committee, Subcommittee and NSF response to strategic plan for particle physics outlined in the May 2014 Particle Physics Project Prioritization Panel (P5) report
- Action Item: National High Magnetic Field Laboratory (NHMFL)
- Action Item: Regional Class Research Vessel (RCRV) project
- Action Item: National Optical Astronomy Observatory (NOAO)
- Action Item: National Radio Astronomy Observatory (NRAO)
- Action Item: Gemini Observatory

Wednesday, May 6, 2015

Plenary

Executive Closed Session: 8:00–8:30 a.m.

- Approval of executive closed session minutes, February 2015
- Election of Executive Committee members
- Board member proposal
- Chairman's remarks

Plenary Board Meeting

Closed Session: 8:30–10:30 a.m.

- Approval of closed session minutes, February 2015
- Discussion of risks to NSF
- Awards and Agreements/CPP action items, including RCRV, NOAO, NRAO and Gemini Observatory
- Closed committee reports
- Chairman's remarks

Plenary Board Meeting

Open Session: 10:45–11:05 a.m.

- Presentation by the NSF 2015 Alan T. Waterman Award Recipient, Dr. Andrea Alù

Plenary Board Meeting

Open Session: 11:05–11:25 a.m.

- Presentation by the recipient of the NSB 2015 Vannevar Bush Award

Plenary Board Meeting

Open Session: 12:30–1:15 p.m.

- Approval of open session minutes, February 2015
- Chairman's report
- Resolution votes
- Director's report
- Open committee reports
- Chairman's remarks

Committee on Science & Engineering Indicators (SEI)

Open Session: 1:15–3:00 p.m.

- Chairman's introduction
- Approval of the February 2015 meeting minutes
- Discussion of the rollout of the Companion Report to *Science and Engineering Indicators 2014, Revisiting the STEM Workforce*
- Review and discussion of *Indicators 2016* draft chapters
- Chairman's closing remarks

Meeting Adjourns: 3:00 p.m.

Ann Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2015–10252 Filed 4–28–15; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Establish An Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than three years.

DATES: Written comments on this notice must be received by June 29, 2015 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays). You may obtain a copy of the data collection instruments and instructions from Ms. Plimpton.

SUPPLEMENTARY INFORMATION:

Title of Collection: Presidential Awards for Excellence in Mathematics and Science Teaching (PAEMST), State Coordinator (SC) Survey.

OMB Number: 3145—NEW.

Expiration Date of Approval: Not Applicable.

Type of request: NEW.

Abstract: The PAEMST is a White House program established by Congress in 1983 authorizing the President to bestow up to 108 awards each year to teachers of mathematics and science at the elementary and secondary levels. The NSF is the designated federal agency for administration of this Presidential program. Awards are given to mathematics and science (including computer science) teachers from each of the 50 states and four U.S. jurisdictions. The jurisdictions are Washington DC; Puerto Rico; Department of Defense Education Activity schools; and the U.S. territories as a group (American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands). The award recognizes those teachers who develop and implement a high-quality instructional program that is informed by content knowledge and enhances student learning. Since the program's inception, more than 4,300 teachers have been recognized for their contributions in the classroom and to their profession. Awardees serve as models for their colleagues, inspiration to their communities, and leaders in the improvement of mathematics and science (including computer science) education.

The State Coordinator (SC) manages the PAEMST program within his or her state or jurisdiction. SCs recruit eligible nominees, select and assign mentors to nominees, coordinate the selection committee, and plan local recognition events within their State. They also carry out the responsibilities as noted in the ''Operational Handbook for State-Level Science and Mathematics Coordinators.''

The purpose of this survey is to seek feedback from the 120 SCs regarding PAEMST management within their state or jurisdiction. The NSF, PAEMST support team will ask directed questions using the survey to gather information that may specifically address the methods and recruitment efforts that SCs use to support the attracting of

prospective award nominees. Additional survey areas may also include:

- Applicant Mentoring
- Mentor Training
- State selection Committee
- State selection Process
- Applicant and State Finalist Notification and Recognition
- In-kind contributions

The survey will evaluate the impact SCs have on attracting prospective award nominees to PAEMST. This will be conducted as a Web-based survey.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30–40 minutes for State Coordinators.

Respondents: Individuals.

Estimated Number of Responses per Form: 120 Coordinators.

Estimated Total Annual Burden on Respondents: 80 hours (120 Coordinators at 40 minutes per survey = 80 hours).

Frequency of Response: One per application cycle.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the PAEMST functions, including whether the information shall have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Dated: April 27, 2015.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–10074 Filed 4–29–15; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Proj–0803; NRC–2013–0235]

Northwest Medical Isotopes, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff has received and is making available the first part of the application for a construction permit, submitted by Northwest Medical Isotopes, LLC (NWMI). NWMI proposes to build a medical radioisotope production facility located in Columbia, Missouri.

DATES: April 30, 2015.

ADDRESSES: Please refer to Docket ID NRC–2013–0235 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michael Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2856; email: *Michael.Balazik@nrc.gov.*

SUPPLEMENTARY INFORMATION: On November 7, 2014, NWMI filed with the NRC, pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), a portion of an application for a construction permit for a medical radioisotope production facility in Columbia, Missouri. By letter dated February 5, 2015 (ADAMS Accession No. ML15086A262), NWMI withdrew and resubmitted this portion of their construction permit application (ADAMS Accession No. ML15086A261) to include a discussion of connected actions in their environmental report in response to a letter from the NRC (ADAMS Accession No. ML14349A501).

An exemption from certain requirements of 10 CFR 2.101(a)(5) granted by the Commission on October 7, 2013 (ADAMS Accession No. ML13238A333), in response to a letter from NWMI dated August 9, 2013 (ADAMS Accession No. ML13227A295), allowed for NWMI to submit its construction permit application in two parts. Specifically, the exemption allowed NWMI to submit a portion of its application for a construction permit up to 6 months prior to the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. On February 5, 2015, in accordance with 10 CFR 2.101(a)(5), NWMI submitted the following in part one of the construction permit application:

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1),
- the environmental report required by 10 CFR 50.30(f),
- the filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21,
- the general information required by 10 CFR 50.33, and
- the agreement limiting access to classified information required by 10 CFR 50.37.

As stated in NWMI's February 5, 2015, letter, part two of NWMI's application for a construction permit will contain the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a) and will be submitted in accordance with the requirements of 10 CFR 2.101(a)(5).

Subsequent **Federal Register** notices will address the acceptability of this part of the tendered construction permit application for docketing and provisions for public participation in the construction permit application review process.

Dated at Rockville, Maryland, this 13th day of April, 2015.

For the Nuclear Regulatory Commission.

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–10127 Filed 4–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0059]

Refining and Characterizing Heat Release Rates From Electrical Enclosures During Fire (RACHELLE–FIRE)

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft NUREG, NUREG–2178 (EPRI 3002005578), ''Refining and Characterizing Heat Release Rates from Electrical Enclosures During Fire (RACHELLE–FIRE), Volume 1: Peak Heat Release Rates and Effect of Obstructed Plume.''

DATES: Submit comments by June 15, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

• Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0059. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Stroup, Office of Nuclear Regulatory Research; telephone: 301–251–7609; email: *David.Stroup@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0059 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0059.

• NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section. Draft NUREG—2178, ''Refining and Characterizing Heat Release Rates from Electrical Enclosures During Fire (RACHELLE–FIRE), is available in ADAMS under Accession No. ML15056A144.

• NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0059 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publically disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The Refining and Characterizing Heat Release Rates From Electrical Enclosures During Fire (RACHELLE–FIRE) program involves a working group of experienced fire protection and fire probabilistic risk assessment researchers and practitioners focused on enhancing the methodology used to model electrical enclosure fires in nuclear power plants. This report documents the results from the working group's efforts to develop technical information in three areas: (1) Classification of electrical enclosures in terms of function, size, contents, and ventilation; (2) determination of peak heat release rate (HRR) probability distributions considering specific electrical enclosure characteristics;, and (3) development of a method to account for the impact of the enclosure on the vertical thermal zone of influence above the enclosure during fire. Electrical enclosures have been classified in groups based on their electrical function, contents, and size. Peak HRR distributions for the different classification groups have been developed. These distributions are based on the results of different experimental programs intended to measure the HRR associated with fires in electrical enclosures. In order to provide a comprehensive characterization of electrical enclosure fires, the working group evaluated the temperature characteristics of fire plumes associated with these events using the Fire Dynamics Simulator program. Computer simulations of various enclosure configurations were developed for evaluating the fire burning inside electrical enclosures and the fire plume temperature characteristics that would be generated. Based on this research, new fire plume temperature profiles reflecting the obstructed nature of fire plumes generated from fires inside electrical enclosures are provided. Finally, examples, consolidating the information described in this report, are provided to illustrate how to incorporate the information documented in this report into existing approaches for modeling fires in electrical enclosures.

Dated at Rockville, Maryland, this 21st day of April, 2015.

For the Nuclear Regulatory Commission.

Mark Henry Salley,

Chief, Fire Research Branch, Division of Risk Analysis, Office of Nuclear Regulatory Research.

[FR Doc. 2015–10130 Filed 4–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271; NRC–2015–0111]

Entergy Nuclear Operations, Inc.; Vermont Yankee Nuclear Power Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft environmental assessment and finding of no significant impact; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of exemptions in response to a request from Entergy Nuclear Operations, Inc. (Entergy or the licensee) that would permit the licensee to reduce its emergency planning (EP) activities at the Vermont Yankee Nuclear Power Station (VY). The licensee is seeking exemptions that would eliminate the requirements for the licensee to maintain offsite radiological emergency plans and reduce some of the onsite EP activities based on the reduced risks at VY, which is permanently shutdown and defueled. However, requirements for certain onsite capabilities to communicate and coordinate with offsite response authorities would be retained. In addition, offsite EP provisions would still exist through State and local government use of a comprehensive emergency management plan process in accordance with the Federal Emergency Management Agency's (FEMA's) Comprehensive Preparedness Guide (CPG) 101, ''Developing and Maintaining Emergency Operations Plans.'' The NRC staff is issuing, for public comment, this draft environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed exemptions.

DATES: Submit comments by June 1, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0111. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Kim, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–4125; email: *James.Kim@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0111 when contacting the NRC about the availability of information regarding this this draft EA and FONSI. You may obtain publicly-available information related to this this draft EA and FONSI using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0111.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0111 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

VY is a permanently shutdown and defueled nuclear power plant that is in the process of decommissioning. VY is located in Windham County, Vermont, 5 miles south of Brattleboro, Vermont. Entergy is the holder of the Renewed Facility Operating License No. DPR–28 for VY. VY has been shut down since December 29, 2014, and the final removal of fuel from the VY reactor vessel was completed on January 12, 2015. By letter dated January 12, 2015, Entergy submitted to the NRC a certification of the permanent cessation of power operations at VY and the permanent removal of fuel from the VY reactor vessel. As a permanently shutdown and defueled facility, and pursuant to section 50.82(a)(2) of Title 10 of the *Code of Federal Regulations* (10 CFR), VY is no longer authorized to be operated or to have fuel placed into its reactor vessel, but the licensee is still authorized to possess and store irradiated nuclear fuel. Irradiated nuclear fuel is currently stored onsite at VY in a spent fuel pool (SFP) and in an independent spent fuel storage installation (ISFSI).

The licensee has requested exemptions for VY from certain EP requirements in 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities.'' The NRC regulations concerning EP do not recognize the reduced risks after a reactor is permanently shut down and defueled. As such, a permanently shutdown and defueled reactor, such as VY, must continue to maintain the same EP requirements as an operating power reactor under the existing regulatory requirements. To establish a level of EP commensurate with the reduced risks of a permanently shutdown and defueled reactor, Entergy requires exemptions from certain EP regulatory requirements before it can change its emergency plans.

The NRC is considering issuing to Entergy exemptions from portions of 10 CFR 50.47, ''Emergency plans,'' and 10 CFR part 50, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' which would eliminate the requirements for Entergy to maintain offsite radiological emergency plans and reduce some of the onsite EP activities based on the reduced risks at VY, due to its permanently shutdown and defueled status. Based on the decision of the United States Court of Appeals for the Second Circuit in *Brodsky* v. *NRC* associated with a fire protection exemption for Indian Point Nuclear Generating Unit No. 3, and demonstrated public interest in this exemption request, particularly the State of Vermont, the NRC is issuing for public comment, pursuant to 10 CFR 51.33, this draft EA and FONSI associated with the exemption request. The NRC has concluded that the proposed action will have no significant environmental impact.

III. Draft Environmental Assessment

Description of the Proposed Action

The proposed action would exempt Entergy from meeting certain requirements set forth in 10 CFR 50.47 and appendix E to 10 CFR part 50. More specifically, Entergy requested exemptions from: (1) Certain requirements in 10 CFR 50.47(b) regarding onsite and offsite emergency response plans for nuclear power reactors; (2) certain requirements in 10 CFR 50.47(c)(2) to establish plume exposure and ingestion pathway EP zones for nuclear power reactors; and (3) certain requirements in 10 CFR part 50, appendix E, section IV, which establishes the elements that make up the content of emergency plans. The proposed action of granting these exemptions would eliminate the requirements for Entergy to maintain offsite radiological emergency plans and reduce some of the onsite EP activities at VY, based on the reduced risks at the permanently shutdown and defueled reactor. However, requirements for certain onsite capabilities to communicate and coordinate with offsite response authorities would be retained. Additionally, if necessary, offsite protective actions could still be implemented using a comprehensive emergency management plan (CEMP) process. A CEMP in this context, also referred to as an emergency operations plan (EOP), is addressed in Federal Emergency Management Agency's (FEMA's) Comprehensive Preparedness Guide (CPG) 101. The CPG 101 is the foundation for State, territorial, tribal, and local EP in the United States. It promotes a common understanding of the fundamentals of risk-informed planning and decision making, and helps planners at all levels of government in their efforts to develop and maintain viable, all-hazards, all-threats emergency plans. An EOP is flexible enough for use in all emergencies. It describes how people and property will be protected; details who is responsible for carrying out specific actions; identifies the personnel, equipment, facilities, supplies, and other resources available; and outlines how all actions will be coordinated. A CEMP is often referred to as a synonym for ''all-hazards'' planning.

The proposed action is in accordance with the licensee's application dated March 14, 2014, as supplemented by letters dated August 29, 2014, and October 21, 2014. In its letters dated August 29, 2014, and October 21, 2014, Entergy provided responses to the NRC staff's requests for additional information concerning the proposed exemptions.

Need for the Proposed Action

The proposed action is needed for Entergy to revise the VY emergency plan to reflect the permanently shutdown and defueled status of the facility. The EP requirements currently applicable to VY are for an operating power reactor. There are no explicit regulatory provisions distinguishing EP requirements for a power reactor that has been permanently shut down from those for an operating power reactor. Therefore, since the 10 CFR part 50 license for VY no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel, as specified in 10 CFR 50.82(a)(2), the occurrence of postulated accidents associated with reactor operation is no longer credible.

In its exemption request, the licensee identified four possible radiological accidents at VY in its permanently shutdown and defueled condition. These are: (1) A fuel-handling accident; (2) a radioactive waste-handling accident; (3) a loss of SFP normal cooling (*i.e.,* boil off); and (4) an adiabatic heat up of the hottest fuel assembly. The NRC staff evaluated these possible radiological accidents in the Commission Paper (SECY) 14–0125, ''Request by Entergy Nuclear Operations, Inc., for Exemptions from Certain Emergency Planning Requirements,'' dated November 14, 2014. In SECY–14–0125, the NRC staff verified that Entergy's analyses and calculations provided reasonable assurance that if the requested exemptions were granted, then: (1) For a design-basis accident (DBA), an offsite radiological release will not exceed the Environmental Protection Agency's (EPA) Protective Action Guides (PAGs) at the site boundary, as detailed in the EPA ''PAG Manual, Protective Action Guides and Planning Guidance for Radiological Incidents,'' dated March 2013, which was issued as Draft for Interim Use and Public Comment; and (2) in the unlikely event of a beyond DBA resulting in a loss of all SFP cooling, there is sufficient time to initiate appropriate mitigating actions, and if a release is projected to occur, there is sufficient time for offsite agencies to take protective actions using a CEMP to protect the health and safety of the public. The Commission approved the NRC staff's recommendation to grant the exemptions based on this evaluation in its Staff Requirements Memorandum to SECY–14–0125, dated March 2, 2015.

Based on these analyses, the licensee states that complete application of the EP rule to VY, in its particular circumstances as a permanently shutdown and defueled reactor would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. Entergy also states that it would incur undue costs in the application of operating plant EP requirements for the maintenance of an emergency response organization in excess of that actually needed to respond to the diminished scope of credible accidents for a permanently shutdown and defueled reactor.

Environmental Impacts of the Proposed Action

The NRC staff concluded that the exemptions, if granted, would not significantly increase the probability or consequences of accidents at VY in its permanently shutdown and defueled condition. There would be no significant change in the types of any effluents that may be released offsite. There would be no significant increase in the amounts of any effluents that may be released offsite. There would be no significant increase in individual or cumulative occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not have any foreseeable impacts to land, air, or water resources, including impacts to biota. In addition,

there are also no known socioeconomic or environmental justice impacts associated with the proposed action. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered the denial of the proposed action (*i.e.,* the ''no-action'' alternative). The denial of the application would result in no change in current environmental impacts. Therefore, the environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

The proposed action does not involve the use of any different resources than those previously considered in the Final Environmental Statement for VY, dated July 1972, as supplemented by NUREG–1437, Supplement 30, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Vermont Yankee Nuclear Power Station,'' Volumes 1 and 2, published in August 2007.

Agencies or Persons Consulted

The NRC staff did not enter into consultation with any other Federal agency or with the State of Vermont regarding the environmental impact of the proposed action. On April 24, 2015, the Vermont State representative was notified of this draft EA and FONSI.

IV. Finding of No Significant Impact

The licensee has proposed exemptions from: (1) Certain requirements in 10 CFR 50.47(b) regarding onsite and offsite emergency response plans for nuclear power reactors; (2) certain requirements in 10 CFR 50.47(c)(2) to establish plume exposure and ingestion pathway EP zones for nuclear power reactors; and (3) certain requirements in 10 CFR part 50, appendix E, section IV, which establishes the elements that make up the content of emergency plans. The proposed action of granting these exemptions would eliminate the requirements for the licensee to maintain offsite radiological emergency plans and reduce some of the onsite EP activities at VY, based on the reduced risks at the permanently shutdown and defueled reactor. However, requirements for certain onsite capabilities to communicate and coordinate with offsite response authorities will be retained and offsite EP provisions will still exist through State and local government use of a CEMP.

Consistent with 10 CFR 51.21, the NRC conducted the EA for the proposed action included in Section III of this document, and incorporated by reference in this finding. On the basis of this EA, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has decided not to prepare an environmental impact statement for the proposed action.

V. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./Web link/
Developing and Maintaining Emergency Operations Plans, Comprehensive Preparedness Guide (CPG) 101, Version 2.0, November 2010.	*http://www.fema.gov*.
Docket No. 50–271, Request for Exemptions from Portions of 10 CFR 50.47 and 10 CFR 50, Appendix E, Vermont Yankee Nuclear Power Station, March 14, 2014.	ADAMS Accession No. ML14080A141.
Docket No. 50–271, Request for Exemptions from Portions of 10 CFR 50.47 and 10 CFR 50, Appendix E—Supplement 1, Vermont Yankee Nuclear Power Station, August 29, 2014.	ADAMS Accession No. ML14246A176.
Docket No. 50–271, Request for Exemptions from Portions of 10 CFR 50.47 and 10 CFR 50, Appendix E—Supplement 2, Vermont Yankee Nuclear Power Station, October 21, 2014.	ADAMS Accession No. ML14297A159.
Protective Action Guides and Planning Guidance for Radiological Incidents, U.S. Environmental Protection Agency Draft for Interim Use and Public Comment, March 2013.	*http://www.epa.gov*.
SECY–14–0125, ''Request by Entergy Nuclear Operations, Inc. for Exemptions from Certain Emergency Planning Requirements,'' November 14, 2014.	ADAMS Accession No. ML14227A711.
Staff Requirements Memorandum to SECY–14–0125, ''Request by Entergy Nuclear Operations, Inc., for Exemptions from Certain Emergency Planning Requirements,'' March 2, 2015.	ADAMS Accession No. ML15061A516.
NUREG–1437, Supplement 30, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Vermont Yankee Nuclear Power Station,'' August 2007.	ADAMS Accession No. ML071840398.

Dated at Rockville, Maryland, this 24th day of April, 2015.

For the Nuclear Regulatory Commission.

Meena K. Khanna,

Chief, Plant Licensing IV–2 and Decommissioning Transition Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–10126 Filed 4–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0107]

Net Positive Suction Head for Emergency Core Cooling and Containment Heat Removal System Pumps

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing regulatory guide (RG), RG 1.1 ''Net Positive Suction Head for Emergency Core Cooling and Containment Heat Removal System Pumps.'' The guide is being withdrawn because the same guidance is provided with more detail by RG 1.82, ''Water Sources for Long-Term Recirculation Cooling Following a Loss-of-Coolant Accident.''

DATES: Effective April 30, 2015, the NRC withdraws RG 1.1.

ADDRESSES: Please refer to Docket ID NRC–2015–0107 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0107. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ahsan Sallman, Office of Nuclear Reactor Regulation, telephone: 310–415–2380 email: *Ahsan.Sallman@nrc.gov, and* Richard Jervey, Office of Nuclear Regulatory Research, telephone: 301–251–7404, email: *Richard.Jervey@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is withdrawing RG 1.1 because its guidance has been incorporated into RG 1.82, ''Water Sources for Long-Term Recirculation Cooling Following a Loss-of-Coolant Accident.''

II. Further Information

The withdrawal of RG 1.1 does not alter any prior or existing licensing commitments based on its use. Although a regulatory guide is withdrawn, its use in existing licenses is still valid, and changes to the licenses can be accomplished using other regulatory products. Withdrawal of an RG means that the guide no longer provides useful information or has been superseded by other guidance, technological innovations, congressional actions, or other events. A withdrawn guide should not be used for future NRC licensing activities.

This RG 1.1 provides guidance on meeting the requirements in part 50, appendix A of Title 10 of the *Code of Federal Regulations* (10 CFR), General Design Criteria (GDC), GDC 35, ''Emergency Core Cooling,'' and GDC 38, ''Containment Heat Removal.'' The GDC 35 and 38 require that the emergency cooling and containment heat removal systems be capable of accomplishing their required safety functions assuming loss of offsite power and single failure. The ability to accomplish these safety functions reliably depends in part on the proper performance of system pumps which, in turn, depends on the conditions under which the pumps must operate. One of these conditions is suction pressure and the closely related characteristic net positive suction head. The information in RG 1.82 has been updated from extensive reviews of the emergency core cooling system recirculation systems which have reduced the uncertainties contained in modeling studies of these systems. The NRC staff has determined that the RG 1.82 guidance is more thorough and provides the needed detail to allow consideration of nuances in design which were not contemplated when RG 1.1 was written in 1970.

The guidance from RG 1.1 pertaining to suction pressure and net positive suction head has been incorporated into RG 1.82, ''Water Sources for Long-Term Recirculation Cooling Following a Loss-of-Coolant Accident,'' which includes detailed guidance related to emergency cooling systems. The RG 1.1 is superseded by RG 1.82.

Dated at Rockville, Maryland, this 23rd day of April, 2015.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2015–10076 Filed 4–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8907, NRC–2013–0036]

United Nuclear Corporation; Church Rock Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application from United Nuclear Corporation for an amendment of Materials License No. SUA–1475. The amendment would change License Condition 30.A by adding two new monitoring wells that are already in service, and License Condition 30.C by removing requirements for work that has been completed. These changes are administrative in nature.

DATES: A request for a hearing or petition for leave to intervene must be filed by June 29, 2015.

ADDRESSES: Please refer to Docket ID NRC–2013–0036 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0036. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Thomas McLaughlin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–5869, email: *Thomas.McLaughlin@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has received, by letter dated January 22, 2015 (ADAMS Accession No. ML15033A453), an application from United Nuclear Corporation to amend Materials License No. SUA–1475. The

application was amended by email dated January 29, 2015 (ADAMS Accession No. ML15041A475), after a phone call from NRC staff requesting a clarification. The amendment would change License Conditions 30.A and 30.C. These changes are administrative in nature. The change to License Condition 30.A would add two monitoring wells that are currently being used to sample ground water. The change to License Condition 30.C would update the language and remove tasks that have already been accomplished and will not need to be repeated in the future. No safety evaluation report or environmental assessment will be completed for these changes.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located in One White Flint North, Room O1–F21 (first floor), 11555 Rockville Pike, Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition. The Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth, with particularity, the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by June 29, 2015. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by June 29, 2015.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in

accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Dated at Rockville, Maryland, this 14th day of April, 2015.

For the Nuclear Regulatory Commission.

Andrew Persinko,

Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2015–10129 Filed 4–29–15; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

National Science and Technology Council; National Space Weather Strategy

ACTION: Notice for public comment.

SUMMARY: The National Science and Technology Council; Committee on Environment, Natural Resources, and Sustainability; Subcommittee on Disaster Reduction requests public comments on the draft 2015 National Space Weather Strategy: *http://www.dhs.gov/national-space-weather-strategy.*

DATES: Responses must be received by May 29, 2015 to be considered.

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

• *Email: spaceweather@ostp.gov.* Include [National Space Weather Strategy] in the subject line of the message.

• *Fax:* (202) 456–6071, Attn: William Murtagh.

• *Mail:* Attn: William Murtagh, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW., Washington, DC 20504.

Instructions: Response to this request for public comment is voluntary. Responses exceeding 500 words will not be considered; please reference page and line numbers in your response, as appropriate. Please be aware that your comments may be posted online. The Office of Science and Technology Policy (OSTP) therefore requests that no business proprietary information, copyrighted information, confidential, or personally identifiable information be submitted in response to this request. Please note that the U.S. Government will not pay for response preparation or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: William Murtagh, 202–456–4444, *wmurtagh@ostp.eop.gov,* OSTP.

SUPPLEMENTARY INFORMATION: Space weather refers to the dynamic conditions of the space environment that arise from interactions with emissions from the sun, including solar flares, solar energetic particles, and coronal mass ejections. These emissions can affect Earth and its surrounding space, potentially causing disruption to electric power transmission; satellite, aircraft, and spacecraft operations; telecommunications; position, navigation, timing services; and other technology and infrastructure. Given the growing importance and reliance of the Nation on these services and infrastructures, it is critical that the Nation prepare for the effects of space weather events.

In November 2014, the Space Weather Operations, Research, and Mitigation (SWORM) Task Force was established by the National Science and Technology Council (NSTC); Committee on Environment, Natural Resources, and Sustainability; Subcommittee on Disaster Reduction (SDR). The SWORM Charter directed the Task Force to develop a National Space Weather Strategy (NSWS) that will articulate high-level strategic goals for enhancing National preparedness to space weather events. This notice solicits public input to inform the development of this strategy.

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2015–10113 Filed 4–29–15; 8:45 am]

BILLING CODE 3270–F5–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74809; File No. SR–MIAX–2015–19]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 515

April 24, 2015.

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 April 13, 2015, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 515.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange has identified several additional enhancements to the functionality of two order types—Customer Cross Order [3] and Qualified Contingent Cross Order [4]—that the Exchange believes should be included in the Rules prior to deployment of the Qualified Contingent Cross Order functionality. The Exchange proposes to amend Exchange Rule 515 accordingly. The Exchange notes that both order types were included in the original MIAX Rules that were approved as part of its registration as a national securities exchange. The Customer Cross Order was deployed when the Exchange deployed PRIME functionality.[5] The proposed changes would codify existing functionality for Customer Cross Orders that is not currently detailed in the Exchange's Rules. The Qualified Contingent Cross Order is currently not deployed, however, will be available after approval of this filing.

Rule 515(h)(1) provides that Customer Cross Orders are automatically executed upon entry provided that the execution (i) is at or between the best bid and offer on the Exchange; (ii) is not at the same price as a Priority Customer Order on the Exchange's Book; and (iii) will not trade at a price inferior to the NBBO. Customer Cross Orders will be automatically canceled if they cannot be executed. Customer Cross Orders may only be entered in the minimum trading increments applicable to the options class under Rule 510.[6] Rule 515(h)(2) provides that Qualified Contingent Cross Orders are automatically executed upon entry provided that the execution (i) is not at the same price as a Priority Customer Order on the Exchange's Book; and (ii) is at or between the NBBO. Qualified Contingent Cross Orders will be automatically canceled if they cannot be executed. Qualified Contingent Cross Orders may only be entered in the minimum trading increments applicable to the options class under Rule 510.[7]

Although neither the Customer Cross Order nor the Qualified Contingent Cross Order may be executed at a price inferior to the NBBO, the Exchange notes that there are situations at the

[3] *See* MIAX Rules 515(h)(1), 516(i).

[4] *See* MIAX Rules 515(h)(2), 516(j). *See also* MIAX Rule 516, Interpretations and Policies .01.

[5] *See* MIAX Options Regulatory Circulars, RC–2014–64 and RC–2015–05.

[6] *See* MIAX Rule 515(h)(1).

[7] *See* MIAX Rule 515(h)(2).

Exchange during which trading interest may exist in the Exchange's System that could be executable at prices up to the NBBO but is not automatically executed because the Exchange is either attempting to obtain additional price improvement for the order or additional liquidity to trade against the order on the Exchange. The Exchange employs a variety of timers and auctions to provide market participants with opportunity to obtain additional price improvement for their order or access additional liquidity to trade against the order on the Exchange. Specifically, during the liquidity refresh pause or managed interest process pursuant to Rule 515(c),[8] or a route timer pursuant to Rule 529, [9] the Exchange has trading interest that exists that may be executable up to the NBBO but is displayed at a price one minimum price increment away. In addition, during the price improvement mechanisms such as PRIME Auction or PRIME Solicitation Auction pursuant to Rule 515A,[10] the Exchange has trading interest that exists that may be executable up to the NBBO but is not displayed. The Exchange believes that the execution of a Customer Cross Order or Qualified Contingent Cross Order that arrives during a timer or auction at a potentially better price than the interest subject to the timer or auction, has the potential to cause confusion and perceived disruption to market participants that are subject to the pre-existing timers or auctions that may see executions occurring at better prices than their trading interest. In addition, the Exchange believes that the timers and auctions provide a valuable service to market participants and that the use of these mechanisms, that provide market participants with opportunities to obtain additional price improvement for their orders or access additional liquidity to trade against the orders, should be promoted on the Exchange. Therefore, the Exchange proposes to modify its Rules in order to maintain the priority of trading interest subject to timers and auctions that are initiated prior to the arrival of these specified order types.

The Exchange proposes to amend Rule 515(h)(1) and Rule 515(h)(2) to provide that the Customer Cross Order and Qualified Contingent Cross Order will be rejected if there is a timer or price improvement auction in progress when either of these orders are received. Specifically, the Exchange proposes to amend Rule 515(h)(1) to provide that if trading interest exists on the MIAX Book that is subject to the liquidity refresh pause or managed interest process pursuant to Rule 515(c), or a route timer pursuant to Rule 529 when the Exchange receives a Customer Cross Order, the System will reject the Customer Cross Order. If trading interest exists that is subject to a PRIME Auction or PRIME Solicitation Auction pursuant to Rule 515A when the Exchange receives a Customer Cross Order, the System will reject the Customer Cross Order. In addition, the Exchange proposes to amend Rule 515(h)(2) to provide that if trading interest exists on the MIAX Book that is subject to the liquidity refresh pause or managed interest process pursuant to Rule 515(c), or a route timer pursuant to Rule 529 when the Exchange receives a Qualified Contingent Cross Order, the System will reject the Qualified Contingent Cross Order. If trading interest exists that is subject to a PRIME Auction or PRIME Solicitation Auction pursuant to Rule 515A when the Exchange receives a Qualified Contingent Cross Order, the System will reject the Qualified Contingent Cross Order. The Exchange notes that the Exchange proposes no changes to the Customer Cross Order and the Qualified Contingent Cross Order order types themselves; both order types will continue to be subject to the same requirements as before.[11]

The Exchange proposes to make these enhancements to ensure that both the Customer Cross Order and the Qualified Contingent Cross Order will work seamlessly with the Exchange's timers and auctions in a manner that would ensure a fair and orderly market by maintaining priority of orders and quotes that initiated a timer or auction prior to the receipt of a Customer Cross Order or Qualified Contingent Cross Order on the Exchange. The Exchange believes that by using such additional reasons for rejecting these two order types during a timer or auction will improve the interaction between the timers and auctions and the Exchange's Book and the national market system. Without such proposed changes, the Exchange believes that the deployment of the Customer Cross Order and Qualified Contingent Cross Order functionality would reduce the benefits of its timer and auction functionality that currently provides market participants with opportunities to obtain additional price improvement for their orders or access additional liquidity to trade against the order on the Exchange. While rejecting Customer Cross Orders and Qualified Contingent Cross Orders received during timers and auctions may cause a disruption to market participants sending such orders in such situations, the Exchange believes the benefits to market participants participating in timers and auctions and to the national market system, as a whole, outweigh the temporary opportunity costs of a Customer Cross Orders and Qualified Contingent Cross Orders rejection. The Exchange notes Customer Cross Orders and Qualified Contingent Cross Orders are readily available on other competing exchanges; [12] if rejected by the Exchange's System, market participants can either choose to route their Customer Cross Orders and Qualified Contingent Cross Orders to those competing venues or simply just resubmit their orders to the Exchange. The Exchange believes that the proposed changes to its Rules will provide clear notice to market participants that their Customer Cross Orders and Qualified Contingent Cross

[8] The ''liquidity refresh pause'' is a process during which the System will pause the market for a time period not to exceed one second to allow additional orders or quotes refreshing the liquidity at the MBBO to be received when at the time of receipt or reevaluation of the initiating order by the System: (A) either the initiating order is a limit order whose limit price crosses the NBBO or the initiating order is a market order, and the limit order or market order could only be partially executed; (B) a Market Maker quote was all or part of the MBBO when the MBBO is alone at the NBBO; and (C) and the Market Maker quote was exhausted. *See* MIAX Rule 515(c)(2). The ''managed interest process'' is a process for non-routable orders during which, if the limit price locks or crosses the current opposite side NBBO, the System will display the order one MPV away from the current opposite side NBBO, and book the order at a price that will lock the current opposite side NBBO. Should the NBBO price change to an inferior price level, the order's Book price will continuously re-price to lock the new NBBO and the managed order's displayed price will continuously re-price one MPV away from the new NBBO until (i) the order has traded to and including its limit price, (ii) the order has traded to and including its price protection limit at which any remaining contracts are cancelled, (iii) the order is fully executed or (iv) the order is cancelled. *See* MIAX Rule 515(c)(1)(ii).

[9] *See* MIAX Rule 529. The ''route timer'' is a process for those initiating Public Customer orders that are routable, but do not meet the additional criteria for Immediate Routing, during which the System will implement a route timer not to exceed one second, in order to allow Market Makers and other participants an opportunity to interact with the initiating order.

[10] The ''PRIME Auction'' is a process by which a Member may electronically submit for execution (''auction'') an order it represents as agent (''agency order'') against principal interest, and/or an agency order against solicited interest. *See* MIAX Rule 515A(a). The ''PRIME Solicitation Mechanism'' is a process by which a Member that represents agency orders of a size of 500 contracts or more may electronically execute against solicited orders provided it submits both the agency order and solicited orders for electronic execution into the PRIME Solicitation Mechanism pursuant to Rule 515A. *See* MIAX Rule 515A(b).

[11] *See supra* notes 3 and 4.

[12] *See e.g.,* ISE Rule 715(i), (j); NYSE Arca Options Rules 6.47(e) and 6.62(bb).

Orders may be rejected during auctions and timers.

The Exchange notes that the proposed changes detailed above will likely result in fewer executions of Customer Cross Orders and Qualified Contingent Cross Orders on the Exchange. However, the Exchange notes that rejecting these orders may likely result in better opportunities for market participants with orders subject to timers and auctions for price improvement on the Exchange as more liquidity may be available to trade against trading interest in the timers and auctions. The Exchange believes that the proposed changes will reduce the potential of confusion and perceived disruption to market participants when a Customer Cross Order or Qualified Contingent Cross Order arrives during a timer or auction, potentially executing at a better price than their trading interest that subject to the timer or auction. The Exchange believes that the benefits to market participants (including those participating in timers/auctions and outside of timers/auctions) as a result of the new proposed enhancements to make both the Customer Cross Order and Qualified Contingent Cross Order more integrated with the Exchange's Book and the national market system, exceed any potential loss of opportunity for executions caused by the proposed changes.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with section 6(b) of the Act [13] in general, and furthers the objectives of section 6(b)(5) of the Act [14] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposal to reject the Customer Cross Order and Qualified Contingent Cross Order if there is a timer or price improvement auction at the time of receipt of these order types is designed to facilitate transactions, to remove impediments to and perfect the mechanism of a free and open market to the benefit of market participants by promoting the use of timer and auction functionality on the Exchange which provide market participants with opportunities to obtain additional price improvement for their orders or access additional liquidity to trade against the orders. The proposed enhancements to the Rules are designed to further ensure that the Customer Cross Order and Qualified Contingent Cross Order types will work seamlessly with the auctions and timers on the Exchange in a manner that would ensure a fair and orderly market by maintaining priority of orders and quotes subject to timers and auctions on the Exchange.

The Exchange believes that the proposed changes to its Rules will provide clear notice to market participants that their Customer Cross Orders and Qualified Contingent Cross Orders may be rejected during auctions and timers in a manner that is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed enhancements to reject Customer Cross Orders and Qualified Contingent Cross Orders during timers and price improvement auctions are designed to increase competition for order flow on the Exchange by promoting the use of timer and auction functionality on the Exchange which provide market participants with opportunities to obtain additional price improvement for their orders or access additional liquidity to trade against the orders in a manner intended to be beneficial to investors seeking to effect option orders with an opportunity to access additional liquidity and receive price improvement. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. The Exchange believes that the proposed changes to the order types are pro-competitive by providing market participants with functionality that would ensure a fair and orderly market by maintaining priority of orders and quotes that initiated a timer or auction prior to the receipt of a Customer Cross Order or Qualified Contingent Cross Order on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MIAX–2015–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2015–19. 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

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

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–MIAX–2015–19 and should be submitted on or before May 21, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2015–10040 Filed 4–29–15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74804; File No. SR–ISE–2015–15]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

April 24, 2015.

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 April 10, 2015, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange 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 ISE proposes to amend the Schedule of Fees as described in more detail below. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Schedule of Fees as described in more detail below.

1. Market Maker Fees & Tier Discounts

The Exchange charges a taker fee for regular orders in Select Symbols[3] that is $0.42 per contract for Market Maker[4] orders, including Market Maker Plus[5] orders, $0.45 per contract for Non-ISE Market Maker,[6] Firm Proprietary[7]/Broker-Dealer,[8] and Professional Customer[9] orders, and $0.30 per contract for Priority Customer[10] orders. The Exchange now proposes to increase this taker fee to $0.44 per contract for Market Maker orders, including Market Maker Plus orders.

The Exchange also charges Market Makers a maker/taker fee and a fee for Crossing Orders[11] that is $0.22 per contract for regular orders in Non-Select Symbols[12] as well as regular and complex orders in Foreign Currency (''FX'') Option Symbols.[13] In addition, Market Makers that execute a monthly volume of 250,000 contracts or more are entitled to a discounted rate of $0.15 per contract (together, ''Market Maker Discount Tiers''). The Exchange now proposes to increase these fees. In particular, applicable Market Maker orders will now be charged a fee of $0.25 per contract, subject to a discounted rate of $0.20 per contract for Market Makers that meet the volume threshold described above.

2. Fees for Firm Proprietary/Broker-Dealer, Non-ISE Market Maker, & Professional Customer Orders

The Exchange also charges a maker/taker fee for regular orders in Non-Select Symbols as well as regular and complex orders in FX Option Symbols that is $0.30 per contract for Firm Proprietary/Broker-Dealer, and Professional Customer orders, and $0.45 per contract for Non-ISE Market Maker orders. The Exchange now proposes to increase fees for each of these market participants to $0.50 per contract.

3. Complex Order Maker Fees

The Exchange charges a maker fee for complex orders in Non-Select Symbols that is $0.10 per contract for Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer orders, and $0.20 per contract for Non-ISE Market Maker orders, in each case when trading against other non-Priority Customer orders. The Exchange now proposes to increase this maker fee to $0.20 per contract for Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer orders, in line with the current fees charged for Non-ISE Market Maker orders.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Select Symbols'' are options overlying all symbols listed on the ISE that are in the Penny Pilot Program.

[4] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* ISE Rule 100(a)(25).

[5] A Market Maker Plus is a Market Maker who is on the National Best Bid or National Best Offer at least 80% of the time for series trading between $0.03 and $3.00 (for options whose underlying stock's previous trading day's last sale price was less than or equal to $100) and between $0.10 and $3.00 (for options whose underlying stock's previous trading day's last sale price was greater than $100) in premium in each of the front two expiration months. A Market Maker's single best and single worst quoting days each month based on the front two expiration months, on a per symbol basis, will be excluded in calculating whether a Market Maker qualifies for this rebate, if doing so will qualify a Market Maker for the rebate.

[6] A ''Non-ISE Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[7] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[8] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[9] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer.

[10] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in ISE Rule 100(a)(37A).

[11] The fee for Crossing Orders applies to Crossing Orders other than PIM orders of 100 or fewer contracts, which are billed separately.

[12] ''Non-Select Symbols'' are options overlying all symbols excluding Select Symbols.

[13] Fees in FX options do not apply to Early Adopter Market Makers. Market Maker orders sent by an Electronic Access Member (''EAM'') are charged separately.

The Exchange also charges a uniform maker fee of $0.43 per contract for non-Priority Customer orders that trade against Priority Customer orders in Complex Quoting Symbols,[14] *i.e.,* symbols in which Market Makers can enter quotes in the complex order book. In addition, Market Makers receive a discount of $0.02 per contract in Complex Quoting Symbols when trading against Priority Customer orders preferenced to them in the complex order book. The Exchange now proposes to eliminate these special fees applicable to Complex Quoting Symbols. As such, Non-Priority Customer orders in Complex Quoting Symbols will now be charged applicable maker fee for Select Symbols when trading against Priority Customer orders. This fee is $0.44 per contract for Non-ISE Market Maker, Firm Proprietary/Broker-Dealer and Professional Customer orders, and $0.43 per contract (subject to a preference discount) for Market Maker orders.

4. Fee for Responses to Crossing Orders

The Exchange charges all market participants a fee for responses to Crossing Orders that is $0.45 per contract for regular and complex orders in Select Symbols and FX Option Symbols,[15] as well as regular orders in Non-Select Symbols. The Exchange now proposes to increase this response fee to $0.47 per contract. The Exchange is not proposing any changes to the response fees for complex orders in Non-Select Symbols, which will continue to be charged at a rate of $0.90 per contract for Market Maker orders, and $0.95 per contract for all other market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[16] in general, and Section 6(b)(4) of the Act,[17] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

1. Market Maker Fees & Tier Discounts

The Exchange believes that it is reasonable and equitable to increase Market Maker fees (including applicable Market Maker Discount Tiers) as the proposed fees are designed to continue to be attractive to Market Makers that trade on ISE, and are within the range of fees charged by other options exchanges. Furthermore, the Exchange notes that while it is increasing Market Maker fees, Market Makers will continue to be charged fees that are generally lower than the fees applicable to other market participants, except for Priority Customers. The Exchange does not believe that it is unfairly discriminatory to provide lower fees to Market Maker orders as Market Makers are subject to additional requirements and obligations (such as quoting requirements) that other market participants are not.

2. Fees for Firm Proprietary/Broker-Dealer, Non-ISE Market Maker, & Professional Customer Orders

The Exchange believes that it is reasonable and equitable to increase the fees charged to Firm Proprietary/Broker-Dealer, Non-ISE Market Maker, and Professional Customer orders as the proposed fees are designed to be attractive to market participants that choose to bring order flow to the ISE, and remain well within the range of fees charged by some of the Exchange's competitors. Furthermore, the Exchange does not believe that the proposed fees are unfairly discriminatory as the fees would apply to equally to Non-ISE Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer orders. In connection with this proposed change, the Exchange notes that fees charged to Market Maker orders are also increasing (see above) but will remain lower than the fees described here for Firm Proprietary/Broker-Dealer, Non-ISE Market Maker, and Professional Customer orders. The Exchange does not believe that this is unfairly discriminatory for the reasons already discussed.

3. Complex Order Maker Fees

The Exchange believes that the proposed change to increase complex order maker fees is reasonable and equitable as the proposed fees are set at levels that the Exchange believes will continue be attractive to market participants that provide liquidity in complex orders, and are within the range of fees charged by other options exchanges. Moreover, with the proposed change, Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer complex orders in Non-Select Symbols will now be charged the same maker fee as is currently applicable to Non-ISE Market Maker complex orders. As the proposed fees will be applied equally to all market participants that trade complex orders in these symbols, the Exchange further believes that this proposed change is not unfairly discriminatory. In addition, the Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to eliminate special fees for Complex Quoting Symbols, as the Exchange believes that these fee discounts are no longer needed to attract liquidity in these symbols. Furthermore, the Exchange believes that it is not unfairly discriminatory to eliminate this distinction for Complex Quoting Symbols, as members will now be charged the standard maker fee for all complex orders in Select Symbols, including the Complex Quoting Symbols.

4. Fee for Responses to Crossing Orders

The Exchange believes that the proposed fees for responses to Crossing Orders, which are being increased slightly, are appropriate to attract price improvement for Crossing Orders submitted to ISE, and therefore qualify as reasonable and equitable. In this regard, the Exchange notes that other options exchanges charge various fees for responses to Crossing Orders, and the fees proposed here are within the range of fees charged by these competitor markets. Additionally, the Exchange believes that the proposed response fees are not unfairly discriminatory as the Exchange will continue to charge a uniform response fee that is applicable to all market participants that respond to Crossing Orders in affected symbols. As is the case today, responses to Crossing Orders will be charged a higher fee than contra-side orders submitted as part of a crossing transaction. The Exchange continues to believe that this is reasonable, equitable, and not unfairly discriminatory as contra-side orders guarantee the agency order, and are subject to market risk during the time period that the agency order is exposed to other market participants for potential price improvement. Finally, the Exchange notes that it will continue to charge a higher fee for responses to complex Crossing Orders in Non-Select symbols, which reflects the higher fees and rebates generally applicable to complex orders in these symbols.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or

[14] The Complex Quoting Symbols are AA, ABX, EFA, GLD, MSFT, MU, NVDA, VXX, VZ, WFC, XLB and XOP.

[15] The Exchange notes that Early Adopter Market Makers in FX option classes are not charged a fee for responses to Crossing Orders. The Exchange is not proposing any changes to response fees for Early Adopter Market Makers.

[16] 15 U.S.C. 78f.

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(8).

intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed fees and rebates are competitive with fees and rebates offered to orders executed on other options exchanges. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [19] and subparagraph (f)(2) of Rule 19b–4 thereunder,[20] because it establishes a due, fee, or other charge imposed by ISE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal 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 No. SR–ISE–2015–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File No. SR–ISE–2015–15. 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 changes 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 ISE. 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 No. SR–ISE–2015–15 and should be submitted on or before May 21, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Brent J. Fields,

Secretary.

[FR Doc. 2015–10038 Filed 4–29–15; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 240.19b–4(f)(2).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74807; File No. SR–FINRA–2015–008]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Delay the Implementation Date of Trade Reporting Amendments Approved Pursuant to SR–FINRA–2013–050

April 24, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 21, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

FINRA is proposing to delay the implementation date of amendments to the trade reporting rules relating to the Alternative Display Facility (''ADF'') and the Trade Reporting Facilities (''TRFs'') approved pursuant to SR–FINRA–2013–050. The proposed rule change would not make any changes to FINRA rules.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On November 12, 2013, FINRA filed proposed rule change SR–FINRA–2013–050 to On November 12, 2013, FINRA filed proposed rule change SR–FINRA–2013–050, which among other things, proposed to amend FINRA rules governing the reporting of over-the-counter (''OTC'') transactions in NMS stocks to the ADF and TRFs. The proposed rule change was approved by the Commission on February 27, 2014.[4] The amendments to the ADF and TRF rules relating to millisecond reporting that were approved pursuant to SR–FINRA–2013–050 became effective on November 10, 2014.[5]

Pursuant to proposed rule change SR–FINRA–2014–039,[6] FINRA proposed to implement the remaining amendments to the ADF and TRF trade reporting rules no later than April 30, 2015, and announced an effective date of April 20, 2015.[7] Specifically, the amendments to the ADF and TRF rules (i) require firms to report an additional time field for Stop Stock transactions [8] and transactions that reflect an execution price that is based on a prior reference point in time,[9] and when reporting block transactions using the exception for Intermarket Sweep Orders (ISOs) (outbound) under SEC Rule 611 of Regulation NMS, if the time the firm routed the ISOs is different from the execution time; [10] (ii) require firms to identify the original trade when reporting a reversal by including the control number and report date for the original trade report; [11] (iii) require firms to report trades executed on non-business days and trades reported more than 365 days after trade date (T+365) to the ADF or a TRF (and not on ''Form T'' through FINRA's Firm Gateway) and further to report non-business day trades on an ''as/of'' basis by 8:15 a.m. the next business day with the unique trade report modifier to denote their execution outside normal market hours; [12] (iv) provide that where both sides are submitting a clearing-only report to effectuate a step-out, the member transferring out of the position must report a step-out and the member receiving the position must report a ''step-in''; [13] and (v) address the processing of trades that are submitted for clearing.[14] In addition, SR–FINRA–2013–050 made a number of non-substantive technical and conforming changes to the ADF and TRF rules that were otherwise being amended.

Firms have requested additional time to make the systems changes necessary to comply with the new reporting requirements, and in particular, have indicated they need additional time to test the systems changes.[15] Given the scope of the changes, FINRA believes that it is appropriate to extend the implementation date and is proposing to implement the changes to the ADF and TRF rules approved pursuant to SR–FINRA–2013–050 on July 13, 2015. FINRA believes that this will provide firms ample time to implement and test the changes, as it will afford firms approximately seven months from the date of updated technical specifications (technical specifications for the FINRA/NYSE TRF were published on December 17, 2014 and for the FINRA/NASDAQ TRF on December 23, 2014) [16] and more than three months of testing (testing became available on March 16, 2015 for the FINRA/NYSE TRF and April 1, 2015 for the FINRA/NASDAQ TRF).[17]

Some firms also have requested that they be permitted to report in accordance with the amendments to the ADF and TRF rules prior to the implementation date. The TRFs and the ADF are unable to make the necessary systems changes available in production prior to July 13, 2015 to accommodate voluntary reporting in accordance with the new reporting requirements by some firms, while other firms continue to report under the current reporting requirements. Therefore, all firms must begin reporting in accordance with the amendments on July 13, 2015. As noted above, however, firms will have ample opportunity to test their systems changes and new reporting processes prior to July 13, 2015.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing. The operative date will be the date of filing of the proposed rule change.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[18] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes the proposed rule change is consistent with the Act in that it provides firms additional time to complete the systems changes necessary to comply with SR–FINRA–2013–050, which amendments will, among other things, ensure a more accurate and complete audit trail, enable FINRA to recreate more accurately members' market activity and enhance FINRA's ability to surveil on an automated basis for compliance with FINRA trade reporting and other rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that providing adequate time

[4] *See* Securities Exchange Act Release No. 71623 (February 27, 2014), 79 FR 12558 (March 5, 2014) (Order Approving File No. SR–FINRA–2013–050).

[5] The amendments to other rule sets approved pursuant to SR–FINRA–2013–050 are also effective. Specifically, the amendments to the Order Audit Trail System rules became effective on April 7, 2014, and the amendments to the OTC Reporting Facility rules became effective on November 17, 2014.

[6] *See* Securities Exchange Act Release No. 73289 (October 2, 2014), 79 FR 60874 (October 8, 2014) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2014–039).

[7] *See Regulatory Notice* 14–21 (May 2014).

[8] *See* paragraph (F) of Rules 6282(a)(4), 6380A(a)(5) and 6380B(a)(5). ''Stop stock transaction'' means a transaction resulting from an order in which a firm and another party agree that the order will be executed at a stop stock price or better, which price is based upon the prices at which the security is trading at the time the firm receives the order. *See* Rules 6220, 6320A and 6320B.

[9] *See* paragraph (G) of Rules 6282(a)(4), 6380A(a)(5) and 6380B(a)(5).

[10] *See* Rules 6282.03, 6380A.03 and 6380B.03.

[11] *See* Rules 6282(g), 6380A(g) and 6380B(f).

[12] *See* Rules 6282(a)(2), 6380A(a)(2) and 6380B(a)(2).

[13] *See* Rules 7130(g), 7230A(i) and 7230B(h).

[14] *See* Rules 7140, 7240A and 7240B.

[15] *See, e.g.,* email dated February 12, 2015 from Manisha Kimmel, Managing Director, Financial Information Forum (''FIF''), requesting a delay of implementation of the amendments to the ADF and TRF rules approved pursuant to SR–FINRA–2013–050.

[16] Updated technical specifications have not yet been published for the ADF; however, we note that currently no member firms use the ADF for trade reporting to FINRA. FINRA anticipates publishing updated technical specifications for the ADF shortly.

[17] FINRA notes that this implementation schedule is consistent with FIF's recommendation in its comment letter on SR–FINRA–2013–050 that FINRA release TRF technical specifications within seven months, and make available a robust test environment within three months, of the implementation date. *See* Letter from Manisha Kimmel, Executive Director, Financial Information Forum, to Elizabeth M. Murphy, Secretary, SEC, dated December 20, 2013.

[18] 15 U.S.C. 78*o*–3(b)(6).

for firms to make and test the systems changes necessary to comply with SR–FINRA–2013–050 will benefit all interested parties.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

A copy of the request for a delay from FIF is attached to the filing submitted by the Exchange but not attached to the published notice of this filing. In response to FIF's request, as discussed above, FINRA is proposing to delay implementation of the amendments to the ADF and TRF rules approved under SR–FINRA–2013–050 to July 13, 2015. FINRA believes that the revised implementation date will provide members additional time to make the necessary system changes while balancing the need to implement the amendments without undue delay.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act [19] and subparagraph (f)(6) of Rule 19b–4 thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing.[21] However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.[22] FINRA has requested that the Commission waive the 30-day operative delay so that FINRA can immediately delay the implementation dates, as provided in this proposal.

The Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow FINRA to extend the implementation dates of certain changes approved pursuant to SR–FINRA–2013–050 in a timely manner. Therefore, the Commission designates the proposal operative upon filing.[23]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act.[24] If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.[25]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2015–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2015–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–008, and should be submitted on or before May 21, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Brent J. Fields,

Secretary.

[FR Doc. 2015–10039 Filed 4–29–15; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] *Id.*

[23] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[24] 15 U.S.C. 78s(b)(3)(C).

[25] *Id.*

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Jet Neko, Inc., Order of Suspension of Trading

April 28, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Jet Neko, Inc. (CIK No. 1541371), a void Delaware corporation with its principal place of business listed as Miyazaki, Japan with stock quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link'') under the ticker symbol NEKO, because it has not filed any periodic reports since it filed a Form 10 registration statement on February 9, 2012. On February 5, 2015, a delinquency letter was sent by the Division of Corporation Finance to Jet Neko, Inc. requesting compliance with their periodic filing obligations, but Jet Neko, Inc. did not receive the delinquency letter due to its failure to maintain a valid address on file with the Commission as required by Commission rules (Rule 301 of Regulation S–T, 17 CFR 232.301 and Section 5.4 of EDGAR Filer Manual).

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Jet Neko, Inc.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the

securities of Jet Neko, Inc. is suspended for the period from 9:30 a.m. EDT on April 28, 2015, through 11:59 p.m. EDT on May 11, 2015.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2015–10187 Filed 4–28–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Securities Act of 1933 Release No. 9760/ April 24, 2015; Securities Exchange Act of 1934 Release No. 74810/April 24, 2015]

Order Regarding Review of FASB Accounting Support Fee For 2015 Under Section 109 of the Sarbanes-Oxley Act of 2002

The Sarbanes-Oxley Act of 2002 (the ''Act'') provides that the Securities and Exchange Commission (the ''Commission'') may recognize, as generally accepted for purposes of the securities laws, any accounting principles established by a standard setting body that meets certain criteria. Consequently, Section 109 of the Act provides that all of the budget of such a standard setting body shall be payable from an annual accounting support fee assessed and collected against each issuer, as may be necessary or appropriate to pay for the budget and provide for the expenses of the standard setting body, and to provide for an independent, stable source of funding, subject to review by the Commission. Under Section 109(f) of the Act, the amount of fees collected for a fiscal year shall not exceed the ''recoverable budget expenses'' of the standard setting body. Section 109(h) amends Section 13(b)(2) of the Securities Exchange Act of 1934 to require issuers to pay the allocable share of a reasonable annual accounting support fee or fees, determined in accordance with Section 109 of the Act.

On April 25, 2003, the Commission issued a policy statement concluding that the Financial Accounting Standards Board (''FASB'') and its parent organization, the Financial Accounting Foundation (''FAF''), satisfied the criteria for an accounting standard-setting body under the Act, and recognizing the FASB's financial accounting and reporting standards as ''generally accepted'' under Section 108 of the Act.[1] As a consequence of that recognition, the Commission undertook a review of the FASB's accounting support fee for calendar year 2015. In connection with its review, the Commission also reviewed the budget for the FAF and the FASB for calendar year 2015.

Section 109 of the Act also provides that the standard setting body can have additional sources of revenue for its activities, such as earnings from sales of publications, provided that each additional source of revenue shall not jeopardize, in the judgment of the Commission, the actual or perceived independence of the standard setter. In this regard, the Commission also considered the interrelation of the operating budgets of the FAF, the FASB, and the Governmental Accounting Standards Board (''GASB''), the FASB's sister organization, which sets accounting standards used by state and local government entities. The Commission has been advised by the FAF that neither the FAF, the FASB, nor the GASB accept contributions from the accounting profession.

The Commission understands that the Office of Management and Budget (''OMB'') has determined the FASB's spending of the 2015 accounting support fee is sequestrable under the Budget Control Act of 2011.[2] So long as sequestration is applicable, we anticipate that the FAF will work with the Commission and Commission staff as appropriate regarding its implementation of sequestration.

After its review, the Commission determined that the 2015 annual accounting support fee for the FASB is consistent with Section 109 of the Act. Accordingly,

It is ordered, pursuant to Section 109 of the Act, that the FASB may act in accordance with this determination of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2015–10034 Filed 4–29–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–31578]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

April 24, 2015.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of April 2015. A copy of each 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. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 19, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, 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: The Commission: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549–8010.

UBS Cashfund Inc. [File No. 811–2802]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 19, 2014, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant has retained $4,093 in cash to pay outstanding liabilities. Expenses of $66,724 incurred in connection with the liquidation were paid by UBS Global Asset Management (Americas) Inc., applicant's investment adviser.

Filing Date: The application was filed on March 12, 2015.

Applicant's Address: c/o UBS Global Asset Management (Americas) Inc., Attn: Keith A. Weller, 1285 Avenue of the Americas, 12th Floor, New York, NY 10019–6028.

Ambassador Funds [File No. 811–9941]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 15, 2012, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses incurred in

[1] Financial Reporting Release No. 70.

[2] See ''OMB Report Pursuant to the Sequestration Transparency Act of 2012'' (P.L. 112–155), page 222 of 224 at: *http://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/stareport.pdf.*

connection with the liquidation were paid by applicant's investment adviser.

Filing Date: The application was filed on May 7, 2013.

Applicant's Address: 500 Griswold St., Suite 2800, Detroit, MI 48226.

ISI Strategy Fund, Inc. [File No. 811–8291]

Total Return U.S. Treasury Fund, Inc. [File No. 811–5040]

North American Government Bond Fund, Inc. [File No. 811–7292]

Managed Municipal Fund, Inc. [File No. 811–6023]

Summary: Each applicant seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to corresponding series of Centre Funds, and on March 17, 2015, made a distribution to their shareholders based on net asset value. Expenses of $64,178 incurred in connection with the reorganizations were paid by International Strategy & Investment Inc., the investment adviser of the acquiring trust.

Filing Date: The applications were filed on April 7, 2015.

Applicants' Address: ALPS Fund Services, Inc., 1290 Broadway, Ste. 1100, Denver, CO 80203.

Exchange Listed Funds Trust [File No. 811–23026]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on March 13, 2015.

Applicant's Address: 2545 S. Kelly Ave. Ste. C, Edmond, OK 73013.

Sound Point Floating Rate Income Fund [File No. 811–22768]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Trust for Advised Portfolios, and on May 30, 2014, made distributions to its shareholders based on net asset value. Expenses of approximately $85,103 incurred in connection with the reorganization were paid by Sound Point Capital Management, L.P., applicant's investment adviser.

Filing Dates: The application was filed on February 18, 2015, and amended on April 7, 2015.

Applicant's Address: 375 Park Ave., 25th Floor, New York, NY 10152.

Wexford Trust [File No. 811–5469]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Managed Portfolio Series, and on September 5, 2014, made a distribution to its shareholders based on net asset value. Expenses of $147,793 incurred in connection with the reorganization were paid by Muhlenkamp & Company, Inc., applicant's investment adviser.

Filing Date: The application was filed on April 7, 2015.

Applicant's Address: 5000 Stonewood Dr., Ste. 300, Wexford, PA 15090–8388.

Global Equity Long/Short Master Fund [File No. 811–22459]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its asset to Morgan Creek Global Equity Long/Short Institutional Fund in a despoking transaction, and on July 1, 2014, made distributions to its shareholders based on net asset value. Expenses of $31,920 incurred in connection with the liquidation were ultimately paid by applicant's shareholders.

Filing Dates: The application was filed on December 10, 2014, and amended on April 2, 2015.

Applicant's Address: 301 West Barbee Chapel Rd., Suite 200, Chapel Hill, NC 27517.

American Strategic Income Portfolio Inc. [File No. 811–6404]

American Strategic Income Portfolio Inc. II [File No. 811–6640]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Diversified Real Asset Income Fund, and on September 8, 2014 made distributions to their shareholders based on net asset value. Expenses of $233,545 and $752,809, respectively, incurred in connection with the reorganizations were paid by applicants and the investment advisers of the applicants and the acquiring fund, or their affiliates.

Filing Dates: The applications were filed on December 22, 2014, and amended on March 20, 2015.

Applicants' Address: 800 Nicollet Mall, BC–MN–H04N, Minneapolis, MN 55402.

Hatteras GPEP Fund II, LLC [File No. 811–22594]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering. Applicant currently has fewer than 100 holders of its securities and intends to continue operation as a private fund in reliance on section 3(c)(1) of the Act. Applicant has notified its beneficial owners that certain legal protections afforded to shareholders of an investment company registered under the Act will no longer apply.

Filing Dates: The application was filed on January 9, 2015, and amended on April 9, 2015.

Applicant's Address: 6601 Six Forks Rd., Suite 340, Raleigh, NC 27615.

Eaton Vance Structured Emerging Markets Premium Income

Trust [File No. 811–22536]

Eaton Vance Inflation-Linked Income Credit Trust [File No. 811–22567]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants have never made a public offering of their securities and do not propose to make a public offering or engage in business of any kind.

Filing Date: The applications were filed on March 26, 2015.

Applicants' Address: Two International Place, Boston, MA 02110.

Helios High Income Fund, Inc. [File No. 811–21332]

Helios Strategic Income Fund, Inc. [File No. 811–21487]

Helios Advantage Income Fund, Inc. [File No. 811–21631]

Helios Multi-Sector High Income Fund, Inc. [File No. 811–21833]

Summary: Each applicant, each a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Each applicant transferred its assets to Brookfield High Income Fund Inc., and on August 13, 2014, made distributions to their shareholders based on net asset value. Expenses of $64,949, $62,360, $92.044 and $73,813, respectively, incurred in connection with the reorganizations were paid by each applicant and the acquiring fund.

Filing Dates: The applications were filed on December 24, 2014, and amended on March 17, 2015.

Applicants' Address: Brookfield Place, 250 Vesey St., New York, NY 10281–1023.

Putnam Capital Appreciation Fund [File No. 811–7061]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Putnam Investors Fund, and on December 29, 2008, made a distribution to its shareholders based on net asset value. Expenses of approximately $66,568 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on April 15, 2015.

Applicant's Address: One Post Office Sq., Boston, MA 02109.

Putnam Classic Equity Fund [File No. 811–7223]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to The Putnam Fund for Growth and Income, and on December 29, 2008, made distributions to its shareholders based on net asset value. Expenses of approximately $66,568 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on April 15, 2015.

Applicant's Address: One Post Office Sq., Boston, MA 02109.

Putnam Discovery Growth Fund [File No. 811–6203]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Putnam New Opportunities Fund (now known as Putnam Multi-Cap Growth Fund), and on December 29, 2008, made a distribution to its shareholders based on net asset value. Expenses of approximately $66,568 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on April 15, 2015.

Applicant's Address: One Post Office Sq., Boston, MA 02109.

Putnam OTC & Emerging Growth Fund [File No. 811–3512]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Putnam Vista Fund, and on December 29, 2008, made distributions to its shareholders based on net asset value. Expenses of approximately $66,568 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on April 15, 2015.

Applicant's Address: One Post Office Sq., Boston, MA 02109.

Putnam Tax-Free Health Care Fund [File No. 811–6659]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Putnam Tax Exempt Income Fund, and on September 17, 2007, made a distribution to its shareholders based on net asset value. Expenses of approximately $335,299 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on April 13, 2015.

Applicant's Address: One Post Office Sq., Boston, MA 02109.

Martin Currie Business Trust [File No. 811–8612]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On January 30, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $87,460 incurred in connection with the liquidation were paid by Martin Currie, Inc., applicant's investment adviser.

Filing Dates: The application was filed on March 24, 2015, and amended on April 23, 2015.

Applicant's Address: Saltire Court, 20 Castle Terrace, Edinburgh, Scotland EH1 2ES.

Security Equity Fund [File No. 811–22932]

Summary: Applicant seeks an order declaring that i0t has ceased to be an investment company. Applicant transferred its assets to a corresponding shell series of Guggenheim Funds Trust, and on January 27, 2014 and September 23, 2014, made distributions to its shareholders based on net asset value. Expenses of $523,662 incurred in connection with the reorganization were paid by applicant and Security Investors, LLC, applicant's investment adviser.

Filing Dates: The application was filed on February 19, 2015, and amended on April 23, 2015.

Applicant's Address: 805 King Farm Blvd., Ste. 600, Rockville, MD 20850.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2015–10094 Filed 4–29–15; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2015–0027]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions and an extension of OMB-approved information collections, and one new information collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2015–0015].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than June 29, 2015. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Application for a Social Security Number Card, the Social Security Number Application Process (SSNAP), and Internet SSN Replacement Card (iSSNRC) Application—20 CFR 422.103–422.110—0960–0066. SSA collects information on the SS–5 (used in the United States) and SS–5–FS (used outside the United States) to issue original or replacement Social Security cards. SSA also enters the application data into the Social Security Number Application Process (SSNAP) when

applicants request a new or replacement card via telephone or in person. In addition, hospitals collect the same information on SSA's behalf for newborn children through the Enumeration-at-Birth process. In this process, parents of newborns provide hospital birth registration clerks with information required to register these newborns. Hospitals send this information to State Bureaus of Vital Statistics (BVS), and they send the information to SSA's National Computer Center. SSA then uploads the data to the SSA mainframe along with all other enumeration data, and we assign the newborn a Social Security number (SSN) and issue a Social Security card. Respondents can also use these modalities to request a change in their SSN records. Additionally, the iSSNRC application will collect information similar to the paper SS–5 for no-change replacement SSN cards for adult U.S. citizens.

A new iSSNRC modality included in the current clearance will allow certain applicants for an SSN replacement card to apply by completing an internet application and submitting the required evidence online rather than completing a paper Form SS–5, Application for a Social Security Card.

The respondents for this collection are applicants for original and replacement Social Security cards, or individuals who wish to change information in their SSN records, who use any of the modalities described above.

Type of Request: Revision of an OMB-approved information collection.

Application scenario	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Respondents who do not have to provide parents' SSNs	10,500,000	1	8.5	1,487,500
*Adult U.S. Citizens requesting a replacement card with no changes through new iSSNRC modality	1,500,000	1	5	125,000
Respondents whom we ask to provide parents' SSNs (when applying for original SSN cards for children under age 18)	400,000	1	9	60,000
Applicants age 12 or older who need to answer additional questions so SSA can determine whether we previously assigned an SSN	1,500,000	1	9.5	237,500
Applicants asking for a replacement SSN card beyond the new allowable limits (i.e., who must provide additional documentation to accompany the application)	900	1	60	900
Authorization to SSA to obtain personal information cover letter	500	1	15	125
Authorization to SSA to obtain personal information follow-up cover letter	500	1	15	125
Totals	13,901,900			1,911,150

*The total timeline for complete national coverage of the iSSNRC application is two years from the date of initial implementation and is dependent on the contractor enrolling each State into the network. By FY 2018, we would expect to issue about 1.5 million replacement cards annually via the iSSNRC application. However, the estimated volume could vary based on the date of implementation, when the contractor acquires States, and our marketing efforts to the public.

Cost Burden: The state BVSs incur costs of approximately $11 million for transmitting data to SSA's mainframe. However, SSA reimburses the states for these costs.

2. Third Party Liability Information Statement—42 CFR 433.136–433.139—0960–0323. To reduce Medicaid costs, Medicaid state agencies must identify third party insurers liable for medical care or services for Medicaid beneficiaries. Regulations at 42 CFR 433.136–433.139 require Medicaid state agencies to obtain this information on Medicaid applications and redeterminations as a condition of Medicaid eligibility. States may enter into agreements with the Commissioner of Social Security to make Medicaid eligibility determinations for aged, blind, and disabled beneficiaries in those states. Applications for and redeterminations of Supplemental Security Income (SSI) eligibility in jurisdictions with such agreements are applications and redeterminations of Medicaid eligibility. Under these agreements, SSA obtains third party liability information using Form SSA–8019, and provides that information to the Medicaid state agencies. The Medicaid state agencies use the information to bill third parties liable for medical care, support, or services for a beneficiary to guarantee that Medicaid remains the payer of last resort. The respondents are SSI claimants and recipients.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–8012 Paper form	200	1	5	17
Modernized SSI Claims System (MSSICS)	51,381	1	5	4,282
Totals	51,581			4,299

3. Request for Deceased Individual's Social Security Record—20 CFR 402.130—0960–0665. When a member of the public requests an individual's Social Security record, SSA needs the name and address of the requestor as well as a description of the requested record to process the request. SSA uses the information the respondent provides on Form SSA–711, or via an Internet request through SSA's electronic Freedom of Information Act (eFOIA) Web site, to (1) verify the wage earner is deceased and (2) access the correct Social Security record. Respondents are members of the public requesting deceased individuals' Social Security records.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Internet Request through eFOIA	49,800	1	7	5,810
SSA–711 (paper)	200	1	7	23
Total	50,000			5,833

Cost Burden *: In addition, SSA charges fees to the respondent for this information. The following chart shows the fees per transaction based on the information the respondent provides on the SSA–711 (or in eFOIA):

Modality of completion	Information provided (or not provided)	Cost per transaction
SSA–711 (paper)	SSN of decedent is not provided	$29
SSA–711 (paper)	SSN of decedent is provided	$27
eFOIA (Internet)	SSN of decedent is not provided	$18

* As these costs are dependent on the respondent's provided information, we charge them on an as needed basis, and cannot provide a total annual estimate of the cost burden. We do not know whether the respondent provided the decedent's SSN until we manually review and process each SSA–711.

4. Function Report Adult—20 CFR 404.1512 & 416.912—0960–0681. Individuals receiving or applying for Social Security disability insurance (SSDI) or SSI must provide medical evidence and other proof SSA requires to prove their disability. SSA, and State disability determinations services on our behalf, collect the information using Form SSA–3373. We use the information to document how claimants' disabilities affect their ability to function, and to determine eligibility for SSI and SSDI claims. The respondents are Title II and Title XVI applicants (or current recipients undergoing redeterminations) for disability payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3373	2,085,721	1	61	2,120,483

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than June 1, 2015. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Data Exchange Request Form—20 CFR 401.100—0960–NEW. SSA maintains approximately 3,000 data exchange agreements and regularly receives new requests from Federal, State, local, and foreign governments, as well as private organizations, to share data electronically. SSA engages in various forms of data exchanges from Social Security number verifications to computer matches for benefit eligibility, depending on the requestor's business needs. Section 1106 of the Social Security Act requires we consider the requestor's legal authority to receive the data, our disclosure policies, systems' feasibility, systems' security, and costs before entering into a data exchange agreement. We will use Form SSA–157, Data Exchange Request Form, for this purpose. Requesting agencies, governments, or private organizations will use the form when voluntarily initiating a request for data exchange from SSA. Respondents are Federal, State, local, and foreign governments, as well as private organizations seeking to share data electronically with SSA.

This is a correction notice: SSA published the incorrect burden information for this collection at 80 FR 9499, on February 23, 2015. We are correcting this error here.

Type of Request: This is a new information collection request.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–157	121	1	30	61

2. Statement of Self-Employment Income—20 CFR 404.101, 404.110, 404.1096(a)–(d)—0960–0046. To qualify for insured status and thus collect Social Security benefits, self-employed individuals must demonstrate they have

earned the minimum amount of self-employment income (SEI) in a current year. SSA uses Form SSA–766, Statement of Self-Employment Income, to collect the information we need to determine if the individual will have at least the minimum amount of SEI needed for one or more quarters of coverage in the current year. Based on the information we obtain, we may credit additional quarters of coverage to give the individual insured status thus expediting benefit payments.

Respondents are self-employed individuals who may be eligible for Social Security benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–766	2,500	1	5	208

3. Request for Workers' Compensation/Public Disability Benefit Information—20 CFR 404.408(e)—0960–0098. Claimants for Social Security disability payments who are also receiving Worker's Compensation/Public Disability Benefits (WC/PDB) must notify SSA about their WC/PDB, so the agency can reduce claimants' Social Security disability payments accordingly. If claimants provide necessary evidence, such as a copy of their award notice, benefit check, etc., that is sufficient verification. In cases where claimants cannot provide such evidence, SSA uses Form SSA–1709. The entity paying the WC/PDB benefits, its agent (such as an insurance carrier), or an administering public agency complete this form. The respondents are Federal, State, and local agencies, insurance carriers, and public or private self-insured companies administering WC/PDB benefits to disability claimants.

This is a correction notice. SSA published this information collection as a revision on February 23, 2015 at 80 FR 9500. Since we are not revising the Privacy Act Statement, this is now an extension of an OMB-approved information collection.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1709	120,000	1	15	30,000

Dated: April 27, 2015.

Faye I. Lipsky,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2015–10057 Filed 4–29–15; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 9119]

Culturally Significant Objects Imported for Exhibition Determinations: ''American Encounters: The Simple Pleasures of Still Life''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''American Encounters: The Simple Pleasures of Still Life,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Crystal Bridges Museum of American Art, Bentonville, Arkansas, from on or about May 16, 2015, until on or about September 14, 2015, the High Museum of Art, Atlanta, Georgia, from on or about September 26, 2015, until on or about January 31, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of the Legal Adviser, U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505, telephone (202–632–6471), or email at *section2459@state.gov.*

Dated: April 20, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–10147 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9116]

Culturally Significant Objects Imported for Exhibition Determinations: ''FRIDA KAHLO: Art, Garden, Life'' Exhibition

SUMMARY: Notice is hereby given of the following Determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''*FRIDA KAHLO: Art, Garden, Life,*'' imported from abroad for temporary exhibition

within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The New York Botanical Garden, Bronx, New York, from on or about May 16, 2015, until on or about November 1, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: April 20, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–10139 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9114]

Shipping Coordinating Committee; Notice of Committee Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:00 a.m. on Tuesday, May 26, 2015, Room 8, 9, 10 of the United States Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590. The primary purpose of the meeting is to prepare for the ninety fifth Session of the International Maritime Organization's (IMO) Maritime Safety Committee to be held at the IMO Headquarters, United Kingdom, from June 3 to June 12, 2015.

The agenda items to be considered include:

—Adoption of the agenda; report on credentials

—Decisions of other IMO bodies

—Consideration and adoption of amendments to mandatory instruments

—Measures to enhance maritime security

—Goal-based new ship construction standards

—Passenger ship safety

—Performance review and audit of LRIT Data Centres

—Carriage of cargoes and containers (report of the first session of the Sub-Committee)

—Human element, training and watch keeping (report of the second session of the Sub-Committee)

—Ship design and construction (report of the second session of the Sub-Committee)

—Navigation, communications and search and rescue (report of the second session of the Sub-Committee)

—Ship systems and equipment (urgent matters emanating from the second session of the Sub-Committee)

—Capacity building for the implementation of new measures

—Formal safety assessment, including general cargo ship safety

—Piracy and armed robbery against ships

—Implementation of instruments and related matters

—Relations with other organizations

—Application of the Committee's Guidelines

—Work programme

—Election of Chairman and Vice-Chairman for 2016

—Any other business

—Consideration of the report of the Committee on its ninety-fifth session

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Tiffany Duffy, by email at *tiffany.a.duffy@uscg.mil,* by phone at (202) 372–1403, by fax at (202) 372–1925, or in writing at Commandant (CG–5PS), U.S. Coast Guard, 2100 2nd Street SW., Stop 7126, Washington, DC 20593–7126 not later than May 19, 2015, 7 days prior to the meeting. Requests made after May 19, 2015 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the building. The Department of Transportation building is accessible by taxi and privately owned conveyance and public transportation. However, parking in the vicinity of the building is limited. Additional information regarding this and other IMO SHC public meetings may be found at: *www.uscg.mil/imo.*

Dated: April 22, 2015.

Marc Zlomek,

Executive Secretary, Shipping Coordinating Committee, Department of State.

[FR Doc. 2015–10148 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice 9115]

Culturally Significant Objects Imported for Exhibition Determinations: ''Frances Stark: Intimism'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Frances Stark: Intimism,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Art Institute of Chicago, Chicago, Illinois, from on or about May 21, 2015, until on or about August 30, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: April 20, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–10138 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9118]

Culturally Significant Object Imported for Exhibition Determinations: ''North Cape''

SUMMARY: Notice is hereby given of the following Determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C.

2459), E. O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the object to be included in the exhibition ''North Cape'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at The Metropolitan Museum of Art, New York, New York, from on or about May 15, 2015, until on or about May 15, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a description of the imported object, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: *April 20, 2015.*

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–10145 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9117]

Culturally Significant Objects Imported for Exhibition Determinations: ''Sargent: Portraits of Artists and Friends'' Exhibition

SUMMARY: Notice is hereby given of the following Determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Sargent: Portraits of Artists and Friends,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about June 30, 2015, until on or about October 4, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: April 20, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–10141 Filed 4–29–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of a Land Release Affecting the Federal Grant Assurance Obligations at Ryan Field Airport, Tucson, Pima County, Arizona

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of a Land Release.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application for a land release of approximately 5.12 acres of airport property, along with an easement over 2.09 acres, at Ryan Field Airport, Tucson, Pima County, Arizona from the airport use provisions of the Grant Agreement Assurances since the land is not needed for airport purposes. The property will be used by the Arizona Department of Transportation to widen State Route 86 that is located along the southern edge of the airport. The airport will be compensated for the fair market value of the released property. The use of the land for a roadway represents a compatible land use that will not interfere with the airport or its operation, thereby protecting the interests of civil aviation.

DATES: Comments must be received on or before June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed or delivered to the FAA at the following address: Mike N. Williams, Manager, Airports District Office, **Federal Register** Comment, Federal Aviation Administration, Phoenix Airports District Office, 3800 N. Central Avenue, Suite 1025, Phoenix, Arizona 85012. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Tom Coyle, Director of Planning, Tucson Airport Authority, 7005 South Plumer Avenue, Tucson, Arizona 85756.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 106–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the DOT Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

The Tucson Airport Authority (TAA) requested a release from the provisions of the Grant Agreement Assurances to permit the disposal of approximately 5.12 acres of land at Ryan Field Airport, Tucson, Pima County, Arizona to permit the construction of highway improvements to State Route 86 by the Arizona Department of Transportation. The highway that traverses the southern boundary of the airport from east to west will be widened to accommodate four lanes, thereby providing two lanes in each direction. The release will allow 5.12 acres of land to be conveyed to the State of Arizona, along with an easement for 2.09 acres over land not being conveyed in fee simple. In return, TAA will be compensated for the fair market value of the property subject to the release. Continued use of the land as an improved highway represents a compatible land use that will not interfere with or impede the operations and development of the airport. Based on the benefits of fair compensation in exchange for the land, the interests of civil aviation will be properly served.

Issued in Hawthorne, California, on April 23, 2015.

Brian Q. Armstrong,

Manager, Safety and Standards Branch, Airports Division, Western-Pacific Region.

[FR Doc. 2015–10097 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2014–0313]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration, DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA confirms its decision to exempt 78 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions were effective on March 24, 2015. The exemptions expire on March 24, 2017.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov*.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

II. Background

On February 19, 2015, FMCSA published a notice of receipt of Federal diabetes exemption applications from 78 individuals and requested comments from the public (80 FR 8629). The public comment period closed on March 23, 2015, and two comments were received.

FMCSA has evaluated the eligibility of the 78 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 78 applicants have had ITDM over a range of one to 45 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the February 19, 2015, **Federal Register** notice and they will not be repeated in this notice.

III. Discussion of Comments

FMCSA received two comments in this proceeding. The comments are discussed below.

An anonymous commenter stated he or she believes that it is discriminatory for truck driving schools and employers to disqualify applicants due to insulin-dependent diabetes and other medications they may take.

Gabriel Villa stated she believes all of the drivers listed in this notices should be granted an exemption since they have received their endocrinologist's approval.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual

medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Conclusion

Based upon its evaluation of the 78 exemption applications, FMCSA exempts the following drivers from the diabetes requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above 949 CFR 391.64(b)):

Timothy R. Adkins (KY)
John Angelesco, III (MA)
Matthew D. Anthony (MN)
Daniel S. Arke (HI)
Raul Arlequin, Jr. (NJ)
Dale A. Bahr (WI)
Darren E. Barrett (TX)
Chad W. Beeman (NY)
William W. Bell III (VT)
Jeffrey S. Bohle (IA)
Bradley T. Boyd (IA)
Bradley M. Brauer (NE)
Gary W. Brendel (NY)
Thomas Browning (PA)
Kell D. Busby, Jr. (MI)
Norman W. Camp (TN)
Rafael B. Castillo (NJ)
Camille M. Converse-Smith (WI)
Zachary D. Craig (ND)
Terry R. Darnall (IL)
Raymond W. Dropps (MN)
Curtis W. Fox (IN)
William H. Geiselhart, Jr. (PA)
Darrel G. Goetz (MO)
Chris S. Hammack (CO)
James P. Hancock, Jr. (PA)
Donald S. Hanson (MN)
Michael Hasley (AR)
Gene A. Heibult (SD)
Ronald R. Herrington (WV)
Jay H. Hess (PA)
Kevin L. Holmes (IL)
Claude E. Hoskins (WA)
Brian L. Hughes (PA)
Ulysses Jones, II (IN)
Sean M. Jordan (PA)
Steven N. Kemp (TX)
Tracy A. Knake (IA)
Cory D. Knowles (TN)
Eric J. Kuster (IA)
Daniel J. Lacroix (MA)
Robert E. Lane (IN)
James D. Langer (WI)
Jason C. Lewis (MD)
Corey A. Maas (KS)
James P. MacDonald (MA)
Michael T. Markowitz (IL)
Timothy D. Maxson (NY)
Roger McDonald (UT)
Cuy D. McGuire (MD)
Roy A. Montalvan (PA)
William M. Nafus (PA)
Harold L. Overholtzer (PA)
Pandy T. Perry (VA)
Justin M. Powell (NC)
Jackie Riley (NC)
Rudy A. Rodriguez (OR)
R.N. Schoonmaker (NY)
Philip M. Schopp (MO)
Andrew T. Segetti (CT)
Roger L. Shones (MN)
William L. Sirabella (RI)
Ronald D. Strobo (FL)
Rodney H. Swartz
John S. Tingley (VT)
David A. Tipps (IL)
Keith J. Tschetter (ND)
Sean E. Twohig (NY)
Robert A. Wais (NY)
Ashley D. Waite (VT)
Jimmie W. Ward (NC)
Michael R. Waskow (WI)
Brent J. Weber (CO)
James B. Westphal (WI)
Nathan L. Wilkerson (UT)
John A. Winquist (SD)
Robert J. Wyand (NY)
Michael E. Zincone (RI)

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption is valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 20, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–10070 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–xxxx–xxxx]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on an information collection supporting Driver Distraction Measurement Research.

DATES: Comments must be received on or before June 29, 2015.

ADDRESSES: You may submit comments using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, 1200 New Jersey Ave. SE., Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. Fax: (202) 493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without changes to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mazzae, Applied Crash Avoidance Research Division, Vehicle Research and Test Center, NHTSA, 10820 State Route 347—Bldg. 60, East Liberty, Ohio 43319; Telephone (937) 666–4511; Facsimile: (937) 666–3590; email address: *elizabeth.mazzae@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) how to enhance the quality, utility, and clarity of the information to be collected;

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information:

Title: Driver Distraction Measurement Research.

Type of Request: New collection.

OMB Clearance Number: None.

Form Number: NHTSA Form 1157.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: NHTSA proposes to collect information from the public as part of a multi-study research effort that supports the development of measurement techniques for auditory-vocal interactions involving in-vehicle and portable devices. Questions will be asked in conjunction with driving experiments involving both driving simulator and visual occlusion apparatus research tools. The research will involve driving simulator-based experiments in which participants perform specific secondary tasks while driving. The questions will be used to assess individuals' suitability for study participation, to obtain ratings of task difficulty that can be compared to driving performance data, and to assess the incidence and severity of any discomfort stemming from driving the simulator.

Description of the Need for the Information and Proposed Use of the Information: The National Highway Traffic Safety Administration's (NHTSA) mission is to save lives, prevent injuries, and reduce healthcare and other economic costs associated with motor vehicle crashes. An April 2010 program plan document titled ''Overview of the National Highway Traffic Safety Administration's Driver Distraction Program'' announced multiple efforts to reduce the dangers associated with distracted driving. This research aims to inform the development of test procedures and criteria that could be used for voice systems.

Respondents: We estimate that 1,650 persons will complete at least a portion of the information collection. Respondents will be licensed drivers aged 18–70 years who drive at least 3,000 miles annually, are in good health, and do not require to assistive devices to safely operate a vehicle.

Estimated Number of Respondents: In support of this research, it is estimated that 1,650 individuals will complete the first set of screening questions and 1,400 will complete the second set of screening questions. Of the 1,400, it is estimated that 1,000 individuals will meet criteria for participation. From those 1,000, approximately 425 individuals will be chosen to produce a sample providing a balance of age and genders and will be scheduled for study participation.

Estimated Time per Response: Completion of the screening questions is estimated to take approximately 5 minutes for the first set and 10 minutes for the second set. The Rating Scale for Mental Effort (RSME) is estimated to take 2.5 minutes per participant and the simulator sickness questionnaire is estimated to take 2 minutes per participant.

Total Estimated Annual Burden: 176 hours.

Frequency of Collection: The data collection described will be performed once to obtain the target number of valid test participants.

Authority: 44 U.S.C. 3506(c)(2)(A).

Nathaniel Beuse,

Associate Administrator for Vehicle Safety Research.

[FR Doc. 2015–10009 Filed 4–29–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

AGENCY: Department of the Treasury.

ACTION: Notice.

SUMMARY: 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 June 1, 2015 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Number: 1513–0007.

Type of Review: Revision of a currently approved collection.

Title: Brewer's Report of Operations and Quarterly Brewer's Report of Operations.

Form: TTB F 5130.9, 5130.26.

Abstract: The Internal Revenue Code (IRC) requires brewers to file periodic reports of their brewing and associated operations. Brewers that anticipate an annual Federal excise tax liability of $50,000 or more with respect to beer must use TTB F 5130.9 to file monthly operational reports. Brewers that were liable for not more than $50,000 in Federal excise taxes with respect to beer in the preceding calendar year and that reasonably expect to be liable for not more than $50,000 in such taxes during the current calendar year may use either TTB F 5130.9 or the simplified TTB F 5130.26 to file quarterly operational reports. TTB uses these reports to determine whether the brewer's operations are in compliance with the requirements of Federal law and regulations. We also use this information to assist us in determining whether the brewer pays the proper Federal excise taxes in a timely and accurate manner.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 18,036.

OMB Number: 1513–0008.

Type of Review: Extension without change of a currently approved collection.

Title: Application and Permit to Ship Liquors and Articles of Puerto Rican Manufacture Taxpaid to the United States.

Form: TTB F 5170.7.

Abstract: Industry members use TTB F 5170.7 to document the shipment of

taxpaid (or tax deferred) Puerto Rican distilled spirits and other alcohol products to the United States. Puerto Rican and U.S. Treasury Department officials review the form to certify that the products are either taxpaid or tax deferred under appropriate bond. This serves as a method of protecting the revenue.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 100.

OMB Number: 1513–0037.

Type of Review: Revision of a currently approved collection.

Title: Withdrawal of Spirits, Specially Denatured Spirits, or Wines for Exportation.

Form: TTB F 5100.11.

Abstract: Exporters complete TTB F 5100.11 to report the withdrawal of spirits, denatured spirits, and wines from internal revenue bonded premises, without payment of tax, for direct exportation, for transfer to a foreign trade zone, Customs manufacturer's bonded warehouse or Customs bonded warehouse, or for use as supplies on vessels or aircraft.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,500.

OMB Number: 1513–0040.

Type of Review: Revision of a currently approved collection.

Title: Application for Operating Permit Under 26 U.S.C. 5171(d).

Form: TTB F 5110.25.

Abstract: Applicants that wish to engage in the production, warehousing, or bottling of alcohol for industrial use, or that wish to warehouse bulk distilled spirits for non-industrial use without bottling, use TTB F 5110.25 to apply for an operation permit, as required by the Internal Revenue Code at 26 U.S.C. 5171(d). TTB National Revenue Center personnel use the information provided on this form to identify the applicant, the location of the business, the types of activities to be conducted, and the qualifications of the applicant.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 25.

OMB Number: 1513–0042.

Type of Review: Revision of a currently approved collection.

Title: Drawback on Distilled Spirits Exported.

Form: TTB F 5110.30.

Abstract: Persons who export tax-paid distilled spirits use TTB F 5110.30 to claim drawback of the Federal alcohol excise taxes paid. The form requests information regarding the claimant, the tax-paid spirits exported, the amount of tax to be refunded, and a certification by a U.S. government agent attesting to the exportation.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,200.

OMB Number: 1513–0043.

Type of Review: Extension without change of a currently approved collection.

Title: Application and Permit to Ship Puerto Rican Spirits to the United States Without Payment of Tax.

Form: TTB F 5110.31.

Abstract: TTB F 5110.31 is used by industry members to ship Puerto Rican distilled spirits in bulk into the United States without payment of tax. The form identifies the person in Puerto Rico shipping the spirits, from where shipments are to be made, the person in the U.S. receiving the spirits, and the amount of spirits to be shipped.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 750.

Dated: April 27, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015–10091 Filed 4–29–15; 8:45 am]

BILLING CODE 4810–31P

DEPARTMENT OF THE TREASURY

Financial Research Advisory Committee

AGENCY: Office of Financial Research, Treasury.

ACTION: Financial Research Advisory Committee—Solicitation of Applications for Committee Membership.

SUMMARY: The Office of Financial Research is soliciting applications for membership on its Financial Research Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Andrea B. Ianniello, Designated Federal Officer, Office of Financial Research, Department of the Treasury, (202) 622–3002.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, (Pub. L. 92–463, 5 U.S.C. App. 2 § 1–16, as amended), the Treasury Department established a Financial Research Advisory Committee (FRAC, or Committee) to provide advice and recommendations to the Office of Financial Research (OFR) and to assist the OFR in carrying out its duties and authorities.

(I) Authorities of the OFR

Background

The OFR was established under Title I of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, July 21, 2010). The purpose of the OFR is to support the Financial Stability Oversight Council (Council) in fulfilling the purposes and duties of the Council and to support the Council's member agencies by:

—Collecting data on behalf of the Council, and providing such data to the Council and member agencies;
—Standardizing the types and formats of data reported and collected;
—Performing applied research and essential long-term research;
—Developing tools for risk measurement and monitoring;
—Performing other related services;
—Making the results of the activities of the OFR available to financial regulatory agencies; and
—Assisting such member agencies in determining the types and formats of data authorized by the Dodd-Frank Act to be collected by such member agencies.

(II) Scope and Membership of the FRAC

The FRAC was established to advise the OFR on issues related to the responsibilities of the office. It may provide its advice, recommendations, analysis, and information directly to the OFR and the OFR may share the Committee's advice and recommendations with the Secretary of the Treasury or other Treasury officials. The OFR will share information with the Committee as the Director determines will be helpful in allowing the FRAC to carry out its role.

The FRAC is an advisory committee that was established on April 6, 2012 and renewed on April 4, 2014. The OFR is currently soliciting applications for membership in order to provide for rotation of membership, as provided in its original and renewed charter, as well as to provide for a diverse and balanced body with a variety of interests, backgrounds, and viewpoints represented. Providing for such diversity enhances the views and advice offered by the FRAC.

(II) Application for Advisory Committee Appointment

Treasury seeks applications from individuals representative of a constituency within the fields of economics, financial institutions and markets, statistical analysis, financial markets analysis, econometrics, applied sciences, risk management, data management, information standards,

technology, or other areas related to OFR's duties and authorities. The terms of members chosen to serve may vary from one to three years. No person who is a Federally-registered lobbyist may serve on the Committee. Membership on the Committee is limited to the individuals appointed and is non-transferrable. Regular attendance is essential to the effective operation of the Committee. Some members of the Committee may be required to adhere to the conflict of interest rules applicable to Special Government Employees, as such employees are defined in 18 U.S.C. 202(a). These rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 12674 (as modified by Executive Order 12731).

To apply, an applicant must submit an appropriately-detailed resume and a cover letter describing their interest, reasons for application, and qualifications. In accordance with Department of Treasury Directive 21–03, a clearance process includes fingerprints, tax checks, and a Federal Bureau of Investigation criminal check. Applicants must state in their application that they agree to submit to these pre-appointment checks.

The application period for interested candidates will extend to May 11, 2015. Applications should be submitted in sufficient time to be received by the close of business on the closing date and should be sent to *Andrea.B.IannielloOFR@treasury.gov* or by mail to: Office of Financial Research, Department of the Treasury, Attention: Andrea B. Ianniello, 1500 Pennsylvania Avenue NW., MT–1330, Washington, DC 20220.

Dated: April 20, 2015.

William Ruberry,

Associate Director, Communications.

[FR Doc. 2015–10087 Filed 4–29–15; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

AGENCY: Department of the Treasury.

ACTION: Notice.

SUMMARY: 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 June 1, 2015 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request may be found at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

OMB Number: 1545–0143.

Type of Review: Revision of a currently approved collection.

Title: Heavy Highway Vehicle Use Tax Return.

Form: 2290, 2290–SP, 2290–V, 2290–V(SP).

Abstract: Form 2290 is used to compute and report the tax imposed by section 4481 on the highway use of certain motor vehicles. The information is used to determine whether the taxpayer has paid the correct amount of tax.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 27,120,040.

OMB Number: 1545–0240.

Type of Review: Extension without change of a currently approved collection.

Title: Claim for Refund of Income Tax Return Preparer Penalties.

Form: 6118.

Abstract: Form 6118 is used by preparers to file for a refund of penalties incorrectly charged. The information enables the IRS to process the claim and have the refund issued to the tax return preparer.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 11,400.

OMB Number: 1545–0429.

Type of Review: Extension without change of a currently approved collection.

Title: Request for Copy of Tax Return.

Form: 4506.

Abstract: 26 U.S.C. 7513 allows for taxpayers to request a copy of a tax return. Form 4506 is used by a taxpayer to request a copy of a Federal tax form. The information provided will be used for research to locate the tax form and to ensure that the requester is the taxpayer or someone authorized by the taxpayer.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 260,000.

OMB Number: 1545–0499.

Type of Review: Extension without change of a currently approved collection.

Title: Simplified Employee Pension-Individual Retirement Accounts Contribution Agreement.

Form: 5305–SEP.

Abstract: This form is used by an employer to make an agreement to provide benefits to all employees under a Simplified Employee Pension (SEP) described in section 408(k). This form is not to be filed with the IRS but to be retained in the employer's records as proof of establishing a SEP and justifying a deduction for contributions to the SEP. The data is used to verify the deduction.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 495,000.

OMB Number: 1545–0768.

Type of Review: Extension without change of a currently approved collection.

Title: TD 7898—Employers Qualified Educational Assistance Programs.

Abstract: Section 127(a) of the Internal Revenue Code provides that the gross income of any employee does not include amounts paid or expenses incurred by an employer if furnished to the employee pursuant to a qualified educational assistance program. Section 127(b) sets forth the requirements which must be met in order for a program to be a qualified educational assistance program. Among these requirements, section 127(b)(1) requires that a program be a separate written plan of the employer. No advance approval of the plan is required. Employees must be notified of the availability and terms of the program. Pursuant to sec. 6001, substantiation may be required to verify that employees are entitled to exclude the value of such benefits from their gross incomes.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 615.

OMB Number: 1545–0949.

Type of Review: Extension without change of a currently approved collection.

Title: Application for Special Enrollment Examination.

Form: 2587.

Abstract: This information relates to the determination of the eligibility of individuals seeking enrollment status to practice before the Internal Revenue Service.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 11,000.

OMB Number: 1545–1029.

Type of Review: Extension without change of a currently approved collection.

Title: Low-Income Housing Credit Disposition Bond or Treasury Direct Account Application.

Form: 8693.

Abstract: Form 8693 is needed per IRC section 42(j)(6) to post bond or establish a Treasury Direct Account and waive the recapture requirements under section 42(j) for certain disposition of a building on which the low-income housing credit was claimed. Internal Revenue regulations § 301.7101–1 requires that the posting of a bond must be done on the appropriate form as determined by the Internal Revenue Service.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,589.

OMB Number: 1545–1221.

Type of Review: Extension without change of a currently approved collection.

Title: TD 8376 (EE–147–87) Qualified Separate Lines of Business.

Abstract: The affected public includes employers who maintain qualified employee retirement plans. Where applicable, the employer must furnish notice to the IRS that the employer treats itself as operating qualified separate lines of business and some may request an IRS determination that such lines satisfy administrative scrutiny.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 444.

OMB Number: 1545–1237.

Type of Review: Extension without change of a currently approved collection.

Title: REG–209831–96 (TD 8823) Consolidated Returns—Limitation on the Use of Certain Losses and Deductions.

Abstract: TD 8823 contains final regulations regarding certain deductions and losses, including built-in deductions and losses, of members who join a consolidated group. The regulations provide rules for computing the limitation with respect to separate return limitation year (SRLY) losses, and the carryover or carryback of losses to consolidated and separate return years. The regulations also eliminate the application of the SRLY rules in certain circumstances in which the rules of section 382 of the Internal Revenue Code also apply. The collection of information in this regulation is in § 1.1502–21(b)(3). This information is required to ensure that an election to relinquish a carryback period is properly documented, and will be used for that purpose. The collection of information is required to obtain a benefit (relating to the carryover of losses which would otherwise be carried back).

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 2,000.

OMB Number: 1545–1414.

Type of Review: Revision of a currently approved collection.

Title: Credit for Employer Social Security and Medicare Taxes Paid on Certain Employee Tips.

Form: 8846.

Abstract: Employers in food or beverage establishments where tipping is customary can claim an income tax credit for the amount of social security and Medicare taxes paid (employer's share) on tips, other than tips used to meet the minimum wage requirement.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 143,592.

OMB Number: 1545–1487.

Type of Review: Extension without change of a currently approved collection.

Title: Failure To File Gain Recognition Agreements or Satisfy Other Reporting Obligations (TD 9704).

Abstract: Sections 367(e)(1) and 367(e)(2) provide for gain recognition on certain transfers to foreign persons under sections 355 and 332. Section 6038B(a) requires U.S. persons transferring property to foreign persons in exchanges described in sections 332 and 355 to furnish information regarding such transfers.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 2,471.

OMB Number: 1545–1500.

Type of Review: Revision of a currently approved collection.

Title: Pre-Screening Notice and Certification Request for the Work Opportunity and Welfare-to-Work Credits.

Form: 8850.

Abstract: A job applicant completes and signs, under penalties of perjury, the top portion of the form to indicate that he or she is a member of a targeted group. If the employer has a belief that the applicant is a member of a targeted group, the employer signs the other portion of the form under penalties of perjury and submits it to their state workforce agency (SWA) as part of a written request for certification.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,242,800.

OMB Number: 1545–1517.

Type of Review: Extension without change of a currently approved collection.

Title: Distributions From an Archer MSA or Medicare+Choice MSA.

Form: 1099–SA.

Abstract: This form is used to report distributions from a medical savings account as set forth in section 220(h).

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,618.

OMB Number: 1545–1657.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 99–32—Conforming Adjustments Subsequent to Section 482 Allocations.

Abstract: This revenue procedure prescribes the applicable procedures for the repatriation of cash by a United States taxpayer via an interest-bearing account receivable or payable in an amount corresponding to the amount allocated under section 482 from, or to a related person with respect to a controlled transaction.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,620.

OMB Number: 1545–1660.

Type of Review: Extension without change of a currently approved collection.

Title: Notice 99–43 Nonrecognition Exchanges under Section 897.

Abstract: Notice 99–43 This notice announces a modification of the current rules under Temporary Regulation Sec. 1.897–6T(a)(1) regarding transfers, exchanges, and other dispositions of U.S. real property interests in nonrecognition transactions occurring

after June 18, 1980. The new rule will be included in regulations finalizing the temporary regulations.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 200.

OMB Number: 1545–1799.

Type of Review: Extension without change of a currently approved collection.

Title: Notice 2002–69, Interest Rates and Appropriate Foreign Loss Payment Patterns For Determining the Qualified Insurance Income of Certain Controlled Corporations under Section 954(f).

Abstract: This notice provide guidance on how to determine the foreign loss payment patterns of a foreign insurance company owned by U.S. shareholder for purposes of determining the amount of investment income earned by the insurance company that is not treated as Subpart F income under section 954(i).

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 300.

OMB Number: 1545–1817.

Type of Review: Extension without change of a currently approved collection.

Title: Application for United States Residency Certification.

Form: 8802.

Abstract: All requests for U.S. residency certification must be received on Form 8802, Application for United States Residency Certification. This application must be sent to the Philadelphia Service Center. As proof of residency in the United States and of entitlement to the benefits of a tax treaty, U.S. treaty partner countries require a U.S. Government certification that you are a U.S. citizen, U.S. corporation, U.S. partnership, or resident of the United States for purposes of taxation.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 472,380.

OMB Number: 1545–1856.

Type of Review: Extension without change of a currently approved collection.

Title: Consent To Disclosure of Return Information.

Form: 13362.

Abstract: The Consent Form is provided to external applicant that will allow the Service the ability to conduct tax checks to determine if an applicant is suitability for employment once they are determined qualified and within reach to receive an employment offer.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 7,664.

OMB Number: 1545–1913.

Type of Review: Extension without change of a currently approved collection.

Title: Payment of Gift/GST Tax and/or Application for Extension of Time To File Form 709.

Form: 8892.

Abstract: Form 8892 was created to serve a dual purpose. First, the form enables taxpayers to request an extension of time to File 709, when they are not filing an individual income tax extension. Second, it serves as a payment voucher for taxpayers, who are filing an individual income tax extension (by Form 4868) and will have a gift tax balance due on Form 709.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 7,200.

OMB Number: 1545–1942.

Type of Review: Extension without change of a currently approved collection.

Title: Notice 2005–44, Charitable Contributions of Certain Motor Vehicles, Boats, and Airplanes.

Abstract: The notice provides guidance under new Subsection 170(f)(12) and 6720 regarding how to determine the amount of a charitable contribution for certain vehicles and the related substantiation and information reporting requirements.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 3,041.

OMB Number: 1545–1950.

Type of Review: Extension without change of a currently approved collection.

Title: Return by a Shareholder Making Certain Late Elections To End Treatment as a Passive Foreign Investment Company.

Abstract: Form 8621–A is used by certain taxpayer/investors to request ending of their treatment as investing in a Passive Foreign Investment Company. New regulations are being written in support of the new products. The underlying law is in IRC sections 1297 and 1298.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 785.

OMB Number: 1545–2215.

Type of Review: Revision of a currently approved collection.

Title: Application for Voluntary Classification Settlement Program.

Form: 8952.

Abstract: Form 8952 was created by the IRS in conjunction with a new program developed to permit taxpayers to voluntarily reclassify workers as employees for federal employment tax purposes and obtain similar relief to that obtained in the current Classification Settlement Program. To participate in the program, taxpayers must meet certain eligibility requirements, apply to participate in VCSP, and enter into closing agreements with the IRS.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 16,745.

Dated: April 27, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015–10078 Filed 4–29–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0791]

Proposed Information Collection (Notice of Disagreement) Activity: Comment Request

AGENCY: Veterans Benefits Administration, VA.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

VA Form 21–0958, will be used by the Veteran to initiate an appeal by indicating disagreement with a decision issued by a Regional Office (RO).

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 29, 2015.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to

''OMB Control No. 2900–0791'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Notice of Disagreement (VA Form 21–0958).

OMB Control Number: 2900–0791.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–0958, will be used by the Veteran to initiate an appeal by indicating disagreement with a decision issued by a Regional Office (RO). Historically, VBA commenced a pilot program on March 1, 2012 and provided the NOD in all decision and notification letters at the pilot location. VA Form 21–0958, is the first step in the appeal process. The respondent may or may not continue with an appeal to the Board of Veterans Appeals (BVA). If the Veteran opts to continue to BVA for an appeal, this form will be included in the claim folder as evidence. VA will provide VA Form 21–0958 to claimants with the notification letter of the decision in paper form, via hyperlink to VA's Web site, or through its electronic claims processing system. The use of VA Form 21–0958 is mandatory when claimants want to initiate an appeal from a decision on disability compensation claims dated on or after March 24, 2015.

Affected Public: Individuals or households.

Estimated Annual Burden: 72,000.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 144,000.

By direction of the Secretary:

Crystal Rennie,

VA Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015–10104 Filed 4–29–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0321]

Agency Information Collection (Appointment of Veterans Service Organization as Claimant's Representative and Appointment of Individual as Claimant's Representative) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–21), this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before June 1, 2015.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0321'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0321'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Appointment of Veterans Service Organization as Claimant's Representative and Appointment of Individual as Claimant's Representative (VA Forms 21–22 and 21–22a).

OMB Control Number: 2900–0321.

Type of Review: Revision of a currently approved collection.

Abstract: VA Forms 21–22 and 21–22a are used to collect the information needed to determine whom claimants have appointed to represent them in the preparation, presentation, and prosecution of claims for VA benefits. The information is also used to determine the extent of representatives' access to claimants' records.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 80 FR 8763 on February 18, 2015.

Affected Public: Individuals or Households.

Estimated Annual Burden: 27,616.

Estimated Average Burden Per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 331,400.

By direction of the Secretary.

Crystal Rennie,

VA Clearance Officer, U.S. Department of Veterans Affairs.

[FR Doc. 2015–10100 Filed 4–29–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0682]

Agency Information Collection (Advertising, Sales, and Enrollment Materials, and Candidate Handbooks) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before June 1, 2015.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0682'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0682.''

SUPPLEMENTARY INFORMATION:

Title: Advertising, Sales, and Enrollment Materials, and Candidate Handbooks; 38 CFR 21.4252(h).

OMB Control Number: 2900–0682.

Type of Review: Revision of a currently approved collection.

Abstract: The statute prohibits approval of the enrollment of a Veteran in a course if the educational institution uses advertising, sales, or enrollment practices that are erroneous, deceptive, or misleading either by actual statement, omission, or intimation. The advertising, sales and enrollment materials are reviewed to determine if the institution is in compliance with guidelines for approval.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on 80 FR 2782 on January 20, 2015.

Affected Public: Small entities.

Estimated Annual Burden: 3,484 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 13,936.

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015–10096 Filed 4–29–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0265]

Agency Information Collection Educational/Vocational Counseling Application (VA Form 28–8832) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before June 1, 2015.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0265'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0265.''

SUPPLEMENTARY INFORMATION:

Title: Educational/Vocational Counseling Application, VA Form 28–8832.

OMB Control Number: 2900–0265.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 28–8832 collects information that the Vocational Rehabilitation and Employment (VR&E) program needs to quickly assess the applicant's probable eligibility to educational and vocational counseling services, as authorized by Title 38 of the United States Code, Section 3697A.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 80 FR 2482 on January 16, 2015.

Affected Public: Individuals or households.

Estimated Annual Burden: 2,550 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 5,100.

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015–10101 Filed 4–29–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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No. 83 April 30, 2015

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412
Office of the Secretary

45 CFR Part 170
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

Office of the Secretary

45 CFR Part 170

[CMS–1632–P]

RIN–0938–AS41

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2016. Some of these changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act), the Pathway for Sustainable Growth Reform (SGR) Act of 2013, the Protecting Access to Medicare Act of 2014, and other legislation. We also are addressing the update of the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2016.

We also are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2016 and implement certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 and the Protecting Access to Medicare Act of 2014.

In addition, we are proposing to establish new requirements or to revise existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare, including related proposals for eligible hospitals and critical access hospitals participating in the Medicare Electronic Health Record (EHR) Incentive Program. We also are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

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 June 29, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1632–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–1632–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–1632–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Ing-Jye Cheng, (410) 786–4548 and Donald Thompson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Deficit Reduction Act Hospital-Acquired Acquired Conditions—Present on Admission (DRA HAC–POA) Program, Hospital-Acquired Conditions Reduction Program, Hospital Readmission Reductions Program, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, and Medicare Disproportionate Share Hospital (DSH) Issues.

Michele Hudson, (410) 786–4487, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Pierre Yong, (410) 786–8896, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spalding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Deborah Krauss, (410) 786–5264, and Alexandra Mugge, (410–786–4457), EHR Incentive Program Clinical Quality Measure Related Issues.

Elizabeth Myers, (410) 786–4751, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Lauren Wu, (202) 690–7151, Certified EHR Technology Related Issues.

Kellie Shannon, (410) 786–0416, Simplified Cost Allocation Methodology Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All public 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 public 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.

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 Publishing Office. This database can be accessed via the Internet at: *http://www.gpo.gov/fdsys*.

Tables Available Only Through the Internet on the CMS Web site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables are generally only available through the Internet. The IPPS tables for this proposed rule are available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2016 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2016 proposed rule are available through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1632–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
APRN Advanced practice registered nurse
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
ASPE Assistant Secretary for Planning and Evaluation [DHHS]
ATRA American Taxpayer Relief Act of 2012, Public Law 112–240
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 [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CABG Coronary artery bypass graft [surgery]
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CAUTI Catheter-associated urinary tract infection
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Center for Disease Control and Prevention
CERT Comprehensive error rate testing
CDI *Clostridium difficile* (C. difficile)
CFR Code of Federal Regulations
CLABSI Central line-associated bloodstream infection
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
COPD Chronis obstructive pulmonary disease
CPI Consumer price index
CQM Clinical quality measure
CY Calendar year
DACA Data Accuracy and Completeness Acknowledgement
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External Bean Radiotherapy
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR Federal Register
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor
GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCP Healthcare personnel
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center

HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
HwH Hospital-within-hospital
IBR Intern- and Resident-to-Bed Ratio
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
ICU Intensive care unit
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCH QRP Long-Term Care Hospital Quality Reporting Program
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and 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
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
MU Meaningful Use [EHR Incentive Program]
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NUBC National Uniform Billing Code
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB [Executive] Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPM [U.S.] Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PAC Postacute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPI Producer price index
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
QIG Quality Improvement Group [CMS]
QRDA Quality Reporting Data Architecture
RFA Regulatory Flexibility Act, Public Law 96–354
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RSMR Risk-standardized mortality rate
RSRR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCHIP State Child Health Insurance Program
SCIP Surgical Care Improvement Project
SFY State fiscal year
SGR Sustainable Growth Rate
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/Total knee arthroplasty
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set
UMRA Unfunded Mandate Reform Act, Public Law 104–4
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment

system (LTCH PPS). It also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2016 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-Exempt Cancer Hospitals.''
- Section 1886(d)(4)(D) of the Act, which addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are complications or comorbidities (CCs) or major complications or comorbidities (MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions. Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not POA.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. A payment for indirect medical education (IME) is made under section 1886(d)(5)(B) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes an adjustment to hospital payments for hospital-acquired conditions (HACs), or a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act now requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a disproportionate share hospital payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of patient criteria for payment under the LTCH PPS for implementation beginning in FY 2016.
- Section 1206(b)(1) of the Pathway for SGR Reform Act of 2013, which further amended section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act, by retroactively reestablishing and extending the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for ''grandfathered'' hospital-within-hospitals (HwHs), which are permanently exempt from this policy); and section 1206(b)(2) (as amended by section 112(b) of Pub. L. 113–93), which together further amended section 114(d)

of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish a new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities beginning January 1, 2015 and ending on September 30, 2017; and section 1206(d), which instructs the Secretary to evaluate payments to LTCHs classified under section 1886(b)(1)(C)(iv)(II) of the Act and to adjust payment rates in FY 2015 or FY 2016 under the LTCH PPS, as appropriate, based upon the evaluation findings.

- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206 (c) of the Pathway for SGR Reform Act of 2013, which provides for the establishment, no later than October 1, 2015, of a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support.
- Section 1899B of the Act, as added by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act of 2014), which imposes new data reporting requirements for certain postacute care providers, including LTCHs.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in one year, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a −0.8 percent recoupment adjustment to the standardized amount in FY 2014 and FY 2015. We are proposing to make an additional −0.8 percent recoupment adjustment to the standardized amount in FY 2016.

b. Reduction of Hospital Payments for Excess Readmissions

We are proposing changes in policies to the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FYs 2013 and 2014, these conditions are acute myocardial infarction, heart failure, and pneumonia. For FY 2014, we established additional exclusions to the three existing readmission measures (that is, the excess readmission ratio) to account for additional planned readmissions. We also established additional readmissions measures, chronic obstructive pulmonary disease (COPD), and total hip arthroplasty and total knee arthroplasty (THA/TKA), to be used in the Hospital Readmissions Reduction Program for FY 2015 and future years. We expanded the readmissions measures for FY 2017 and future years by adding a measure of patients readmitted following coronary artery bypass graft (CABG) surgery.

In this proposed rule, we are proposing a refinement to the pneumonia readmissions measure, which would expand the measure cohort for the FY 2017 payment determination and subsequent years. In addition, we are proposing to adopt an extraordinary circumstance exception policy that would align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and would allow hospitals that experience an extraordinary circumstance (such as a hurricane or flood) to request a waiver for use of data from the affected time period.

c. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.

For FY 2016, we are proposing to adopt one additional measure beginning with the FY 2018 program year and one measure beginning with the FY 2021 program year. We also are proposing to remove two measures beginning with the FY 2018 program year. In addition, we are proposing to move one measure to the Safety domain and to remove the Clinical Care—Process subdomain and rename the Clinical Care—Outcomes subdomain as the Clinical Care domain. Finally, we are signaling our intent to propose in future rulemaking to expand one measure and to update the standard population data we use to calculate several measures beginning with the FY 2019 program year.

d. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014 and for subsequent program years. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. The amount of payment shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable.

In this proposed rule, we are proposing three changes to existing Hospital-Acquired Condition Reduction Program policies: (1) An expansion to the population covered by the central line-associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) measures to include patients in select nonintensive care unit sites within a hospital; (2) an adjustment to the relative contribution of each domain to the Total HAC Score which is used to determine if a hospital will receive the payment adjustment; and (3) a policy that would align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and would allow hospitals to request a waiver for use of data from the affected time period.

e. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH hospital will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2016. We are proposing to continue to use the methodology we established in FY 2015 to calculate the uncompensated care payment amounts for merged hospitals such that we combine uncompensated care data for the hospitals that have undergone a merger in order to calculate their relative share of uncompensated care. We also are proposing a change to the time period of the data used to calculate the uncompensated care payment amounts to be distributed.

f. Proposed Changes to the LTCH PPS

Under the current LTCH PPS, all discharges are paid under the LTCH PPS standard Federal payment rate. In this proposed rule, we are proposing to implement section 1206 of the Pathways for SGR Reform Act, which requires the establishment of an alternative site neutral payment rate for Medicare inpatient discharges from an LTCH that fail to meet certain statutory defined criteria, beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. We include proposals regarding the application of the site neutral payment rate and the criteria for exclusion from the site neutral payment rate, as well as proposals on a number of methodological and implementation issues, such as the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, the intensive care unit (ICU) criterion, the ventilator criterion, the definition of ''immediately preceded'' by a subsection (d) hospital discharge, limitation on beneficiary charges in the context of the new site neutral payment rate, and the transitional blended payment rate methodology for FY 2016 and FY 2017.

In addition, we are proposing changes to address certain statutory requirements related to an LTCH's average length of stay criterion and discharge payment percentage. We also are providing technical clarifications relating to our FY 2015 implementation of the new statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities (subject to certain defined exceptions) and on bed increases in existing LTCHs and LTCH satellite facilities as well as proposing a technical revision to the regulations to more clearly reflect our established policies.

g. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase in payments. In past years, we have established measures for reporting data and the process for submittal and validation of the data.

In this proposed rule, we are proposing to update considerations for measure removal and retention. In addition, we are proposing to remove nine measures for the FY 2018 payment determination and subsequent years: Six of these measures are ''topped-out'' and two of the measures are suspended. However, we are retaining the electronic version of six of these measures. We also are proposing to refine two previously adopted measures as well as for the FY 2018 payment determination and subsequent years and add eight new measures: Seven new claims-based measures and one structural measure.

Further, for the FY 2018 payment determination, we are proposing to require hospitals to report 16 of the 28 electronic clinical quality measures under the Hospital IQR Program that align with the Medicare EHR Incentive Program and span 3 different NQS domains. We also are proposing to require that hospitals submit two quarters (Q3 and Q4) of data within 2 months following the last discharge date of the quarter. We are proposing to delay and footnote public reporting of electronic clinical quality measure data submitted by hospitals for the CY 2016/FY 2018 payment determination.

We are proposing to align the reporting and submission timelines for the electronic submission of clinical quality measures for the Medicare EHR Incentive Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and submission timelines for the Hospital IQR Program. Lastly, ONC is proposing a 2015 Edition certification criterion for ''CQMs—report'' as part of the proposed 2015 Edition of certification criteria that would require a certified Health IT Module to enable a user to electronically create a data file for transmission of clinical quality measurement data. This proposed certification criterion would apply to eligible professionals, eligible hospitals, and CAHs.

h. Long-Term Care Quality Reporting Program (LTCH QRP)

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act to require the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The IMPACT Act of 2014 amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act of 2014 added section 1899B of the Act, and section 2(c)(3) of the IMPACT Act of 2014 amended section 1886(m)(5) of the Act. Under section 1899B(a)(1) of the Act, the Secretary must require post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include HHAs, SNFs, IRFs, and LTCHs) to submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use and other measures required under section 1899B(d)(1) of the Act. The Act also sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures not later than the applicable specified application date defined in section 1899B(a)(2)(E) of the Act.

In this proposed rule, we are proposing three previously finalized quality measures: One measure proposal establishes the newly NQF-endorsed status of that quality measure; two other

measure proposals are for the purpose of establishing the cross-setting use of the previously finalized quality measures, in order to satisfy the IMPACT Act of 2014 requirement of adopting quality measures under the domains of skin integrity and falls with major injury. We are proposing to adopt an ''application of'' a fourth previously finalized LTCH functional status measure in order to meet the requirement of the IMPACT Act of 2014 to adopt a cross-setting measure under the domain of functional status, such as self-care or mobility. All four measure proposals effect the FY 2018 annual payment update determination and beyond.

In addition, we are proposing to publicly report LTCH quality data beginning in fall 2016, on a CMS Web site, such as *Hospital Compare.* We are proposing to initially publicly report quality data on four quality measures.

Finally, we are proposing to lengthen our quarterly data submission deadlines from 45 days to 135 days beyond the end of each calendar year quarter beginning with quarter four (4) 2015 quality data. We are proposing this change in order to align with other quality reporting programs, and to allow an appropriate amount of time for LTCHs to review and correct quality data prior to the public posting of that data.

3. Summary of Costs and Benefits

• Adjustment for MS–DRG Documentation and Coding Changes. We are proposing to make a −0.8 percent recoupment adjustment to the standardized amount for FY 2016 to implement, in part, the requirement of section 631 of the ATRA that the Secretary make an adjustment totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This proposed recoupment adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases and the adjustment we made for FY 2014, we are proposing to make a −0.8 percent recoupment adjustment to the standardized amount in FY 2016. Considering the −0.8 percent adjustments made in FY 2014 and FY 2015, we estimate that the combined impact of the proposed adjustment for FY 2016 and leaving the FY 2014 and FY 2015 adjustments in place would be to recover up to $3 billion in FY 2016. Combined with the effects of the −0.8 percent adjustments implemented in FY 2014 and FY 2015, we estimate that the proposed FY 2016 −0.8 percent adjustment would result in the recovery of a total of approximately $6 billion of the $11 billion in overpayments required to be recovered by section 631 of the ATRA.

• Proposed Changes to the Hospital Readmissions Reduction Program. We are proposing a refinement to the pneumonia readmissions measure, which would expand the measure cohort for the FY 2017 payment determination and subsequent years. In addition, we are proposing to adopt an extraordinary circumstance exception policy that would align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and would allow hospitals that experience an extraordinary circumstance (such as a hurricane or flood) to request a waiver for use of data from the affected time period. These proposed changes would not significantly impact the program in FY 2016, but could impact future years, depending on actual experience.

• Value-Based Incentive Payments under the Hospital VBP Program. We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2016 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2016 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2016 discharges is approximately $1.5 billion. We believe that the program benefits will be seen in improved patient outcomes, safety, and in the patient's experience of care. However, we cannot estimate these benefits in actual dollar and patient terms.

• Proposed Changes to the HAC Reduction Program for FY 2016. We are proposing three changes to existing HAC Reduction Program policies: (1) An expansion to the population covered by the central line-associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) measures to include patients in select nonintensive care unit sites within a hospital; (2) an adjustment to the relative contribution of each domain to the Total HAC Score that is used to determine if a hospital will receive the payment adjustment; and (3) a policy that would align with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs and would allow hospitals to request a waiver for use of data from the affected period. While hospitals in the top quartile of HAC scores will continue to have their HAC Reduction Program payment adjustment applied, as required by law, because a hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depend on several different factors, any significant impact due to the proposed changes, including which hospitals receive the adjustment, would depend on actual experience.

• Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3313 of the Affordable Care Act), disproportionate share hospital payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals beginning in FY 2014. Hospitals that receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2016, we are proposing to provide that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 63.69 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words,

approximately 47.76 percent (the product of 75 percent and 63.69 percent) of our estimate of Medicare DSH payments prior to the application of section 3133 of the Affordable Care Act is available to make additional payment to hospitals for their relative share of the total amount of uncompensated care. We project that Medicare DSH payments and additional payments for uncompensated care made for FY 2016 would reduce payments overall by approximately 1 percent as compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2015. The additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the proposed payment amount is not directly tied to a hospital's number of discharges.

- Proposed Update to the LTCH PPS Payment Rates and Other Payment Factors. Based on the best available data for the 418 LTCHs in our data base, we estimate that the proposed changes to the payment rates and factors that we are presenting in the preamble and Addendum of this proposed rule, including the proposed application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act, the proposed update to the LTCH PPS standard Federal rate for FY 2016, and the proposed changes to short-stay outlier and high-cost outlier payments would result in an estimated decrease in payments from FY 2015 of approximately $251 million (or 4.6 percent).
- Hospital Inpatient Quality Reporting (IQR) Program. In this proposed rule, we are proposing to remove nine measures for the FY 2018 payment determination and subsequent years. We are proposing to add eight measures to the hospital IQR Program for the FY 2018 payment determination and subsequent years. We also are proposing to require hospitals to report 16 of the 28 Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program and span three different NQS domains. We estimate that our proposals for the adoption and removal of measures will result in total hospital costs of $169 million across 3,300 IPPS hospitals.
- Changes in LTCH Payments Related to the LTCH QRP Proposals. We believe that the increase in costs to LTCHs related to our LTCH QRP proposals in this proposed rule is zero. We refer readers to sections VIII.C. of the preamble of this proposed rule for detailed discussion of the proposals.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. (We note that the statutory provision for Medicare payments to MDHs expired on March 31, 2015, under current law.) SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services ''in accordance with a prospective payment system established by the Secretary.'' The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS

are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; certain cancer hospitals; and short-term acute care hospitals located in Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and American Samoa. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, certain cancer hospitals, short-term acute care hospitals located in Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and American Samoa, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs, as updated annually by the percentage increase in the IPPS operating market basket.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of section 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. Section 1206(a) of Public Law 113–67 established the site neutral payment rate under the LTCH PPS. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs will be paid for LTCH discharges at the new site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning with FY 2009, annual updates to the LTCH PPS are published in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Discussed in This Proposed Rule

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, made a number of changes that affect the IPPS. We announced changes related to certain IPPS provisions for FY 2013 in accordance with sections 605 and 606 of Public Law 112–240 in a notice that appeared in the **Federal Register** on March 7, 2013 (78 FR 14689).

The Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, also made a number of changes that affect the IPPS and the LTCH PPS. We implemented changes related to the low-volume hospital payment adjustment and MDH provisions for FY 2014 in accordance with sections 1105 and 1106 of Public Law 113–67 in an interim final rule with comment period that appeared in the **Federal Register** on March 18, 2014 (79 FR 15022).

The Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, also made a number of changes that affect the IPPS and LTCH PPS.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Quality Reporting Program (LTCH QRP).

1. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

In this proposed rule, we are proposing to make policy changes to implement section 631 of the American Taxpayer Relief Act of 2012, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring in FY 2014 through FY 2017 to fully offset $11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

2. Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67)

In this proposed rule, we are proposing to make policy changes to implement and discuss the need for future policy changes to carry out provisions under section 1206 of the Pathway for SGR Reform Act of 2013. These include:

- Section 1206(a), which provides for the establishment of patient criteria for exclusion from the new ''site neutral'' payment rate under the LTCH PPS, beginning in FY 2016.
- Section 1206(a)(3), which requires changes to the LTCH average length of stay criterion.
- Section 1206(b)(1), which further amended section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and

10312(a) of the Affordable Care Act by retroactively reestablishing, and extending, the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for grandfathered hospitals-within-hospitals (HwHs), which it permanently exempted from this policy).

• Section 1206(b)(2), which amended section 114(d) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities.

3. Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)

In this proposed rule, we are proposing to make policy changes to implement, or making conforming changes to regulations in accordance with, the following provisions (or portions of the following provisions) of the Protecting Access to Medicare Act of 2014 that are applicable to the IPPS and the LTCH PPS for FY 2016:

• Section 112, which makes certain changes to Medicare LTCH provisions, including modifications to the statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities.

• Section 212, which prohibits the Secretary from requiring implementation of ICD–10 code sets before October 1, 2015.

4. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185)

In this proposed rule, we are proposing to implement portions of section 2 of the IMPACT Act of 2014, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

D. Summary of the Major Provisions of This Proposed Rule

In this proposed rule, we set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals for FY 2016. We also set forth proposed changes relating to payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in this proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2016.

Below is a summary of the major changes that we are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

• Proposed changes to MS–DRG classifications based on our yearly review, including a discussion of the conversion of MS–DRGs to ICD–10 and the implementation of the ICD–10–CM and ICD–10–PCS systems.

• Proposed application of the documentation and coding adjustment for FY 2016 resulting from implementation of the MS–DRG system.

• Proposed recalibrations of the MS–DRG relative weights.

• Proposed changes to hospital-acquired conditions (HACs) and a discussion of HACs, including infections, that would be subject to the statutorily required adjustment in MS–DRG payments for FY 2016.

• A discussion of the FY 2016 status of new technologies approved for add-on payments for FY 2015 and a presentation of our evaluation and analysis of the FY 2016 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed included the following:

• The proposed FY 2016 wage index update using wage data from cost reporting periods beginning in FY 2012.

• Calculation of the proposed occupational mix adjustment for FY 2016 based on the 2013 Occupational Mix Survey.

• Analysis and implementation of the proposed FY 2016 occupational mix adjustment to the wage index for acute care hospitals.

• Proposed application of the rural floor, the proposed imputed rural floor, and the proposed frontier State floor.

• Transitional wage indexes relating to the continued use of the revised OMB labor market area delineations based on 2010 Decennial Census data.

• Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.

• The proposed out-migration adjustment to the wage index for acute care hospitals for FY 2016 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index. Beginning in FY 2016, we are proposing new out-migration adjustments based on commuting patterns obtained from 2010 Decennial Census data.

• The timetable for reviewing and verifying the wage data used to compute the proposed FY 2016 hospital wage index.

• Determination of the labor-related share for the proposed FY 2016 wage index.

• Proposed changes to the 3-year average pension policy and proposed changes to the wage index timetable regarding pension cost for FY 2017 and subsequent years.

• Clarification of the allocation of pension costs for the wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

In section IV. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

• Proposed changes to the inpatient hospital updates for FY 2016, including the adjustment for hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act.

• The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

• The statutorily required IME adjustment factor for FY 2016.

• Proposal for determining Medicare DSH payments and the additional payments for uncompensated care for FY 2016.

• Proposed changes to the measures and payment adjustments under the Hospital Readmissions Reduction Program.

• Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.

• Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2016.

• Proposed elimination of the election by hospitals to use the simplified cost allocation methodology for Medicare cost reports.

• Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality

adjustment for the demonstration program.

• Proposed changes in postacute care transfer policies as a result of proposed new MS–DRGs.

• A statement of our intent to discuss issues related to short inpatient hospital stays, long outpatient stays with observation services, and the related −0.2 percent IPPS payment adjustment in the CY 2016 hospital outpatient prospective payment system proposed rule that will be published this summer.

4. Proposed FY 2016 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2016.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss proposed changes to payments to certain excluded hospitals for FY 2016.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth—

• Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2016.

• Proposals to implement section 1206(a)(1) of the Pathway for SGR Reform Act, which established the site neutral payment rate as the default means of paying for discharges in LTCH cost reporting periods beginning on or after October 1, 2015.

• Provisions to make technical clarifications regarding the moratoria on the establishment of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities that were established by section 1206(b)(2) of the Pathway for SGR Reform, as amended, as well as a proposal to make a technical revision to the regulations to more clearly reflect our established policies.

• Proposal to revise the average length of stay criterion for LTCHs to implement section 1206(a)(3) of the Pathway for SGR Reform Act.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we address—

• Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.

• Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).

• Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).

• Proposed changes to align the reporting and submission timelines for the electronic submission of clinical quality measures for the Medicare Electronic Health Record (EHR) Incentive Program for eligible hospitals and CAHs with the reporting and submission of timelines for the Hospital IQR Program, including a proposal to establish in regulations an EHR technology certification criterion for reporting clinical quality measures.

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2016 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also are proposing to establish the threshold amounts for outlier cases. In addition, we address the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2016 for certain hospitals excluded from the IPPS.

9. Determining Standard Federal Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2016 LTCH PPS standard Federal payment rate. We are proposing to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

10. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, LTCHs, and PCHs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2016 for the following:

• A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs).

• Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.

• The standard Federal payment rate for hospital inpatient services furnished by LTCHs.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2015 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2015 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov*.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary

adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50512), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49871).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. Proposed FY 2016 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, for FY 2015, there are 775 MS–DRGs.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking effective October 1, 2008 (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by section 7(a) of Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Adjustment to the Average Standardized Amounts Required by Public Law 110–90

a. Prospective Adjustment Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

3. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in

the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 IPPS/LTCH PPS proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies recommended by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This CMS Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check (refer to the Web site for the required payment amount) to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting–RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777), we opted to delay the implementation of any documentation and coding adjustment until a full analysis of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 5.4 percent. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an ''appropriate'' adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believed the law provided some discretion as to the manner in which we applied the prospective adjustment of −3.9 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that fiscal year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment to the standardized amount instead of the full −3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 by finalizing a −1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

We noted again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated. These overpayments could not be recovered by CMS because section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.

5. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110–90

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that there was a 5.8 percentage point difference resulting in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in payment rate adjustments over more than one year in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of −2.9 percent, representing approximately one-half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012). For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110–90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

6. Proposed Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment, once the necessary amount of overpayment is recovered.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimate that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates.

Consistent with the approach discussed in the FY 2014 IPPS/LTCH PPS final rule for recouping the $11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49873 through 49874), we implemented an additional −0.8 percent recoupment adjustment to the standardized amount for FY 2015. We estimated that this level of adjustment, combined with leaving the −0.8 percent adjustment made for FY 2014 in place, will recover up to $2 billion in FY 2015. When combined with the approximately $1 billion adjustment made in FY 2014, we estimated that approximately $8 billion would be left to recover under section 631 of the ATRA.

Consistent with the approach discussed in the FY 2014 IPPS/LTCH PPS final rule for recouping the $11 billion required by section 631 of the ATRA, in this FY 2016 IPPS/LTCH PPS proposed rule, we are proposing to implement a −0.8 percent recoupment adjustment to the standardized amount for FY 2016. Considering the −0.8 percent adjustments made in FY 2014 and FY 2015, we estimate that the combined impact of the proposed adjustment for FY 2016 and leaving the FY 2014 and FY 2015 adjustments in place would be to recover up to $3 billion in FY 2016. Combined with the effects of the −0.8 percent adjustments implemented in FY 2014 and FY 2015, we estimate that the proposed FY 2016 −0.8 percent adjustment would result in the recovery of a total of approximately $6 billion of the $11 billion in overpayments required to be recovered by section 631 of the ATRA.

As we explained in the FY 2014 IPPS/LTCH PPS final rule, estimates of any future adjustments are subject to slight variations in total savings. Therefore, we have not yet addressed the specific amount of the final adjustment required under section 631 of the ATRA for FY 2017. We continue to believe that the proposed −0.8 percent adjustment for FY 2016 is a reasonable and fair approach that will help satisfy the requirements of the statute while mitigating extreme annual fluctuations in payment rates. In addition, we again note that this proposed −0.8 percent recoupment adjustment for FY 2016, the respective −0.8 percent adjustments made in FY 2014 and FY 2015, and any future adjustment made under this authority, will be eventually offset by an equivalent positive adjustment once the full $11 billion recoupment requirement has been realized.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to ''charge compression,'' which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower

percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single cost-to-charge ratio (CCR) is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453). In addition, we refer readers to RTI's July 2008 final report titled ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights'' (*http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for ''Medical Supplies Charged to Patients'' and another line for ''Implantable Devices Charged to Patients.'' We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. Accordingly, a new subscripted line for ''Implantable Devices Charged to Patients'' was created in July 2009. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI also found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost 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 costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRIs, 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. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of 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 reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new ''Implantable Devices Charged to Patients'' cost center to develop a CCR for ''Implantable Devices Charged to Patients'' in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report Form CMS 2552–10, we determined that a new CCR for ''Implantable Devices Charged to Patients'' might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRIs, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, we checked the availability of data in the ''Implantable Devices Charged to Patients'' cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for ''Implantable Devices Charged to Patients'' for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS–2552–96 to the new cost report Form CMS–2552–10. Therefore, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010; that is, those cost reports on Form CMS–2552–96. Data from the Form CMS–2552–10 cost reports were not available because cost reports filed on the Form CMS–2552–10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that, prior to proposing to create these

CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed a policy to calculate the MS–DRG relative weights using 19 CCRs, creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization.

We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS–DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculate the IPPS MS–DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion for FY 2016 and Request for Comments on Nonstandard Cost Center Codes

Consistent with the policy established beginning for FY 2014, we calculated the proposed MS–DRG relative weights for FY 2016 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2016 is included in section II.H.3. of the preamble of this proposed rule.

In preparing to calculate the 19 national average CCRs developed from the cost reports, we reviewed the HCRIS data and noticed inconsistencies in hospitals' cost reporting and use of nonstandard cost center codes. In addition, we discovered that hospitals typically report the nonstandard codes with standard cost centers that are different from the standard cost centers to which CMS maps and ''rolls up'' each nonstandard code in compiling the HCRIS. We are concerned that inconsistencies in hospitals' use of nonstandard codes, coupled with differences in the way hospitals and CMS map these nonstandard codes to standard lines, may have implications for the calculation of the 19 CCRs and the aspects of the IPPS that rely on the CCRs (for example, the calculation of the MS–DRG relative weights).

The Medicare cost report Form CMS–2552–10, Worksheet A, includes preprinted cost center codes that reflect the standard cost center descriptions by category (General Service, Routine, and Ancillary) used in most hospitals. Each preprinted standard cost center is assigned a unique 5-digit code. The preprinted 5-digit codes provide standardized meaning for data analysis, and are automatically coded by CMS-approved cost report software. To accommodate hospitals that have additional cost centers that are sufficiently different from the preprinted standard cost centers, CMS identified additional cost centers known as ''nonstandard'' cost centers. Each nonstandard cost center must be labeled appropriately and reported under a specific standard cost center. For example, under the standard cost center ''Electrocardiology'' with its 5-digit code of 06900, there are six nonstandard cost centers (for EKG and EEG, Electromyography, Cardiopulmonary, Stress Test, Cardiology, and Holter Monitor), each with a unique 5-digit code.

The instructions for the Medicare cost report Form CMS–2552–10 explain the purpose and requirements related to the standard and nonstandard cost centers. Specifically, in CMS Pub. 15–2, Chapter 40, Section 4013, the instructions for Worksheet A of Form CMS–2552–10 state:

''Cost center coding is a methodology for standardizing the meaning of cost center labels as used by health care providers on the Medicare cost report. Form CMS–2552–10 provides for preprinted cost center descriptions on Worksheet A. In addition, a space is provided for a cost center code. The preprinted cost center labels are automatically coded by CMS approved cost reporting software. These cost center descriptions are hereafter referred to as the standard cost centers. Additionally, nonstandard cost center descriptions have been identified through analysis of frequently used labels.

The use of this coding methodology allows providers to continue to use labels for cost centers that have meaning within the individual institution. The five digit cost center codes that are associated with each provider label in their electronic file provide standardized meaning for data analysis. You are required to compare any added or changed label to the descriptions offered on the standard or nonstandard cost center tables. A description of cost center coding and the table of cost center codes are in § 4095, Table 5.''

Section 4095 of CMS Pub. 15–2 (pages 40–805 and 40–806) further provides that:

''Both the standard and nonstandard cost center descriptions along with their cost center codes are shown on Table 5. . . . Cost center codes may only be used in designated lines in accordance with the classification of the cost center(s), *i.e.,* lines 1 through 23 may only contain cost center codes within the general service cost center category of both standard and nonstandard coding. For example, in the general service cost center category for Operation of Plant cost, line 7 and subscripts thereof should only contain cost center codes of 00700–00719 and nonstandard cost center codes. This logic must hold true for all other cost center categories, *i.e.,* ancillary, inpatient routine, outpatient, other reimbursable, special purpose, and non- reimbursable cost centers.''

Table 5 of Section 4095, Chapter 40, of CMS Pub. 15–2 (pages 40–807 through 40–810) lists the electronic reporting specifications for each standard cost center, its 5-digit code, and, separately, the nonstandard cost center descriptions and their 5-digit codes. While the nonstandard codes are categorized by General Service Cost Centers, Inpatient Routine Service Cost Centers, and Ancillary Service Cost Centers, among others, Table 5 does not map the nonstandard cost centers and codes to specific standard cost centers. In addition, the CMS-approved cost reporting software does not restrict the use of nonstandard codes to specific standard cost centers. Furthermore, the softwares do not prevent hospitals from manually entering in a name for a nonstandard cost center code that may

be different from the name that CMS assigned to that nonstandard cost center code. For example, Table 5 specifies that the 5-digit code for the Ancillary Service nonstandard cost center ''Acupuncture'' is 03020. When CMS creates the HCRIS SAS files, CMS maps all codes 03020 to standard line 53, ''Anesthesiology''.[1] However, a review of the December 31, 2014 update of the FY 2013 HCRIS SAS files, from which the proposed 19 CCRs for FY 2016 are calculated, reveals that, of the 3,172 times that nonstandard code 03020 is reported by hospitals, it is called ''Acupuncture'' only 122 times. Instead, hospitals use various names for nonstandard code 03020, such as ''Cardiopulmonary,'' ''Sleep Lab,'' ''Diabetes Center,'' or ''Wound Care''.

As noted above, the Ancillary Service standard cost center for ''Anesthesiology'', line 53 of Worksheet A and subsequent worksheets of the Medicare cost report Form CMS–2552–10 (and its associated nonstandard cost center code 03020 ''Acupuncture'') is an example of a cost center that is subject to inconsistent reporting. Our review of the FY 2013 HCRIS as-submitted cost reports from which the proposed 19 CCRs for FY 2016 are calculated revealed that, regardless of the actual name hospitals assigned to nonstandard code 03020 (for example, ''Acupuncture'' or otherwise), hospitals reported this code almost 100 percent of the time on standard line 76, ''Other Ancillary,'' and never on standard line 53, ''Anesthesiology.'' Yet, as noted above, CMS (and previously HCFA, under earlier versions of the Medicare cost report), in creating the HCRIS database, has had the longstanding practice of mapping and rolling up all instances of nonstandard code 03020 to standard line 53, ''Anesthesiology,'' not to standard line 76, ''Other Ancillary. Therefore, the version of the HCRIS SAS files created by CMS, which CMS uses for ratesetting purposes, may differ somewhat from the as-submitted cost reports of hospitals because CMS moves various nonstandard cost centers based on cost center codes, not cost center descriptions, from the standard cost centers in which hospitals report them and places them in different standard cost centers based on CMS' roll-up specifications.

We are highlighting the discrepancy in the reporting of nonstandard code 03020 ''Acupuncture'' because the placement of nonstandard code 03020 and its related costs and charges seem to have the most significant implications for the calculation of one of the 19 CCRs, the Anesthesia CCR. As stated in section II.H.3. of the preamble of this proposed rule, the proposed FY 2016 CCR for Anesthesia is 0.108. We calculated this proposed CCR based on the December 31, 2014 update of the FY 2013 HCRIS, with the nonstandard cost center codes of 03020 through 03029 rolled up to standard line 53, ''Anesthesiology.'' That is, under the CMS' HCRIS specifications, we roll up the following 5-digit codes to standard line 53, ''Anesthesiology'':[2] standard codes for ''Anesthesiology'' 05300 through 05329; and nonstandard codes for ''Acupuncture '' 03020 through 03029. For simulation purposes, we also created a version of the December 31, 2014 update of the FY 2013 HCRIS which retains nonstandard codes 03020 through 03029 on standard line 76, ''Other Ancillary,'' where hospitals actually reported these codes on their as-submitted FY 2013 cost reports. When all reported uses of nonstandard codes 03020 through 03029 remain on standard line 76, ''Other Ancillary,'' we calculated that the Anesthesia CCR would be 0.084 (instead of 0.108 as proposed in section II.H.3. of the preamble of this proposed rule). We also looked at the effect on the other 18 CCRs. In the version of HCRIS we created for simulation purposes, by keeping the nonstandard cost center codes in standard line 76, ''Other Ancillary,'' where hospitals typically report them, rather than remapping them according to CMS specifications, two other CCRs also are affected, although not quite as significantly as the Anesthesia CCR. Currently, as proposed in section II.H.3. of the preamble of this proposed rule, the proposed FY 2016 Cardiology CCR is 0.119, but when all cardiology-related nonstandard codes are rolled up to standard line 76, ''Other Ancillary'', and not to standard line 69, ''Electrocardiology'' as under CMS' usual practice, the Cardiology CCR would be 0.113. In addition, as proposed in section II.H.3. of the preamble of this proposed rule, the proposed FY 2016 Radiology CCR is 0.159, but when all radiology-related nonstandard codes are rolled up to standard line 76, ''Other Ancillary'', and not to standard lines 54 (Radiology—Diagnostic), 55 (Radiology—Therapeutic), and 56 (Radioisotope) as under CMS' usual practice, the Radiology CCR would be 0.161. Most notably, the CCR that is most impacted is the ''Other Services'' CCR. Currently, as proposed in section II.H.3. of the preamble of this proposed rule, the ''Other Services'' CCR is 0.367. However, if all nonstandard cost center codes would remain in line 76, ''Other Ancillary'' as hospitals have reported them in their FY 2013 as-submitted cost reports, instead of CMS applying its usual practice of rolling up these lines to the applicable ''Electrocardiology'' and ''Radiology'' standard cost centers, among others, the ''Other Services'' CCR would be 0.291. We note that we observed minimal or no differences in the remaining 15 CCRs, when their associated nonstandard cost centers were rolled up to their specific standard cost centers, versus being rolled up to the standard line 76, ''Other Ancillary.''

The differences in these CCRs computed from the HCRIS that was compiled by applying CMS' current rollup procedures of assigning nonstandard codes to specific standard cost centers, as compared to following hospitals' general practice of reporting nonstandard codes ''en masse'' on line 76, ''Other Ancillary,'' have implications for the aspects of the IPPS that rely on the CCRs (for example, the calculation of the MS–DRG relative weights). Some questions that arise are whether CMS' procedures for mapping and rolling up nonstandard cost centers to specific standard cost centers should be updated or whether hospital reporting practices are imprecise, or whether there is a combination of both. CMS' rollup procedures were developed many years ago based on historical analysis of hospitals' cost reporting practices and health care services furnished. It may be that it would be appropriate for CMS to reevaluate its rollup procedures based on hospitals' more current cost reporting practices and contemporary health care services provided. However, one factor complicating the determination of the most accurate standard cost centers to which each respective nonstandard cost center should be mapped is hospitals' own inconsistent reporting practices. For example, it may be determined that CMS should no longer be mapping and rolling up nonstandard cost center ''Acupuncture'' and its associated 5-digit codes 03020 through 03029 to standard cost center line 53, ''Anesthesiology.'' However, determining which other standard line

[1] To view how CMS rolls up the codes to create the HCRIS SAS files, we refer readers to *http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form.html*. On this page, click on ''Hospital-2010–SAS.ZIP (SAS datasets and documentation)'', and from the zip file, choose the Excel spreadsheet ''2552–10 SAS FILE RECORD LAYOUT AND CROSSWALK TO 96.xlsx''. The second tab of this spreadsheet is ''NEW ROLLUPS'', and shows the standard and nonstandard 5-digit codes (columns B and C) that CMS rolls up to each standard line (column G).

[2] Ibid.

''Acupuncture'' and its associated 5-digit codes 03020 through 03029 should be mapped is unclear, given that, as mentioned above, out of the 3,172 times that codes 03020 through 03029 were reported in the FY 2013 HCRIS file, hospitals called these codes ''Acupuncture'' only 122 times, and instead called these codes a variety of other names (such as Cardiopulmonary, Sleep Lab, Wound Care, Diabetes Center, among others). Therefore, without being able to determine the true nature of the services that were actually provided, it is difficult to know which standard cost center to map these services. That is, the question arises as to whether the service provided was acupuncture because a hospital reported code 03020, or whether the service provided was cardiopulmonary, which was the name a hospital assigned to code 03020. Furthermore, if the service provided was in fact cardiopulmonary, then, as Table 5 of Section 4095 of CMS Pub. 15–2 indicates, the correct nonstandard code for cardiopulmonary is 03160, not 03020. A related question would then be, if the hospital provided cardiopulmonary services, which are clearly related to cardiology, why did the hospital report those costs and charges on line 76, ''Other Ancillary,'' instead of subscripting standard line 69, ''Electrocardiology,'' and reporting the cardiopulmonary costs and charges there.

In summary, we believe that the differences between the standard cost centers to which CMS assigns nonstandard codes when CMS rolls up cost report data to create the HCRIS SAS database, and the standard cost centers to which hospitals tend to assign and use nonstandard codes, coupled with the inconsistencies found in hospitals' use and naming of the nonstandard codes, have implications for the aspects of the IPPS that rely on the CCRs. For example, we have explained above and provided examples of how the CCRs used to calculate the MS–DRG relative weights could change, based on where certain nonstandard codes are reported and rolled up in the cost reports. However, before considering changes to our longstanding practices, we are interested in receiving public comments from stakeholders as to how to improve the use of nonstandard cost center codes. One option might be for CMS to allow only certain nonstandard codes to be used with certain standard cost centers, meaning that CMS might require that the CMS-approved cost reporting softwares ''lock in'' those nonstandard codes with their assigned standard cost centers. For example, if a hospital wishes to subscript a standard cost center, the cost reporting software might allow the hospital to choose only from a predetermined set of nonstandard codes. Therefore, for example, if a hospital wished to report Cardiopulmonary costs and charges on its cost report, the only place that the hospital could do that under this approach would be from a drop down list of cardiology-related services on standard line 69, ''Electrocardiology,'' and not on another line (not even line 76, ''Other Ancillary''). Some flexibility could be maintained, but within certain limits, in consideration of unique services that hospitals might provide.

In the interim, while we seek public comments on this issue, we have proposed 19 CCRs for FY 2016 (listed in section II.H.3. of the preamble of this proposed rule) that were calculated from the December 31, 2014 update of the FY 2013 HCRIS, created in accordance with CMS' current longstanding procedures for mapping and rolling up nonstandard cost center codes. As we did with the FY 2015 IPPS/LTCH PPS final rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs on the FY 2016 IPPS Proposed Rule Home Page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Proposed-Rule-Home-Page.html*.[3]

F. Proposed Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections for FY 2016

1. Background

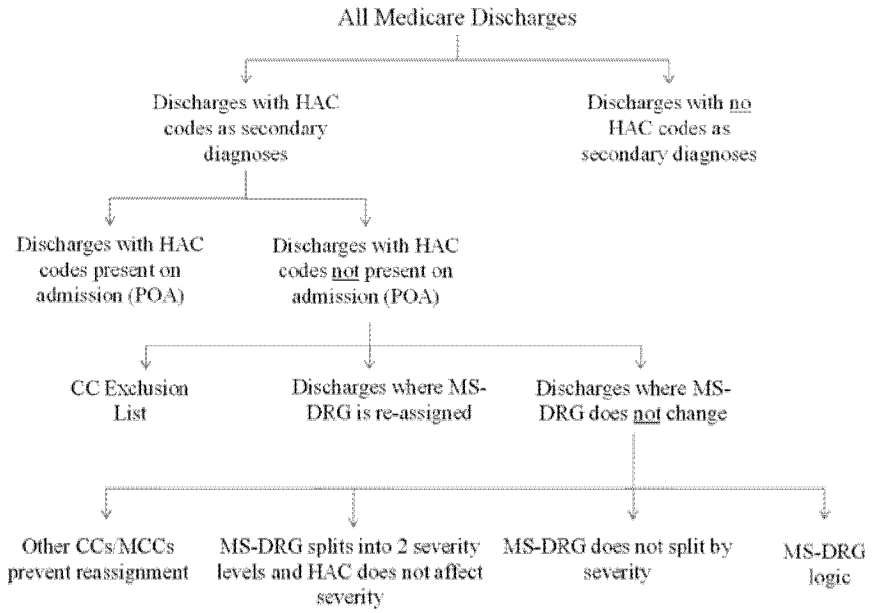
Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of these conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. However, because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS–DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS–DRG system, there are currently 261 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC). The presence of a CC or an MCC generally results in a higher payment.

Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with the CDC, from time to time as long as the list contains at least two conditions.

Effective for discharges occurring on or after October 1, 2008, under the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not present on admission (POA). Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC or MCC appears on the claim, the claim will be paid at the higher MS–DRG rate. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA. When a HAC is not POA, payment can be affected in a manner shown in the diagram below.

[3] Ibid.



2. HAC Selection

Beginning in FY 2007, we have set forth proposals, and solicited and responded to public comments, to implement section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, including a detailed discussion of the collaborative interdepartmental process and public input regarding selected and potential candidate HACs, we refer readers to the following rules: The FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53283 through 53303); the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and final rule (78 FR 50523 through 50527), and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28000 through 28003) and final rule (79 FR 49876 through 49880). A complete list of the 11 current categories of HACs is included on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*.

3. Present on Admission (POA) Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In previous rulemaking, we provided both CMS and CDC Web site resources that are available to hospitals for assistance in this reporting effort. For detailed information regarding these sites and materials, including the application and use of POA indicators, we refer the reader to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 through 51507).

Currently, as we have discussed in the prior rulemaking cited under section II.I.2. of the preamble of this proposed rule, the POA indicator reporting requirement only applies to IPPS hospitals and Maryland hospitals because they are subject to this HAC provision. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting.

There are currently four POA indicator reporting options, ''Y'', ''W'', ''N'', and ''U'', as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting*. We note that prior to January 1, 2011, we also used a POA indicator reporting option ''1''. However, beginning on or after January 1, 2011, hospitals were required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of ''1'' for codes that are exempt from POA reporting. We issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100–20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010, which can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf*. The current POA indicators and their descriptors are shown in the chart below:

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.

Under the HAC payment policy, we treat HACs coded with ''Y'' and ''W'' indicators as POA and allow the condition on its own to cause an increased payment at the CC and MCC level. We treat HACs coded with ''N'' and ''U'' indicators as Not Present on Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC and MCC level. We refer readers to the following rules for a detailed discussion of POA indicator reporting: the FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43784 through 43785); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23881 through 23882) and final rule (75 FR 50081 through 50082); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27893 through 27894) and final rule (77 FR 53284 through 53285); the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27510 through 27511) and final rule (78 FR 50524 through 50525), and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28001 through 28002) and final rule (79 FR 49877 through 49878).

In addition, as discussed previously in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53324), the 5010 format allows the reporting and, effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal diagnosis and all secondary diagnoses up to 25.

4. HACs and POA Reporting in Preparation for Transition to ICD–10–CM and ICD–10–PCS

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 and 51507), in preparation for the transition to the ICD–10–CM and ICD–10–PCS code sets, we indicated that further information regarding the use of the POA indicator with the ICD–10–CM/ICD–10–PCS classifications as they pertain to the HAC policy would be discussed in future rulemaking.

At the March 5, 2012 and the September 19, 2012 meetings of the ICD–9–CM Coordination and Maintenance Committee, an announcement was made with regard to the availability of the ICD–9–CM HAC list translation to ICD–10–CM and ICD–10–PCS code sets. Participants were informed that the list of the ICD–9–CM selected HACs had been translated into codes using the ICD–10–CM and ICD–10–PCS classification system. It was recommended that the public review this list of ICD–10–CM/ICD–10–PCS code translations of the selected HACs available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We encouraged the public to submit comments on these translations through the HACs Web page using the CMS ICD–10–CM/PCS HAC Translation Feedback Mailbox that was set up for this purpose under the Related Links section titled ''CMS HAC Feedback.'' We also encouraged readers to review the educational materials and draft code sets available for ICD–10–CM/PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. Lastly, we provided information regarding the ICD–10 MS–DRG Conversion Project on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html*.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50525), we stated that the final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS would be subject to formal rulemaking. We again encouraged readers to review the educational materials and updated draft code sets available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. In addition, we stated that the draft ICD–10–CM Coding Guidelines could be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*.

However, prior to engaging in rulemaking for the FY 2015 HAC program, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf*. That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Further information of the ICD–10 rules can be found on the Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html*.

As described in section II.F.5. of the preamble of this proposed rule, we are proposing the HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS in this FY 2016 IPPS/LTCH PPS proposed rule.

5. Proposed Changes to the HAC Program for FY 2016

As discussed in section II.G. 1. a. of the preamble of this proposed rule, for FY 2016, we are proposing the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM MS–DRGs Version 32. As part of our DRA HAC update for FY 2016, we are proposing that the ICD–10–CM/PCS Version 33 HAC list replace the ICD–9–CM Version 32 HAC list. We are soliciting public comments on how well the ICD–10–CM/PCS Version 32 HAC list replicates the ICD–9–CM Version 32 HAC list.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. The HAC code list translations from ICD–9–CM to ICD–10–CM/PCS are located in Appendix I of the ICD–10–CM/PCS MS–DRG Version 32 Definitions Manual. The link to this Manual (available in both text and HTML formats) is located in the Downloads section of the ICD–10 MS–DRG Conversion Project Web site.

With respect to the current categories of the HACs, we are not proposing to add or remove any categories in this FY 2016 IPPS/LTCH PPS proposed rule. However, as described more fully in section III.F.7, of the preamble of this proposed rule, we will continue to monitor contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute hospital setting and may use this information to inform future rulemaking. We also continue to encourage public dialogue about refinements to the HAC list through written stakeholder comments. We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS final rule (73 FR 48774 through 48491) for detailed discussion supporting our determination regarding each of the current conditions. We also refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53285 through 53292) for the HAC policy for FY 2013, the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and final rule (78 FR 50523

through 50527) for the HAC policy for FY 2014, and the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28000 through 28003) and final rule (79 FR 49876 through 49880) for the HAC policy for FY 2015.

In summary, we are proposing that the ICD–10–CM/PCS Version 33 HAC list replace the ICD–9–CM Version 32 HAC list and are seeking public comments on how well the ICD–10–CM/PCS Version 32 HAC list replicates the ICD–9–CM Version 32 HAC list.

6. RTI Program Evaluation

On September 30, 2009, a contract was awarded to RTI to evaluate the impact of the Hospital-Acquired Condition-Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This was an intra-agency project with funding and technical support from CMS, OPHS, AHRQ, and CDC. The evaluation also examined the implementation of the program and evaluated additional conditions for future selection. The contract with RTI ended on November 30, 2012. Summary reports of RTI's analysis of the FYs 2009, 2010, and 2011 MedPAR data files for the HAC–POA program evaluation were included in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50085 through 50101), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53292 through 53302). Summary and detailed data also were made publicly available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and the RTI Web site at: *http://www.rti.org/reports/cms/*.

In addition to the evaluation of HAC and POA MedPAR claims data, RTI also conducted analyses on readmissions due to HACs, the incremental costs of HACs to the health care system, a study of spillover effects and unintended consequences, as well as an updated analysis of the evidence-based guidelines for selected and previously considered HACs. Reports on these analyses have been made publicly available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html*.

7. RTI Reports on Evidence-Based Guidelines

The RTI program evaluation included a report that provided references for all evidence-based guidelines available for each of the selected, candidate, and previously considered HACs that provided specific recommendations for the prevention of the corresponding conditions. Guidelines were primarily identified using the AHRQ National Guidelines Clearing House (NGCH) and the CDC, along with relevant professional societies. Guidelines published in the United States were used, if available. In the absence of U.S. guidelines for a specific condition, international guidelines were included.

RTI prepared a final report to summarize its findings regarding these guidelines. This report is titled ''Evidence-Based Guidelines for Selected, Candidate, and Previously Considered Hospital-Acquired Conditions'' and can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Downloads/Evidence-Based-Guidelines.pdf*.

Subsequent to this final report, RTI was awarded a new Evidence-Based Guidelines Monitoring contract. Under this monitoring contract, RTI annually provides a summary report of the contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute care hospital setting. We received RTI's 2014 report and made it available to the public on the CMS Hospital-Acquired Conditions Web page in the ''Downloads'' section at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/*.

Once we receive RTI's 2015 report in the late spring or early summer, we will make it available to the public at this same link as the 2014 report.

G. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

Providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. A later coding edition, the ICD–10 coding system, includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. The ICD–10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the ''ICD–10–CM and ICD–10–PCS final rule''). However, the Secretary of Health and Human Services issued a final rule that delayed the compliance date for ICD–10 from October 1, 2013, to October 1, 2014. That final rule, entitled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets,'' CMS–0040–F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf*. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf*. That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015.

The anticipated move to ICD–10 necessitated the development of an ICD–10–CM/ICD–10–PCS version of the MS–DRGs. CMS began a project to convert the ICD–9–CM-based MS–DRGs to ICD–10 MS–DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public comments on the creation of the ICD–10 version of the MS–DRGs, which will be implemented at the same time as ICD–10 (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this

information through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement their own conversion projects. We posted ICD–10 MS–DRGs based on Version 26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for other payers and providers to follow. Information on the ICD–10 MS–DRG conversion project can be found on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems, as well as the General Equivalence Mappings that assist in conversion through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

During FY 2011, we developed and posted Version 28 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

We reviewed public comments on the ICD–10 MS–DRGs Version 28 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28–R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28–R1 on our ICD–10 MS–DRG Conversion Project Web site. To make the review of Version 28–R1 updates easier for the public, we also made available pilot software on a CD–ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRGs Web page. We stated that we believed that, by providing the ICD–10 MS–DRGs Version 28–R1 Pilot Software (distributed on CD–ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28–R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29, based on the FY 2012 MS–DRGs (Version 29) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28 to Version 29 to facilitate a review. The ICD–10 MS–DRGs Version 29 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again, the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 30 based on the FY 2013 MS–DRGs (Version 30) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29 to Version 30 to facilitate a review. We produced mainframe and computer software for Version 30, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD–10 MS–DRG Conversion Project Web site. The ICD–10 MS–DRGs Version 30 computer software facilitated additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact of converting MS–DRGs to ICD–10. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper was posted on the CMS ICD–10 MS–DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee meeting. The paper described CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27 (FY 2010), which was converted to the ICD–10 MS–DRGs Version 27. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. At the March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update of the impact study was presented at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD–9–CM-based system to an ICD–10 MS–DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS–DRG when using an ICD–10 MS–DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher weighted MS–DRG, while 55 percent of the shifts were to lower weighted MS–DRGs. The net impact across all MS–DRGs was a reduction by 4/10000 or minus 4 pennies per $100. The updated paper is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Downloads'' section. Information on the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. This update of the impact paper and the ICD–10 MS–DRG Version 30 software provided additional information to the public who were evaluating the conversion of the MS–DRGs to ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 31.0 based on the FY 2014 MS–DRGs (Version 31) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a

Definitions Manual of the ICD–10 MS–DRGs Version 31 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 30 to Version 31 to facilitate a review. We produced mainframe and computer software for Version 31, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 31 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 31.

We reviewed public comments received and developed an update of ICD–10 MS–DRGs Version 31, which we called ICD–10 MS–DRGs Version 31.0–R. We made available a Definitions Manual of the ICD–10 MS–DRGs Version 31.0–R on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that describes changes made from Version 31 to Version 31–R to facilitate a review. We will continue to share ICD–10–MS–DRG conversion activities with the public through this Web site.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS–DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 31–R to Version 32 to facilitate a review. We produced mainframe and computer software for Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 32 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 32. We discuss five requests from the public to update the ICD–10 MS–DRGs Version 32 to better replicate the ICD–9–CM MS–DRGs in section II.G.3., 4., and 5. of the preamble of this proposed rule. Therefore, we are proposing to implement the MS–DRG code logic in the ICD–10 MS–DRGs Version 32 along with any finalized updates to the ICD–10 MS–DRGs Version 32 for the final ICD–10 MS–DRGs Version 33. In this FY 2016 IPPS/LTCH PPS proposed rule, we are proposing the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the proposed MS–DRG updates for FY 2016. We are inviting public comments on how well the ICD–10 MS–DRGs Version 32 replicates the logic of the MS–DRGs Version 32 based on ICD–9–CM codes.

b. Basis for Proposed FY 2016 MS–DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2016, comments and suggestions should have been submitted by December 7, 2014. The comments that were submitted in a timely manner for FY 2016 are discussed below in this section.

Following are the changes we are proposing to the MS–DRGs for FY 2016. We are inviting public comment on each of the MS–DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS–DRG classifications, which also are discussed below. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data. For this FY 2016 proposed rule, our MS–DRG analysis is based on claims data from the December 2014 update of the FY 2014 MedPAR file, which contains hospital bills received through September 30, 2014, for discharges occurring through September 30, 2014. In our discussion of the proposed MS–DRG reclassification changes that follows, we refer to our analysis of claims data from the ''December 2014 update of the FY 2014 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modification to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

2. MDC 1 (Diseases and Disorders of the Nervous System): Endovascular Embolization (Coiling) Procedures

We received a request again this year to change the MS–DRG assignment for endovascular embolization (coiling) procedures. This topic was discussed previously in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28005 through 28006) and in the FY 2015

IPPS/LTCH PPS final rule (79 FR 49883 through 49886). For FY 2015, we did not change the MS–DRG assignment for endovascular embolization (coiling) procedures.

After issuance of the FY 2015 IPPS/LTCH PPS final rule, we received a modified request from the commenter asking that CMS consider establishing four new MS–DRGs:

- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures with Principal Diagnosis of Hemorrhage);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with MCC);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with CC); and
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage without CC/MCC).

The requestor stated that these new suggested MS–DRGs will promote clinical cohesiveness and resource comparability. The requestor stated that endovascular intracranial and endovascular embolization procedures are not similar to the open craniotomy procedures with which they are currently grouped. The requestor asserted that the differences in costs between endovascular intracranial procedures and open craniotomy procedures are great, reflecting, for instance, the use of an operating suite versus interventional vascular catheterization lab suite, intensive care and other costs.

In conjunction with the recommended new MS–DRGs, the requestor recommended that the following ICD–9–CM codes, which include endovascular embolization procedures and additional intracranial procedures, be removed from MS–DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC); MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC); MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC); MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant); MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC); MS–DRG 025 (Craniotomy & Endovascular Intracranial Procedures with MCC); MS–DRG 026 (Craniotomy & Endovascular Intracranial Procedures with CC); and MS–DRG 027 (Craniotomy & Endovascular Intracranial Procedures without CC/MCC):

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
- 39.79 (Other endovascular procedures on other vessels).

The requestor asked that the four new requested MS–DRGs be created using these procedure codes. The requestor suggested that the first requested new MS–DRG would be MS–DRG XXX (Endovascular Intracranial Embolization Procedures with Principal Diagnosis of Hemorrhage). The principal diagnoses for hemorrhage would include the same hemorrhage codes in the current MS–DRGs 020, 021, and 022, which are as follows:

- 094.87 (Syphilitic ruptured cerebral aneurysm);
- 430 (Subarachnoid hemorrhage);
- 431 (Intracerebral hemorrhage);
- 432.0 (Nontraumatic extradural hemorrhage);
- 432.1 (Subdural hemorrhage); and
- 432.9 (Unspecified intracranial hemorrhage).

For this first new requested MS–DRG, the requestor suggested that only the following endovascular embolization procedure codes would be assigned:

- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils); and
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils).

The requestor recommended that the three additional new MS–DRGs would consist of a new base MS–DRG subdivided into three severity levels as follows:

- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with MCC);
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with CC); and
- Recommended MS–DRG XXX (Endovascular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage without CC/MCC).

The requestor suggested that these three new recommended MS–DRGs would have endovascular embolization procedures as well as additional percutaneous and endovascular procedures as listed below:

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
- 39.79 (Other endovascular procedures on other vessels).

ICD–10–PCS provides the following more detailed codes for endovascular embolization, which are assigned to MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027 in the ICD–10 MS–DRGs Version 32:

ICD–10–PCS Codes for Endovascular Embolization Assigned to MS–DRGs 020 Through 027 in ICD–10 MS–DRGs Version 32

ICD–10–PCS code	Code description
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 32—Continued

ICD–10–PCS code	Code description
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 32—Continued

ICD–10–PCS code	Code description
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

For this FY 2016 IPPS/LTCH PPS proposed rule request, we first examined claims data on all intracranial vascular procedure cases with a principal diagnosis of hemorrhage reported in MS–DRGs 020, 021, and 022 from the December 2014 update of the FY 2014 MedPAR file. The table below shows our findings. We found a total of 1,755 cases with an average length of stay ranging from 8.28 days to 16.84 days and average costs ranging from $36,998 to $71,665 in MS–DRGs 020, 021, and 022.

INTRACRANIAL VASCULAR PROCEDURES WITH PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020 (with MCC)—All cases	1,285	16.84	$71,655
MS–DRG 021 (with CC)—All cases	372	13.82	52,143
MS–DRG 022 (without CC/MCC)—All cases	98	8.28	36,998

Next, we examined claims data on the first part of the request, which was to create a new MS–DRG for endovascular intracranial embolization procedure cases with a principal diagnosis of hemorrhage that are currently reported in MS–DRGs 020, 021, and 022. Our findings for the first part of this multi-part request are shown in the table below.

ENDOVASCULAR INTRACRANIAL EMBOLIZATION PROCEDURES WITH PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
Requested New Combined MS–DRG	1,275	15.6	$67,831

The requestor suggested that this new requested base MS–DRG would not be subdivided by severity levels. Using the requested code logic, cases with a principal diagnosis of hemorrhage and procedure codes 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels), 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils), and 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils) would be moved out of MS–DRGs 020, 021, and 022 and into a single new MS–DRG with no severity levels.

As can be seen in the table above, the average costs for the new requested combined MS–DRG would be $67,831. The average costs for current MS–DRGs 020, 021, and 022 were $71,655, $52,143, and $36,998, respectively. Based on these findings, if we established this requested new MS–DRG, payments for those cases at the highest severity level (MS–DRG 020, which had average costs of $71,655) would be reduced. We believe that maintaining the current MS–DRG assignment for these types of procedures is appropriate. Our clinical advisors state that the current grouping of procedures within MS–DRGs 020, 021, and 022 reflects patients who are unique in terms of utilization and complexity based on the three severity levels, which are specifically designed to capture clinical differences in these patients, and these factors support maintaining the current structure. Therefore, we are not proposing to move cases with a principal diagnosis of hemorrhage and procedure codes 39.72, 39.75, and 39.76 out of MS–DRGs 020, 021, and 022 and create a new base MS–DRG. We are inviting public comments on this proposal.

As discussed previously, the requestor also recommended the creation of a new set of MS–DRGs for endovascular intracranial embolization procedures without a principal diagnosis of hemorrhage with MCC, with CC, and without CC/MCC. For these new requested MS–DRGs, the requestor suggested assignment of endovascular embolization procedures as well as certain other percutaneous and endovascular procedures. The complete list of endovascular intracranial embolization procedures developed by the requestor is as follows:

- 00.62 (Percutaneous angioplasty of intracranial vessel);
- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s));
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils);

• 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils); and
• 39.79 (Other endovascular procedures on other vessels)

The following table shows our findings from examination of claims data on endovascular intracranial procedures without a principal diagnosis of hemorrhage reported in MS–DRGs 023 through 027 from the December 2014 update of the FY 2014 MedPAR file.

ENDOVASCULAR INTRACRANIAL PROCEDURES WITHOUT PRINCIPAL DIAGNOSIS OF HEMORRHAGE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	5,615	10.96	$37,784
MS–DRG 023—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	1,510	8.88	39,666
MS–DRG 024—All cases	1,848	5.93	26,195
MS–DRG 024—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	867	5.80	27,975
MS–DRG 025—All cases	16,949	9.35	29,970
MS–DRG 025—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	650	8.52	44,082
MS–DRG 026—All cases	8,075	6.09	21,414
MS–DRG 026—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	778	3.07	26,594
MS–DRG 027—All cases	9,883	3.15	16,613
MS–DRG 027—Cases with endovascular intracranial procedure without diagnosis of hemorrhage	1,793	1.66	22,244

As can be seen from this table, if we created a new set of MS–DRGs recommended by the requester, most of the cases would have to be moved out of MS–DRGs 023 and 027. The 1,510 cases that would have to be moved out of MS–DRG 023 have average costs of $39,666 compared to average costs of $37,784 for all cases in MS–DRG 023. The average costs for these cases are not significantly different from the average costs for all cases in MS–DRG 023. The average length of stay for the cases with endovascular intracranial procedure without a diagnosis of hemorrhage in MS–DRG 023 is 8.88 compared to 10.96 days for all cases in MS–DRG 023. We believe that these data support the current MS–DRG assignment for MS–DRG 023. The 1,793 cases that would have to be moved out of MS–DRG 027 have average costs of $22,244 compared to the average costs of $16,613 for all cases in MS–DRG 027. While the average costs for these cases are higher than for all cases in MS–DRG 027, one would expect some procedures within an MS–DRG to have higher average costs and other procedures to have lower average costs than the overall average costs. Cases within the MS–DRGs describing endovascular intracranial procedures are grouped together based on similar clinical and resource criteria. Some cases will have average costs that are higher than the overall average costs for cases in the MS–DRG, while other cases will have lower average costs. These differences in average costs are found within all MS–DRGs. The average length of stay of MS–DRG 027 cases with endovascular intracranial procedure without a diagnosis of hemorrhage is 1.66 days as compared to 3.15 days for all cases in MS–DRG 027. Therefore, while the average costs are higher for the cases with endovascular intracranial procedure without a diagnosis of hemorrhage than for all cases in MS–DRG 027, the length of stay is shorter.

The 867 cases that would have to be moved out of MS–DRG 024 have average costs of $27,975 compared to average costs for all cases in MS–DRG 024 of $26,195. The average costs for these cases are not significantly different than the average costs for all cases in MS–DRG 024. The average length of stay for the 867 cases that would have to be moved out of MS–DRG 024 is 5.80 compared to 5.93 for all cases in MS–DRG 024. Therefore, the lengths of stay for the cases also are quite similar in MS–DRG 024. We have determined that these data findings support maintaining the current MS–DRG assignment of these procedures in MS–DRG 024.

MS–DRGs 025 and 026 show the smallest number of cases that would have to be moved to the requested new MS–DRGs, but these cases have larger differences in average costs. The average costs of cases that would have to be moved out of MS–DRG 025 are $44,082 compared to $29,970 for all cases in MS–DRG 025. The average length of stay for the MS–DRG 025 cases with endovascular intracranial procedure without a diagnosis of hemorrhage is 8.52 days as compared to 9.35 days for all cases in MS–DRG 025. Therefore, the lengths of stay are similar for cases in MS–DRG 025. The average costs of cases that would have to be moved out of MS–DRG 026 are $26,594 compared to $21,414 for all cases. The average length of stay for cases that would have to be moved out of MS–DRG 026 is 3.07 days compared to 6.09 days for all cases in MS–DRG 026, or almost half as long as for all cases in MS–DRG 026. As stated earlier, the average costs for cases that would be moved out of MS–DRGs 023, 024, 025, 026, and 027 under this request are higher than the average costs for all cases in these MS–DRGs, with most of the cases coming out of MS–DRGs 023 and 027. The average costs for these particular cases in MS–DRG 023 are not significantly different from the average costs for all cases in MS–DRG 023. In addition, while the average costs are higher for the cases with a endovascular intracranial procedure without a diagnosis of hemorrhage than for all cases in MS–DRG 027, the length of stay is shorter. We have determined that the overall data do not support making the requested MS–DRG updates to MS–DRGs 023, 024, 025, 026, and 027 and creating three new MS–DRGs. Therefore, we are not proposing to make changes to the current structure for MS–DRGs 023 through 027.

In summary, our clinical advisors reviewed each aspect of this multi-part request and advised us that the endovascular embolization procedures are appropriately assigned to MS–DRGs 020 through 027. They do not support removing the procedures (procedure codes 39.72, 39.75, and 39.76) from MS–DRGs 020, 021, and 022 and creating a single MS–DRG for endovascular intracranial embolization procedures

with a principal diagnosis of hemorrhage with no severity levels. Our clinical advisors stated that the current MS–DRG grouping of three severity levels captures differences in clinical severity, average costs, and length of stay for these patients appropriately. Our clinical advisors also recommended maintaining the current MS–DRG assignments for endovascular embolization and other percutaneous and endovascular procedures within MS–DRGs 023 through 027. They stated that these procedures are all clinically similar to others in these MS–DRGs. In addition, they stated that the surgical techniques are all designed to correct the same clinical problem, and they advised against moving a select number of those procedures out of MS–DRGs 023 through 027.

Based on the findings from our data analysis and the recommendations from our clinical advisors, we are not proposing to create the four new MS–DRGs for endovascular intracranial embolization and other endovascular procedures recommended by the requestor. We are proposing to maintain the current MS–DRG structure for MS–DRGs 020 through 027.

We are inviting public comments on these two proposals.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Adding Severity Levels to MS–DRGs 245 Through 251

During the comment period for the FY 2015 IPPS/LTCH PPS proposed rule, we received a comment that recommended establishing severity levels for MS–DRG 245 (AICD Generator Procedures) and including additional severity levels for MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule. Therefore, we did not address this comment in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider the public comment for possible proposals in future rulemaking as part of our annual review process.

For this FY 2016 IPPS/LTCH PPS proposed rule, we received a separate, but related, request involving most of these same MS–DRGs. Therefore, for this proposed rule, we conducted a simultaneous analysis of claims data to address both the FY 2015 public comment request and the related FY 2016 request. We discuss both of these requests below.

b. Percutaneous Intracardiac Procedures

We received a request to remove the cardiac ablation and other specified cardiovascular procedures from the following MS–DRGs, and to create new MS–DRGs to classify these procedures:

- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

The commenter stated that, historically, the MS–DRGs listed above appropriately reflected the differential cost of percutaneous transluminal coronary angioplasty (PTCA) procedures with and without stents. The commenter noted that PTCA procedures with drug eluting stents were previously paid the highest, followed by PTCA procedures with bare metal stents and PTCA procedures with no stents, respectively. However, the commenter believed that, in recent years, the opposite has begun to occur and cases reporting a PTCA procedure without a stent are being paid more than cases reporting a PTCA procedure with a stent. The commenter further noted that cardiac ablation procedures and PTCA procedures without stents are currently assigned to the same MS–DRGs, notwithstanding that the procedures have different clinical objectives and patient diagnoses. The commenter indicated that cardiac ablation procedures are performed on patients with multiple distinct cardiac arrhythmias to alter electrical conduction systems of the heart, and PTCA procedures are performed on patients with coronary atherosclerosis to open blocked coronary arteries. The commenter also noted that cardiac ablation procedures are performed in the heart chambers by cardiac electrophysiologists, require significantly more resources, and require longer periods of time to complete. Conversely, PTCA procedures are performed in the coronary vessels by interventional cardiologists, require the use of less equipment, and require a shorter period of time to complete. Therefore, the commenter suggested that CMS create new MS–DRGs for percutaneous intracardiac procedures to help improve clinical homogeneity by differentiating percutaneous intracardiac procedures (performed within the heart chambers) from percutaneous intracoronary procedures (performed within the coronary vessels). The commenter further believed that creating new MS–DRGs for these procedures would also better reflect the resource cost of specialized equipment used for more complex structures of electrical conduction systems when performing cardiac ablation procedures.

The following ICD–9–CM procedure codes identify and describe the cardiac ablation procedures and the other percutaneous intracardiac procedures that are currently classified under MS–DRGs 246 through 251 and that the commenter recommended that CMS assign to the newly created MS–DRGs:

- 35.52 (Repair of atrial septal defect with prosthesis, closed technique);
- 35.96 (Percutaneous balloon valvuloplasty);
- 35.97 (Percutaneous mitral valve repair with implant);
- 37.26 (Catheter based invasive electrophysiologic testing);
- 37.27 (Cardiac mapping);
- 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach);
- 37.36 (Excision, destruction, or exclusion of left atrial appendage (LAA)); and
- 37.90 (Insertion of left atrial appendage device).

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM procedure codes listed above that also are currently classified under MS–DRGs 246 through 251 based on the GROUPER Version 32 ICD–10 MS–DRGs. The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 35.52 are shown in the following table.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.52

ICD–10–PCS code	Code description
02U53JZ	Supplement atrial septum with synthetic substitute, percutaneous approach.
02U54JZ	Supplement atrial septum with synthetic substitute, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 35.96 are shown in the following table.

ICD–10–PCS TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.96

ICD–10–PCS code	Code description
027F34Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous approach.
027F3DZ	Dilation of aortic valve with intraluminal device, percutaneous approach.
027F3ZZ	Dilation of aortic valve, percutaneous approach.
027F44Z	Dilation of aortic valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027F4DZ	Dilation of aortic valve with intraluminal device, percutaneous endoscopic approach.
027F4ZZ	Dilation of aortic valve, percutaneous endoscopic approach.
027G34Z	Dilation of mitral valve with drug-eluting intraluminal device, percutaneous approach.
027G3DZ	Dilation of mitral valve with intraluminal device, percutaneous approach.
027G3ZZ	Dilation of mitral valve, percutaneous approach.
027G44Z	Dilation of mitral valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027G4DZ	Dilation of mitral valve with intraluminal device, percutaneous endoscopic approach.
027G4ZZ	Dilation of mitral valve, percutaneous endoscopic approach.
027H34Z	Dilation of pulmonary valve with drug-eluting intraluminal device, percutaneous approach.
027H3DZ	Dilation of pulmonary valve with intraluminal device, percutaneous approach.
027H3ZZ	Dilation of pulmonary valve, percutaneous approach.
027H44Z	Dilation of pulmonary valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027H4DZ	Dilation of pulmonary valve with intraluminal device, percutaneous endoscopic approach.
027H4ZZ	Dilation of pulmonary valve, percutaneous endoscopic approach.
027J34Z	Dilation of tricuspid valve with drug-eluting intraluminal device, percutaneous approach.
027J3DZ	Dilation of tricuspid valve with intraluminal device, percutaneous approach.
027J3ZZ	Dilation of tricuspid valve, percutaneous approach.
027J44Z	Dilation of tricuspid valve with drug-eluting intraluminal device, percutaneous endoscopic approach.
027J4DZ	Dilation of tricuspid valve with intraluminal device, percutaneous endoscopic approach.
027J4ZZ	Dilation of tricuspid valve, percutaneous endoscopic approach.

The ICD–10–PCS code translation for ICD–9–CM procedure code 35.97 is 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach.).

The ICD–10–PCS code translation for ICD–9–CM procedure code 37.26 is 4A023FZ (Measurement of cardiac rhythm, percutaneous approach.).

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.27 are shown in the following table.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.27

ICD–10–PCS code	Code description
02K83ZZ	Map conduction mechanism, percutaneous approach.
02K84ZZ	Map conduction mechanism, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.34 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.34

ICD–10–PCS code	Code description
02553ZZ	Destruction of atrial septum, percutaneous approach.
02563ZZ	Destruction of right atrium, percutaneous approach.
02573ZZ	Destruction of left atrium, percutaneous approach.
02583ZZ	Destruction of conduction mechanism, percutaneous approach.
02593ZZ	Destruction of chordae tendineae, percutaneous approach.
025F3ZZ	Destruction of aortic valve, percutaneous approach.
025G3ZZ	Destruction of mitral valve, percutaneous approach.
025H3ZZ	Destruction of pulmonary valve, percutaneous approach.
025J3ZZ	Destruction of tricuspid valve, percutaneous approach.
025K3ZZ	Destruction of right ventricle, percutaneous approach.
025L3ZZ	Destruction of left ventricle, percutaneous approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.34—Continued

ICD–10–PCS code	Code description
025M3ZZ	Destruction of ventricular septum, percutaneous approach.
02B53ZZ	Excision of atrial septum, percutaneous approach.
02B63ZZ	Excision of right atrium, percutaneous approach.
02B73ZZ	Excision of left atrium, percutaneous approach.
02B83ZZ	Excision of conduction mechanism, percutaneous approach.
02B93ZZ	Excision of chordae tendineae, percutaneous approach.
02BF3ZZ	Excision of aortic valve, percutaneous approach.
02BG3ZZ	Excision of mitral valve, percutaneous approach.
02BH3ZZ	Excision of pulmonary valve, percutaneous approach.
02BJ3ZZ	Excision of tricuspid valve, percutaneous approach.
02BM3ZZ	Excision of ventricular septum, percutaneous approach.
02T83ZZ	Resection of conduction mechanism, percutaneous approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.36 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.36

ICD–10–PCS code	Code description
02573ZK	Destruction of left atrial appendage, percutaneous approach.
02574ZK	Destruction of left atrial appendage, percutaneous endoscopic approach.
02B73ZK	Excision of left atrial appendage, percutaneous approach.
02B74ZK	Excision of left atrial appendage, percutaneous endoscopic approach.
02L73ZK	Occlusion of left atrial appendage, percutaneous approach.
02L74ZK	Occlusion of left atrial appendage, percutaneous endoscopic approach.

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.90 are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.90

ICD–10–PCS code	Code description
02L73CK	Occlusion of left atrial appendage with extraluminal device, percutaneous approach.
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach.
02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach.
02L74DK	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach.

The ICD–10–PCS code translations listed above, along with their respective MS–DRG assignments, can be found in the ICD–10 MS–DRGs Version 32 Definitions Manual posted on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.*

As mentioned earlier, we received a separate, but related, request to add severity levels to MS–DRGs 246 through 251. We address this request at the end of this section.

To address the first of these separate, but related, requests, we reviewed claims data for MS–DRGs 246 through 251 from the December 2014 update of the FY 2014 MedPAR file. Our findings are shown in the following table:

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 246—All cases	30,617	5.52	$23,855
MS–DRG 246—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	244	9.69	$34.099
MS–DRG 247—All cases	79,639	2.69	$15,671
MS–DRG 247—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	260	5.20	$25,797
MS–DRG 248—All cases	9,310	6.37	$22,504
MS–DRG 248 –Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	125	10.76	$33,521
MS–DRG 249—All cases	16,273	3.08	$14,066
MS–DRG 249—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	81	5.12	$23,710
MS–DRG 250—All cases	9,275	7.07	$22,902

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250– Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	5,826	7.90	$24,841
MS–DRG 251—All cases	20,945	3.25	$15,757
MS–DRG 251—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	14,436	3.39	$17,290

As shown in the table above, there were a total of 30,617 cases in MS–DRG 246, with an average length of stay of 5.52 days and average costs of $23,855. For cases reporting a percutaneous intracardiac procedure in MS–DRG 246 (ICD–9–CM procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90), there were a total of 244 cases, with an average length of stay of 9.69 days and average costs of $34,099. For MS–DRGs 247 through 251, a similar pattern was identified; the data reflected that the average costs are higher and the average length of stay is greater for cases reporting a percutaneous intracardiac procedure in comparison to the average costs and average length of stay for all of the cases in their respective MS–DRGs.

As reflected in the following table, a further analysis of the data showed that percutaneous intracardiac procedures represent a total of 20,972 cases in MS–DRGs 246 through 251, with a greater average length of stay (4.79 days versus 3.62 days) and higher average costs ($19,810 versus $17,532) in comparison to all of the remaining cases in MS–DRGs 246 through 251.

SUMMARY OF PERCUTANEOUS CARDIOVASCULAR DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 246 through 251—Cases with procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	20,972	4.79	$19,810
MS–DRGs 246 through 251—Cases without procedure codes 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, and 37.90	145,087	3.62	17,532

The results of these data analyses support removing procedures performed within the heart chambers using intracardiac techniques from MS–DRGs 246 through 251, and assigning these procedures to separate MS–DRGs. The results of these data analyses also support subdividing these MS–DRGs using the ''with MCC'' and ''without MCC'' severity levels based on the application of the criteria established in the FY 2008 IPPS final rule (72 FR 47169), and described in section II.G.1.b. of the preamble of this proposed rule, that must be met to warrant the creation of a CC or an MCC subgroup within a base MS–DRG. Our clinical advisors also agree that this differentiation would improve the clinical homogeneity of these MS–DRGs by separating percutaneous intracardiac procedures (performed within the heart chambers) from percutaneous intracoronary procedures (performed within the coronary vessels). In addition, we believe that creating these new MS–DRGs would better reflect the resource cost of specialized equipment used to perform more complex structures of electrical conduction systems during cardiac ablation procedures. Therefore, for FY 2016, we are proposing to create two new MS–DRGs to classify percutaneous intracardiac procedures. Specifically, we are proposing to create MS–DRG 273, entitled ''Percutaneous Intracardiac Procedures with MCC,'' and MS–DRG 274, entitled ''Percutaneous Intracardiac Procedures without MCC,'' and to assign the procedures performed within the heart chambers using intracardiac techniques to the two proposed new MS–DRGs. We are proposing that existing percutaneous intracoronary procedures with and without stents continue to be assigned to the other MS–DRGs to reflect that those procedures are performed within the coronary vessels and require fewer resources.

The table below represents the distribution of cases, average length of stay, and average costs for these proposed two new MS–DRGs.

PROPOSED NEW MS–DRGS FOR PERCUTANEOUS INTRACARDIAC PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed MS–DRG 273 with MCC	6,195	8.03	$25,380
Proposed MS–DRG 274 without MCC	14,777	3.44	17,475

We are inviting public comments on our proposal to create the two new MS–DRGs for percutaneous intracardiac procedures for FY 2016. In addition, we are inviting public comments on the ICD–10–PCS code translations that were presented earlier in this section and our proposal to assign these procedure codes to the proposed new MS–DRGs 273 and 274.

As mentioned earlier in this section, we received a similar request in

response to the FY 2015 IPPS/LTCH PPS proposed rule to add severity levels to MS–DRGs 246 through 251. We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule. Therefore, we did not address this comment in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider the public comment for possible proposals in future rulemaking as part of our annual review process. Specifically, the commenter recommended including additional severity levels for MS–DRGs 246 through 251 and establishing severity levels for MS–DRG 245 (AICD Generator Procedures).

For our data analysis for this recommendation, we examined claims data from the December 2014 update of the FY 2014 MedPAR file to determine if including additional severity levels in MS–DRGs 246 through 251 was warranted. During our analysis, we applied the criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.G.1.b. of the preamble of this proposed rule. As shown in the table below, we collapsed MS–DRGs 246 through 251 into base MS–DRGs (MS–DRGs 246, 248, and 250) by suggested severity level and applied the criteria.

Percutaneous cardiovascular MS–DRG with and without stent procedures by suggested severity level	Number of cases	Average length of stay	Average costs
Suggested MS–DRG 246 with MCC	30,617	5.52	$23,855
Suggested MS–DRG 246 with CC	45,313	2.96	16,233
Suggested MS–DRG 246 without CC/MCC	34,326	2.33	14,928
Suggested MS–DRG 248 with MCC	9,310	6.37	22,504
Suggested MS–DRG 248 with CC	9,510	3.49	14,798
Suggested MS–DRG 248 without CC/MCC	6,763	2.51	13,037
Suggested MS–DRG 250 with MCC	9,275	7.07	22,903
Suggested MS–DRG 250 with CC	11,653	3.80	16,113
Suggested MS–DRG 250 without CC/MCC	9,292	2.56	15,310

We found that the criterion that there be a $2,000 difference in average costs between subgroups was not met. Specifically, between the ''with CC'' and ''without CC/MCC'' subgroups for base MS–DRG 246, the difference in average costs was only $1,305; for base MS–DRG 248, the difference in average costs was only $1,761; and for base MS–DRG 250, the difference in average costs was only $803. The results of the data analysis of MS–DRGs 246 through 251 confirmed, and our clinical advisors agreed, that the existing 2-way severity level splits for these MS–DRGs (with MCC and without MCC) are appropriate, as displayed in the table below.

PERCUTANEOUS CARDIOVASCULAR MS–DRGS WITH AND WITHOUT STENTS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 246—All cases	30,617	5.52	$23,855
MS–DRG 247—All cases	79,639	2.69	15,671
MS–DRG 248—All cases	9,310	6.37	22,504
MS–DRG 249—All cases	16,273	3.08	14,066
MS–DRG 250—All cases	9,275	7.07	22,903
MS–DRG 251—All cases	20,945	3.25	15,757

Therefore, we are not proposing to further subdivide the severity levels for MS–DRGs 246 through 251. We are inviting public comments on our proposal not to create additional severity levels for MS–DRGs 246 through 251.

Using the same MedPAR claims data for FY 2014, we separately examined cases in MS–DRG 245 to determine whether to subdivide this MS–DRG into severity levels. As displayed in the table below, the results of the FY 2014 data analysis showed there were a total of 1,699 cases, with an average length of stay of 5.49 days and average costs of $34,287, in MS–DRG 245.

AICD GENERATOR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245—All cases	1,699	5.49	$34,287

We applied the five criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.G.1.b. of the preamble of this proposed rule, to determine if it was appropriate to subdivide MS–DRG 245 into severity levels. The table below illustrates our findings.

AICD generator procedures by suggested severity level	Number of cases	Average length of stay	Average costs
Suggested MS–DRG 245 with MCC	542	8.15	$40,004

AICD generator procedures by suggested severity level	Number of cases	Average length of stay	Average costs
Suggested MS–DRG 245 with CC	939	4.51	32,237
Suggested MS–DRG 245 without CC/MCC	218	3.12	28,907

Based on the analysis of the FY 2014 claims data for MS–DRG 245, the results support creating a ''with MCC'' and a ''without MCC'' severity level split. Our clinical advisors indicated that it would not be clinically appropriate to add severity levels based on an isolated year's data fluctuation because this could lead to a lack of stability in MS–DRG payments. We agree with our clinical advisors and note that we annually conduct an analysis of base MS–DRGs to evaluate if additional severity levels are warranted. This analysis includes 2 years of MedPAR claims data to specifically compare data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation. Generally, in past years, for our review of requests to add or establish severity levels, in our analysis of the most recent claims data, there was at least one criterion that was not met. Therefore, it was not necessary to further analyze data beyond 1 year. However, the results of our analysis of claims data in the December 2014 update of the FY 2014 MedPAR file for this particular request involving MS–DRG 245 demonstrate that all five criteria to establish subgroups were met, and, therefore, it was necessary to also examine the FY 2013 MedPAR claims data file.

The results of our analysis from the December 2013 update of the FY 2013 claims data for MS–DRG 245 are shown in the table below.

AICD GENERATOR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245—All cases	1,850	4.81	$33,272

The FY 2013 claims data for MS–DRG 245 do not support creating any severity levels because the data did not meet one or more of the five required criteria for creating new severity levels. The data did not meet the requirement for a 3-way severity level split (with MCC, with CC, and without CC/MCC) or a 2-way severity level split (with MCC and without MCC) because there were not at least 500 cases in the MCC subgroup. While the data did meet this particular criterion for the 2-way severity level split of ''with CC/MCC'' and ''without CC/MCC'' because there were at least 500 cases in the CC subgroup, the data did not meet the criterion that there be at least a 20-percent difference in average costs between subgroups, as shown in the table below.

AICD GENERATOR PROCEDURES

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245 with MCC	44	7.32	$39,536
MS–DRG 245 with CC	1,118	4.26	31,786
MS–DRG 245 without CC/MCC	288	3.10	29,383

As stated previously, we believe that 2 years of data showing that the requested CC or MCC subgroup meets all five of the established criteria for creating severity levels are needed in order to support a proposal to add severity levels for MS–DRG 245. Our clinical advisors also agree that it would not be clinically appropriate to add severity levels based on an isolated year's data fluctuation because this could lead to a lack of stability in payments. Therefore, we are not proposing to add severity levels for MS–DRG 245 for FY 2016. We are inviting public comments on the results of our analysis and our proposal not to create severity levels for MS–DRG 245.

c. Zilver® PTX Drug-Eluting Peripheral Stent (Zilver® PTX®)

Zilver® PTX Drug-Eluting Peripheral Stent (Zilver® PTX®) was approved for new technology add-on payments in FY 2014 (78 FR 50583 through 50585). Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of superficial femoral artery).

We received a request from the manufacturer for an extension of new technology add-on payments for Zilver® PTX® in FY 2016. In the request, the manufacturer asked CMS to consider three options for procedure code 00.60 for FY 2016. The first option was to extend the new technology add-on payment through FY 2016. The request to extend the new technology add-on payment is addressed in section II.I.3.e. of the preamble of this proposed rule. The second option was to establish a new family of MS–DRGs for drug-eluting stents used in the peripheral (noncoronary) vasculature. The third option was to assign all Zilver® PTX® cases to MS–DRG 252 even if there is no MCC (which would necessitate revising the MS–DRG title to ''Other Vascular Procedures).

ICD–10–PCS provides the following more detailed procedure codes for the insertion of drug-eluting stents of superficial femoral artery:

- 047K04Z (Dilation of right femoral artery with drug-eluting intraluminal device, open approach);

- 047K34Z (Dilation of right femoral artery with drug-eluting intraluminal device, percutaneous approach);
- 047K44Z (Dilation of right femoral artery with drug-eluting intraluminal device, percutaneous endoscopic approach);
- 047L04Z (Dilation of left femoral artery with drug-eluting intraluminal device, open approach);
- 047L34Z (Dilation of left femoral artery with drug-eluting intraluminal device, percutaneous approach); and
- 047L44Z (Dilation of left femoral artery with drug-eluting intraluminal device, percutaneous endoscopic approach).

We examined claims data for the drug-eluting peripheral stent procedures cases reported in the December 2014 update of the FY 2014 MedPAR file for MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively). The following table illustrates our findings.

DRUG-ELUTING PERIPHERAL STENT PROCEDURES

MS–DRGs	Number of cases	Average length of stay	Average costs
MS–DRG 252—All cases	30,696	7.89	$23,935
MS–DRG 252—Cases with procedure code 00.60	133	9.08	32,623
MS–DRG 253—All cases	34,746	5.68	19,030
MS–DRG 253—Cases with procedure code 00.60	353	4.99	25,396
MS–DRG 254—All cases	15,394	2.99	12,629
MS–DRG 254—Cases with procedure code 00.60	115	2.62	21,461

Our findings show that there were only 601 peripheral angioplasty cases with a drug-eluting stent reported. Of the 601 peripheral angioplasty cases with a drug-eluting stent, 133 cases were in MS–DRG 252, 353 cases were in MS–DRG 253, and 115 cases were in MS–DRG 254. The average costs for the drug-eluting stent cases in MS–DRGs 252, 253, and 254 were $32,623, $25,396, and $21,461, respectively. The average costs for all cases in MS–DRGs 252, 253, and 254 were $23,935, $19,030, and $12,629, respectively. The average costs for the drug-eluting stent cases in MS–DRG 253 ($25,396) were higher than the average costs for all cases in MS–DRG 252 ($23,935). However, the average costs for the drug-eluting stent cases in MS–DRG 254 ($21,461) were lower than the average costs for all cases in MS–DRG 252 ($23,935).

We have determined that the small number of cases (601) does not provide justification to create a new set of MS–DRGs specifically for angioplasty of peripheral arteries using drug-eluting stents. In addition, the data do not support assigning all the drug-eluting stent cases to the highest severity level (MS–DRG 252), even when there is not an MCC, because the average costs for the drug-eluting stent cases in MS–DRG 254 ($21,461) were lower than the average costs for all cases in MS–DRG 252 ($23,935). The average length of stay for drug-eluting stent cases in MS–DRG 254 was 2.62 days compared to 7.89 days for all cases in MS–DRG 252. Cases are grouped together based on similar clinical and resource criteria.

Our clinical advisors recommended making no MS–DRG updates for peripheral angioplasty cases with a drug-eluting stent and considered the current MS–DRG assignment appropriate. Our clinical advisors agreed that the small number of peripheral angioplasty cases with a drug-eluting stent does not support creating a new MS–DRG for this specific type of treatment. They stated that the cases are clinically similar to other cases within MS–DRGs 252, 253, and 254. Considering the data for peripheral angioplasty cases with a drug-eluting stent found reported in MS–DRGs 252, 253, and 254 and the input from our clinical advisors, we are not proposing to make any MS–DRG updates for peripheral angioplasty cases with a drug-eluting stent. We are proposing to maintain the current MS–DRG assignments for these cases in MS–DRGs 252, 253, and 254. We are inviting public comments on our proposal.

d. Percutaneous Mitral Valve Repair System—Proposed Revision of ICD–10–PCS Version 32 Logic

We received a comment which brought to our attention that the ICD–10 MS–DRGs Version 32 assignment for ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) does not accurately replicate the ICD–9–CM MS–DRGs Version 32, which assign this procedure code to the following MS–DRGs:

- MS–DRG 231 (Coronary Bypass with PTCA with MCC);
- MS–DRG 232 (Coronary Bypass with PTCA without MCC);
- MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents);
- MS DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC);
- MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC); and
- MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC).

We agree with the commenter that the ICD–10 MS–DRGs logic should be consistent with the ICD–9 MS–DRGs logic; that is, the ICD–10 MS–DRGs Version 32 should replicate the ICD–9–CM MS–DRGs Version 32. Therefore, for the proposed FY 2016 ICD–10 MS–DRGs Version 33, we are proposing to assign ICD–10–PCS procedure code 02UG3JZ to MS–DRGs 231 and 232 and MS–DRGs 246 through 251. We are inviting public comments on this proposal.

e. Major Cardiovascular Procedures: Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Graft

The new technology add-on payment for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Graft (Zenith® F. Graft) will end on September 30, 2015. Cases involving the Zenith® F. Graft are identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) in MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively). For additional information on the Zenith® F. Graft, we refer readers to the

FY 2015 IPPS/LTCH PPS final rule (79 FR 49921 through 49922).

We received a request to reassign procedure code 39.78 to the highest severity level in MS–DRGs 237 and 238, including in instances when there is not an MCC present, or to create a new MS–DRG that would contain all endovascular aneurysm repair procedures. We note that, in addition to procedure code 39.78, ICD–9–CM procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta) also describes endovascular aneurysm repair procedures.

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of ICD–9–CM codes 39.71 and 39.78 that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.71 and 39.78 are shown in the following tables:

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 39.71

ICD–10–PCS code	Code description
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 39.78

ICD–10–PCS code	Code description
04793DZ	Dilation of right renal artery with intraluminal device, percutaneous approach.
04794DZ	Dilation of right renal artery with intraluminal device, percutaneous endoscopic approach.
047A3DZ	Dilation of left renal artery with intraluminal device, percutaneous approach.
047A4DZ	Dilation of left renal artery with intraluminal device, percutaneous endoscopic approach.
04753DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous approach.
04754DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

We analyzed claims data reporting procedure code 39.78 for cases assigned to MS–DRGs 237 and 238 in the December 2014 update of the FY 2014 MedPAR file. We found a total of 18,340 cases, with an average length of stay of 9.46 days and average costs of $36,355 in MS–DRG 237. We found 332 cases reporting procedure code 39.78, with an average length of stay of 8.46 days and average costs of $51,397 in MS–DRG 237. For MS–DRG 238, we found a total of 32,227 cases, with an average length of stay of 3.72 days and average costs of $25,087. We found 1,927 cases reporting procedure code 39.78, with an average length of stay of 2.52 days and average costs of $31,739 in MS–DRG 238.

Zenith Fenestrated Graft Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	18,340	9.46	$36,355
MS–DRG 237—Cases with procedure code 39.78	332	8.46	51,397
MS–DRG 238—All cases	32,227	3.72	25,087
MS–DRG 238—Cases with procedure code 39.78	1,927	2.52	31,739

As illustrated in the table above, the results of the data analysis indicate that the average costs for cases reporting procedure code 39.78 assigned to MS–DRG 238 were higher than the average costs for all cases in MS–DRG 238 ($3l,739 compared to $25,087). In addition, the average costs for the 1,927 cases reporting procedure code 39.78 assigned to MS–DRG 238 were $4,616 less than the costs of all cases assigned to MS–DRG 237. We determined that moving cases reporting procedure code 39.78 from MS–DRG 238 to MS–DRG 237 would result in overpayments. We also note that the average length of stay for the 1,927 cases reporting procedure code 39.78 in MS–DRG 238 was 2.52 days in comparison to the average length of stay for all cases in MS–DRG 237 of 9.46 days. Our clinical advisors do not agree with moving cases reporting procedure code 39.78 to a higher severity level (with MCC) MS–DRG.

We believe that the higher average costs could be attributed to the cost of the device. The Zenith® F. Graft is the only fenestrated graft device currently approved by the FDA. Therefore, this manufacturer is able to set its own costs in the market. We point out that the IPPS is not designed to pay solely for the cost of devices. More importantly, moving cases that greatly differ in their severity of illness and complexity of resources into a higher severity level MS–DRG, in the absence of an MCC, would conflict with the objective of the MS–DRGs, which is to maintain homogeneous subgroups that are different from one another in terms of utilization of resources, that have enough volume to be meaningful, and that improve our ability to explain variance in resource use (72 FR 47169). Therefore, we are not proposing to reassign all cases reporting procedure code 39.78 from MS–DRG 238 to MS–DRG 237, as the commenter requested.

However, we recognize that the results of the data analysis also demonstrated that the average costs for cases reporting procedure code 39.78 are higher in both MS–DRG 237 and MS–DRG 238 in comparison to all cases in each respective MS–DRG. As these

higher average costs could be attributable to the cost of the device, we note the commenter's concern that the end of the new technology add-on payment for Zenith® F. Graft, effective September 30, 2015, may result in reduced payment to hospitals and potentially lead to issues involving access to care for the subset of beneficiaries who would benefit from treatment with the Zenith® F. Graft. We continued to review the data to explore other alternatives as we analyzed additional claims data in response to the second part of the request from the commenter; that is, to create a new MS–DRG that would contain all endovascular aneurysm repair procedures.

In our evaluation of the claims data in response to the request to create a new MS–DRG, we again reviewed claims data from the December 2014 update of the FY 2014 MedPAR file. We began our analysis by examining claims data for cases reporting procedure codes 39.71 and 39.78 assigned to MS–DRGs 237 and 238. Our findings are shown in the table below.

ENDOVASCULAR ABDOMINAL AORTA PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	18,340	9.46	$36,355
MS–DRG 237—Cases with procedure codes 39.71 and 39.78	2,425	8.34	47,363
MS–DRG 238—All cases	32,227	3.72	25,087
MS–DRG 238—Cases with procedure codes 39.71 and 39.78	16,502	2.27	28,998

As shown in the table above, the average costs for endovascular abdominal aorta aneurysm repair procedures assigned to MS–DRG 237 were higher than the average costs of all cases assigned to MS–DRGs 237. The average costs for cases reporting procedure codes 39.71 and 39.78 assigned to MS–DRG 237 were $47,363 compared to the average costs of $36,355 for all cases assigned to MS–DRG 237 and $25,087 for all cases assigned to MS–DRG 238. Similarly, the average costs for cases reporting procedure codes 39.71 and 39.78 assigned to MS–DRG 238 were higher than the average costs of all cases assigned to MS–DRG 238 ($28,998 compared to $25,087). The average length of stay for cases reporting procedure codes 39.71 and 39.78 in MS–DRGs 237 and 238 were also shorter than the average length of stay for all cases in the respective MS–DRG.

Our clinical advisors did not support creating a new MS–DRG specifically for endovascular abdominal aortic aneurysm repair procedures only. Therefore, we reviewed other procedure codes currently assigned to MS–DRGs 237 and 238 and found that there were a number of procedures with varying resource requirements and clinical indications that could be analyzed further. We agreed with our clinical advisors that further analysis was warranted to determine how we could better recognize resource utilization, clinical complexity, and average costs by separating the more complex, more invasive, and more expensive procedures used to treat more severely ill individuals from the less complex, less invasive, and less expensive procedures currently grouped to these MS–DRGs.

Therefore, we evaluated all of the procedures currently assigned to MS–DRGs 237 and 238. In our evaluation, we found that MS–DRGs 237 and 238 contained two distinct groups of procedures. We found a high volume of less invasive procedures, such as pericardiotomies and pulsation balloon implants, that had substantially lower costs than the more invasive procedures, such as open and endovascular repairs of the aorta with replacement grafts. We found that the more invasive procedures were primarily associated with procedures on the aorta and heart assist procedures.

For this next phase of our analysis, the following procedure codes were designated as the more complex, more invasive procedures:

- 37.41 (Implantation of prosthetic cardiac support device around the heart);
- 37.49 (Other repair of heart and pericardium);
- 37.55 (Removal of internal biventricular heart replacement system);
- 37.64 (Removal of external heart assist system(s) or device(s));
- 38.04 (Incision of vessel, aorta);
- 38.14 (Endarterectomy, aorta);
- 38.34 (Resection of vessel with anastomosis, aorta);
- 38.44 (Resection of vessel with replacement, aorta, abdominal);
- 38.64 (Other excision of vessels, aorta, abdominal);
- 38.84 (Other surgical occlusion of vessels, aorta, abdominal);
- 39.24 (Aorta-renal bypass);
- 39.71 (Endovascular implantation of other graft in abdominal aorta); and
- 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta).

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM codes listed above that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for these ICD–9–CM procedure codes are shown in the following table:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.41

ICD–10–PCS code	Code description
02UA0JZ	Supplement heart with synthetic substitute, open approach.
02UA3JZ	Supplement heart with synthetic substitute, percutaneous approach.
02UA4JZ	Supplement heart with synthetic substitute, percutaneous endoscopic approach.

For the ICD–9–CM codes that result in greater than 50 ICD–10–PCS comparable code translations, we refer readers to Table 6P (ICD–10–PCS Code Translations for Proposed MS–DRG Changes) for this proposed rule (which

is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The table includes the MDC topic, the ICD–9–CM code, and the ICD–10–PCS code translations.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 37.49

ICD–10–PCS code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 37.49 are shown in Table 6P.1a that is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 37.55

ICD–10–PCS code	Code description
02PA0QZ	Removal of implantable heart assist system from heart, open approach.
02PA3QZ	Removal of implantable heart assist system from heart, percutaneous approach.
02PA4QZ	Removal of implantable heart assist system from heart, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 37.64

ICD–10–PCS code	Code description
02PA0RZ	Removal of external heart assist system from heart, open approach.
02PA3RZ	Removal of external heart assist system from heart, percutaneous approach.
02PA4RZ	Removal of external heart assist system from heart, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 38.04

ICD–10–PCS code	Code description
02CW0ZZ	Extirpation of matter from thoracic aorta, open approach.
02CW3ZZ	Extirpation of matter from thoracic aorta, percutaneous approach.
02CW4ZZ	Extirpation of matter from thoracic aorta, percutaneous endoscopic approach.
04C00ZZ	Extirpation of matter from abdominal aorta, open approach.
04C03ZZ	Extirpation of matter from abdominal aorta, percutaneous approach.
04C04ZZ	Extirpation of matter from abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 38.14

ICD–10–PCS code	Code description
02CW0ZZ	Extirpation of matter from thoracic aorta, open approach.
02CW3ZZ	Extirpation of matter from thoracic aorta, percutaneous approach.
02CW4ZZ	Extirpation of matter from thoracic aorta, percutaneous endoscopic approach.
04C00ZZ	Extirpation of matter from abdominal aorta, open approach.
04C03ZZ	Extirpation of matter from abdominal aorta, percutaneous approach.
04C04ZZ	Extirpation of matter from abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 38.34

ICD–10–PCS code	Code description
02BW0ZZ	Excision of thoracic aorta, open approach.
02BW4ZZ	Excision of thoracic aorta, percutaneous endoscopic approach.
04B00ZZ	Excision of abdominal aorta, open approach.
04B04ZZ	Excision of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS Code Translations for ICD–9–CM Procedure Code 38.44

ICD–10–PCS code	Code description
04R007Z	Replacement of abdominal aorta with autologous tissue substitute, open approach.
04R00JZ	Replacement of abdominal aorta with synthetic substitute, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.44—Continued

ICD–10–PCS code	Code description
04R00KZ	Replacement of abdominal aorta with nonautologous tissue substitute, open approach.
04R047Z	Replacement of abdominal aorta with autologous tissue substitute, percutaneous endoscopic approach.
04R04JZ	Replacement of abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04R04KZ	Replacement of abdominal aorta with nonautologous tissue substitute, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.64

ICD–10–PCS code	Code description
04500ZZ	Destruction of abdominal aorta, open approach.
04503ZZ	Destruction of abdominal aorta, percutaneous approach.
04504ZZ	Destruction of abdominal aorta, percutaneous endoscopic approach.
04B00ZZ	Excision of abdominal aorta, open approach.
04B03ZZ	Excision of abdominal aorta, percutaneous approach.
04B04ZZ	Excision of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.84

ICD–10–PCS code	Code description
04L00CZ	Occlusion of abdominal aorta with extraluminal device, open approach.
04L00DZ	Occlusion of abdominal aorta with intraluminal device, open approach.
04L00ZZ	Occlusion of abdominal aorta, open approach.
04L03CZ	Occlusion of abdominal aorta with extraluminal device, percutaneous approach.
04L03DZ	Occlusion of abdominal aorta with intraluminal device, percutaneous approach.
04L03ZZ	Occlusion of abdominal aorta, percutaneous approach.
04L04CZ	Occlusion of abdominal aorta with extraluminal device, percutaneous endoscopic approach.
04L04DZ	Occlusion of abdominal aorta with intraluminal device, percutaneous endoscopic approach.
04L04ZZ	Occlusion of abdominal aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.24

ICD–10–PCS code	Code description
0410093	Bypass abdominal aorta to right renal artery with autologous venous tissue, open approach.
0410094	Bypass abdominal aorta to left renal artery with autologous venous tissue, open approach.
0410095	Bypass abdominal aorta to bilateral renal artery with autologous venous tissue, open approach.
04100A3	Bypass abdominal aorta to right renal artery with autologous arterial tissue, open approach.
04100A4	Bypass abdominal aorta to left renal artery with autologous arterial tissue, open approach.
04100A5	Bypass abdominal aorta to bilateral renal artery with autologous arterial tissue, open approach.
04100J3	Bypass abdominal aorta to right renal artery with synthetic substitute, open approach.
04100J4	Bypass abdominal aorta to left renal artery with synthetic substitute, open approach.
04100J5	Bypass abdominal aorta to bilateral renal artery with synthetic substitute, open approach.
04100K3	Bypass abdominal aorta to right renal artery with nonautologous tissue substitute, open approach.
04100K4	Bypass abdominal aorta to left renal artery with nonautologous tissue substitute, open approach.
04100K5	Bypass abdominal aorta to bilateral renal artery with nonautologous tissue substitute, open approach.
04100Z3	Bypass abdominal aorta to right renal artery, open approach.
04100Z4	Bypass abdominal aorta to left renal artery, open approach.
04100Z5	Bypass abdominal aorta to bilateral renal artery, open approach.
0410493	Bypass abdominal aorta to right renal artery with autologous venous tissue, percutaneous endoscopic approach.
0410494	Bypass abdominal aorta to left renal artery with autologous venous tissue, percutaneous endoscopic approach.
0410495	Bypass abdominal aorta to bilateral renal artery with autologous venous tissue, percutaneous endoscopic approach.
04104A3	Bypass abdominal aorta to right renal artery with autologous arterial tissue, percutaneous endoscopic approach.
04104A4	Bypass abdominal aorta to left renal artery with autologous arterial tissue, percutaneous endoscopic approach.
04104A5	Bypass abdominal aorta to bilateral renal artery with autologous arterial tissue, percutaneous endoscopic approach.
04104J3	Bypass abdominal aorta to right renal artery with synthetic substitute, percutaneous endoscopic approach.
04104J4	Bypass abdominal aorta to left renal artery with synthetic substitute, percutaneous endoscopic approach.
04104J5	Bypass abdominal aorta to bilateral renal artery with synthetic substitute, percutaneous endoscopic approach.
04104K3	Bypass abdominal aorta to right renal artery with nonautologous tissue substitute, percutaneous endoscopic approach.
04104K4	Bypass abdominal aorta to left renal artery with nonautologous tissue substitute, percutaneous endoscopic approach.
04104K5	Bypass abdominal aorta to bilateral renal artery with nonautologous tissue substitute, percutaneous endoscopic approach.
04104Z3	Bypass abdominal aorta to right renal artery, percutaneous endoscopic approach.
04104Z4	Bypass abdominal aorta to left renal artery, percutaneous endoscopic approach.
04104Z5	Bypass abdominal aorta to bilateral renal artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.71

ICD–10–PCS code	Code description
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.78

ICD–10–PCS code	Code description
04793DZ	Dilation of right renal artery with intraluminal device, percutaneous approach.
04794DZ	Dilation of right renal artery with intraluminal device, percutaneous endoscopic approach.
047A3DZ	Dilation of left renal artery with intraluminal device, percutaneous approach.
047A4DZ	Dilation of left renal artery with intraluminal device, percutaneous endoscopic approach.
04753DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous approach.
04754DZ	Dilation of superior mesenteric artery with intraluminal device, percutaneous endoscopic approach.
04U03JZ	Supplement abdominal aorta with synthetic substitute, percutaneous approach.
04U04JZ	Supplement abdominal aorta with synthetic substitute, percutaneous endoscopic approach.
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V04DZ	Restriction of abdominal aorta with intraluminal device, percutaneous endoscopic approach.

For the next phase of our analysis, the procedure codes shown in the following table were designated as the less complex, less invasive procedures.

ICD–9–CM PROCEDURE CODES THAT WERE DESIGNATED AS THE LESS COMPLEX, LESS INVASIVE PROCEDURES

ICD–9–CM procedure code	Code description
35.00	Closed heart valvotomy, unspecified valve.
35.01	Closed heart valvotomy, aortic valve.
35.02	Closed heart valvotomy, mitral valve.
35.03	Closed heart valvotomy, pulmonary valve.
35.04	Closed heart valvotomy, tricuspid valve.
37.12	Pericardiotomy.
37.24	Biopsy of pericardium.
37.31	Pericardiectomy.
37.61	Implant of pulsation balloon.
37.67	Implantation of cardiomyostimulation system.
37.91	Open chest cardiac massage.
37.99	Other operations on heart and pericardium.
38.05	Incision of vessel, other thoracic vessels.
38.06	Incision of vessel, abdominal arteries.
38.07	Incision of vessel, abdominal veins.
38.15	Endarterectomy, other thoracic vessels.
38.16	Endarterectomy, abdominal arteries.
38.35	Resection of vessel with anastomosis, other thoracic vessels.
38.36	Resection of vessel with anastomosis, abdominal arteries.
38.37	Resection of vessel with anastomosis, abdominal veins.
38.46	Resection of vessel with replacement, abdominal arteries.
38.47	Resection of vessel with replacement, abdominal veins.
38.55	Ligation and stripping of varicose veins, other thoracic vessels.
38.65	Other excision of vessels, thoracic vessels.
38.66	Other excision of vessels, abdominal arteries.
38.67	Other excision of vessels, abdominal veins.
38.85	Other surgical occlusion of vessels, thoracic vessels.
38.86	Other surgical occlusion of vessels, abdominal arteries.
38.87	Other surgical occlusion of vessels, abdominal veins.
39.0	Systemic to pulmonary artery shunt.
39.1	Intra-abdominal venous shunt.
39.21	Caval-pulmonary artery anastomosis.
39.22	Aorta-subclavian-carotid bypass.
39.23	Other intrathoracic vascular shunt or bypass.
39.25	Aorta-iliac-femoral bypass.
39.26	Other intra-abdominal vascular shunt or bypass.
39.52	Other repair of aneurysm.
39.54	Re-entry operation (aorta).
39.72	Endovascular (total) embolization or occlusion of head and neck vessels.
39.75	Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils.

ICD–9–CM PROCEDURE CODES THAT WERE DESIGNATED AS THE LESS COMPLEX, LESS INVASIVE PROCEDURES—Continued

ICD–9–CM procedure code	Code description
39.76	Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils.
39.79	Other endovascular procedures on other vessels.

There are a number of ICD–10–PCS code translations that provide more detailed and specific information for each of the ICD–9–CM codes listed in the table immediately above that also currently group to MS–DRGs 237 and 238 in the ICD–10 MS–DRGs Version 32. The comparable ICD–10–PCS code translations for these ICD–9–CM procedure codes are shown in the following tables:

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.00

ICD–10–PCS code	Code description
02NF3ZZ	Release aortic valve, percutaneous approach.
02NF4ZZ	Release aortic valve, percutaneous endoscopic approach.
02NG3ZZ	Release mitral valve, percutaneous approach.
02NG4ZZ	Release mitral valve, percutaneous endoscopic approach.
02NH3ZZ	Release pulmonary valve, percutaneous approach.
02NH4ZZ	Release pulmonary valve, percutaneous endoscopic approach.
02NJ3ZZ	Release tricuspid valve, percutaneous approach.
02NJ4ZZ	Release tricuspid valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.01

ICD–10–PCS code	Code description
02CF3ZZ	Extirpation of matter from aortic valve, percutaneous approach.
02CF4ZZ	Extirpation of matter from aortic valve, percutaneous endoscopic approach.
02NF3ZZ	Release aortic valve, percutaneous approach.
02NF4ZZ	Release aortic valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATION FOR ICD–9–CM PROCEDURE CODE 35.02

ICD–10–PCS code	Code description
02CG3ZZ	Extirpation of matter from mitral valve, percutaneous approach.
02CG4ZZ	Extirpation of matter from mitral valve, percutaneous endoscopic approach.
02NG3ZZ	Release mitral valve, percutaneous approach.
02NG4ZZ	Release mitral valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.03

ICD–10–PCS code	Code description
02CH3ZZ	Extirpation of matter from pulmonary valve, percutaneous approach.
02CH4ZZ	Extirpation of matter from pulmonary valve, percutaneous endoscopic approach.
02NH3ZZ	Release Pulmonary Valve, Percutaneous Approach.
02NH4ZZ	Release Pulmonary Valve, Percutaneous Endoscopic Approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 35.04

ICD–10–PCS code	Description
02CJ3ZZ	Extirpation of matter from tricuspid valve, percutaneous approach.
02CJ4ZZ	Extirpation of matter from tricuspid valve, percutaneous endoscopic approach.
02NJ3ZZ	Release tricuspid valve, percutaneous approach.
02NJ4ZZ	Release tricuspid valve, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.12

ICD–10–PCS code	Code description
02CN0ZZ	Extirpation of matter from pericardium, open approach.
02CN3ZZ	Extirpation of matter from pericardium, percutaneous approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.12—Continued

ICD–10–PCS code	Code description
02CN4ZZ	Extirpation of matter from pericardium, percutaneous endoscopic approach.
02HN00Z	Insertion of pressure sensor monitoring device into pericardium, open approach.
02HN02Z	Insertion of monitoring device into pericardium, open approach.
02HN30Z	Insertion of pressure sensor monitoring device into pericardium, percutaneous approach.
02HN32Z	Insertion of monitoring device into pericardium, percutaneous approach.
02HN40Z	Insertion of pressure sensor monitoring device into pericardium, percutaneous endoscopic approach.
02HN42Z	Insertion of monitoring device into pericardium, percutaneous endoscopic approach.
02NN0ZZ	Release pericardium, open approach.
02NN3ZZ	Release pericardium, percutaneous approach.
02NN4ZZ	Release pericardium, percutaneous endoscopic approach.
0W9D00Z	Drainage of pericardial cavity with drainage device, open approach.
0W9D0ZX	Drainage of pericardial cavity, open approach, diagnostic.
0W9D0ZZ	Drainage of pericardial cavity, open approach.
0WCD0ZZ	Extirpation of matter from pericardial cavity, open approach.
0WCD3ZZ	Extirpation of matter from pericardial cavity, percutaneous approach.
0WCD4ZZ	Extirpation of matter from pericardial cavity, percutaneous endoscopic approach.
0WHD03Z	Insertion of infusion device into pericardial cavity, open approach.
0WHD0YZ	Insertion of other device into pericardial cavity, open approach.
0WHD33Z	Insertion of infusion device into pericardial cavity, percutaneous approach.
0WHD3YZ	Insertion of other device into pericardial cavity, percutaneous approach.
0WHD43Z	Insertion of infusion device into pericardial cavity, percutaneous endoscopic approach.
0WHD4YZ	Insertion of other device into pericardial cavity, percutaneous endoscopic approach.
0WPD00Z	Removal of drainage device from pericardial cavity, open approach.
0WPD01Z	Removal of radioactive element from pericardial cavity, open approach.
0WPD03Z	Removal of infusion device from pericardial cavity, open approach.
0WPD0YZ	Removal of other device from pericardial cavity, open approach.
0WPD30Z	Removal of drainage device from pericardial cavity, percutaneous approach.
0WPD31Z	Removal of radioactive element from pericardial cavity, percutaneous approach.
0WPD33Z	Removal of infusion device from pericardial cavity, percutaneous approach.
0WPD3YZ	Removal of other device from pericardial cavity, percutaneous approach.
0WPD40Z	Removal of drainage device from pericardial cavity, percutaneous endoscopic approach.
0WPD41Z	Removal of radioactive element from pericardial cavity, percutaneous endoscopic approach.
0WPD43Z	Removal of infusion device from pericardial cavity, percutaneous endoscopic approach.
0WPD4YZ	Removal of other device from pericardial cavity, percutaneous endoscopic approach.
0WWD00Z	Revision of drainage device in pericardial cavity, open approach.
0WWD01Z	Revision of radioactive element in pericardial cavity, open approach.
0WWD03Z	Revision of infusion device in pericardial cavity, open approach.
0WWD0YZ	Revision of other device in pericardial cavity, open approach.
0WWD30Z	Revision of drainage device in pericardial cavity, percutaneous approach.
0WWD31Z	Revision of radioactive element in pericardial cavity, percutaneous approach.
0WWD33Z	Revision of infusion device in pericardial cavity, percutaneous approach.
0WWD3YZ	Revision of other device in pericardial cavity, percutaneous approach.
0WWD40Z	Revision of drainage device in pericardial cavity, percutaneous endoscopic approach.
0WWD41Z	Revision of radioactive element in pericardial cavity, percutaneous endoscopic approach.
0WWD43Z	Revision of infusion device in pericardial cavity, percutaneous endoscopic approach.
0WWD4YZ	Revision of other device in pericardial cavity, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.24

ICD–10–PCS code	Code description
02BN0ZX	Excision of pericardium, open approach, diagnostic
02BN3ZX	Excision of pericardium, percutaneous approach, diagnostic
02BN4ZX	Excision of pericardium, percutaneous endoscopic approach, diagnostic

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.31

ICD–10–PCS code	Code description
025N0ZZ	Destruction of pericardium, open approach.
025N3ZZ	Destruction of pericardium, percutaneous approach.
025N4ZZ	Destruction of pericardium, percutaneous endoscopic approach.
02BN0ZZ	Excision of pericardium, open approach.
02BN3ZZ	Excision of pericardium, percutaneous approach.
02BN4ZZ	Excision of pericardium, percutaneous endoscopic approach.
02TN0ZZ	Resection of pericardium, open approach.
02TN3ZZ	Resection of pericardium, percutaneous approach.
02TN4ZZ	Resection of pericardium, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.61

ICD–10–PCS code	Code description
5A02110	Assistance with cardiac output using balloon pump, intermittent.
5A02210	Assistance with cardiac output using balloon pump, continuous.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.67

ICD–10–PCS code	Code description
02QA0ZZ	Repair heart, open approach.
02QA3ZZ	Repair heart, percutaneous approach.
02QA4ZZ	Repair heart, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.91

ICD–10–PCS code	Code description
02QA0ZZ	Repair heart, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 37.99

ICD–10–PCS code	Code description
02880ZZ	Division of conduction mechanism, open approach.
02883ZZ	Division of conduction mechanism, percutaneous approach.
02884ZZ	Division of conduction mechanism, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.05

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.05 are shown in Table 6P.1b for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.06

ICD–10–PCS code	Code description
04C10ZZ	Extirpation of matter from celiac artery, open approach.
04C13ZZ	Extirpation of matter from celiac artery, percutaneous approach.
04C14ZZ	Extirpation of matter from celiac artery, percutaneous endoscopic approach.
04C20ZZ	Extirpation of matter from gastric artery, open approach.
04C23ZZ	Extirpation of matter from gastric artery, percutaneous approach.
04C24ZZ	Extirpation of matter from gastric artery, percutaneous endoscopic approach.
04C30ZZ	Extirpation of matter from hepatic artery, open approach.
04C33ZZ	Extirpation of matter from hepatic artery, percutaneous approach.
04C34ZZ	Extirpation of matter from hepatic artery, percutaneous endoscopic approach.
04C40ZZ	Extirpation of matter from splenic artery, open approach.
04C43ZZ	Extirpation of matter from splenic artery, percutaneous approach.
04C44ZZ	Extirpation of matter from splenic artery, percutaneous endoscopic approach.
04C50ZZ	Extirpation of matter from superior mesenteric artery, open approach.
04C53ZZ	Extirpation of matter from superior mesenteric artery, percutaneous approach.
04C54ZZ	Extirpation of matter from superior mesenteric artery, percutaneous endoscopic approach.
04C60ZZ	Extirpation of matter from right colic artery, open approach.
04C63ZZ	Extirpation of matter from right colic artery, percutaneous approach.
04C64ZZ	Extirpation of matter from right colic artery, percutaneous endoscopic approach.
04C70ZZ	Extirpation of matter from left colic artery, open approach.
04C73ZZ	Extirpation of matter from left colic artery, percutaneous approach.
04C74ZZ	Extirpation of matter from left colic artery, percutaneous endoscopic approach.
04C80ZZ	Extirpation of matter from middle colic artery, open approach.
04C83ZZ	Extirpation of matter from middle colic artery, percutaneous approach.
04C84ZZ	Extirpation of matter from middle colic artery, percutaneous endoscopic approach.
04C90ZZ	Extirpation of matter from right renal artery, open approach.
04C93ZZ	Extirpation of matter from right renal artery, percutaneous approach.
04C94ZZ	Extirpation of matter from right renal artery, percutaneous endoscopic approach.
04CA0ZZ	Extirpation of matter from left renal artery, open approach.
04CA3ZZ	Extirpation of matter from left renal artery, percutaneous approach.
04CA4ZZ	Extirpation of matter from left renal artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.06—Continued

ICD–10–PCS code	Code description
04CB0ZZ	Extirpation of matter from inferior mesenteric artery, open approach.
04CB3ZZ	Extirpation of matter from inferior mesenteric artery, percutaneous approach.
04CB4ZZ	Extirpation of matter from inferior mesenteric artery, percutaneous endoscopic approach.
04CC0ZZ	Extirpation of matter from right common iliac artery, open approach.
04CC3ZZ	Extirpation of matter from right common iliac artery, percutaneous approach.
04CC4ZZ	Extirpation of matter from right common iliac artery, percutaneous endoscopic approach.
04CD0ZZ	Extirpation of matter from left common iliac artery, open approach.
04CD3ZZ	Extirpation of matter from left common iliac artery, percutaneous approach.
04CD4ZZ	Extirpation of matter from left common iliac artery, percutaneous endoscopic approach.
04CE0ZZ	Extirpation of matter from right internal iliac artery, open approach.
04CE3ZZ	Extirpation of matter from right internal iliac artery, percutaneous approach.
04CE4ZZ	Extirpation of matter from right internal iliac artery, percutaneous endoscopic approach.
04CF0ZZ	Extirpation of matter from left internal iliac artery, open approach.
04CF3ZZ	Extirpation of matter from left internal iliac artery, percutaneous approach.
04CF4ZZ	Extirpation of matter from left internal iliac artery, percutaneous endoscopic approach.
04CH0ZZ	Extirpation of matter from right external iliac artery, open approach.
04CH3ZZ	Extirpation of matter from right external iliac artery, percutaneous approach.
04CH4ZZ	Extirpation of matter from right external iliac artery, percutaneous endoscopic approach.
04CJ0ZZ	Extirpation of matter from left external iliac artery, open approach.
04CJ3ZZ	Extirpation of matter from left external iliac artery, percutaneous approach.
04CJ4ZZ	Extirpation of matter from left external iliac artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.07

ICD–10–PCS code	Code description
06C00ZZ	Extirpation of matter from inferior vena cava, open approach.
06C03ZZ	Extirpation of matter from inferior vena cava, percutaneous approach.
06C04ZZ	Extirpation of matter from inferior vena vava, percutaneous endoscopic approach.
06C10ZZ	Extirpation of matter from splenic vein, open approach.
06C13ZZ	Extirpation of matter from splenic vein, percutaneous approach.
06C14ZZ	Extirpation of matter from splenic vein, percutaneous endoscopic approach.
06C20ZZ	Extirpation of matter from gastric vein, open approach.
06C23ZZ	Extirpation of matter from gastric vein, percutaneous approach.
06C24ZZ	Extirpation of matter from gastric vein, percutaneous endoscopic approach.
06C40ZZ	Extirpation of matter from hepatic vein, open approach.
06C43ZZ	Extirpation of matter from hepatic vein, percutaneous approach.
06C44ZZ	Extirpation of matter from hepatic vein, percutaneous endoscopic approach.
06C50ZZ	Extirpation of matter from superior mesenteric vein, open approach.
06C53ZZ	Extirpation of matter from superior mesenteric vein, percutaneous approach.
06C54ZZ	Extirpation of matter from superior mesenteric vein, percutaneous endoscopic approach.
06C60ZZ	Extirpation of matter from inferior mesenteric vein, open approach.
06C63ZZ	Extirpation of matter from inferior mesenteric vein, percutaneous approach.
06C64ZZ	Extirpation of matter from inferior mesenteric vein, percutaneous endoscopic approach.
06C70ZZ	Extirpation of matter from colic vein, open approach.
06C73ZZ	Extirpation of matter from colic vein, percutaneous approach.
06C74ZZ	Extirpation of matter from colic vein, percutaneous endoscopic approach.
06C80ZZ	Extirpation of matter from portal vein, open approach.
06C83ZZ	Extirpation of matter from portal vein, percutaneous approach.
06C84ZZ	Extirpation of matter from portal vein, percutaneous endoscopic approach.
06C90ZZ	Extirpation of matter from right renal vein, open approach.
06C93ZZ	Extirpation of matter from right renal vein, percutaneous approach.
06C94ZZ	Extirpation of matter from right renal vein, percutaneous endoscopic approach.
06CB0ZZ	Extirpation of matter from left renal vein, open approach.
06CB3ZZ	Extirpation of matter from left renal vein, percutaneous approach.
06CB4ZZ	Extirpation of matter from left renal vein, percutaneous endoscopic approach.
06CC0ZZ	Extirpation of matter from right common iliac vein, open approach.
06CC3ZZ	Extirpation of matter from right common iliac vein, percutaneous approach.
06CC4ZZ	Extirpation of matter from right common iliac vein, percutaneous endoscopic approach.
06CD0ZZ	Extirpation of matter from left common iliac vein, open approach.
06CD3ZZ	Extirpation of matter from left common iliac vein, percutaneous approach.
06CD4ZZ	Extirpation of matter from left common iliac vein, percutaneous endoscopic approach.
06CF0ZZ	Extirpation of matter from right external iliac vein, open approach.
06CF3ZZ	Extirpation of matter from right external iliac vein, percutaneous approach.
06CF4ZZ	Extirpation of matter from right external iliac vein, percutaneous endoscopic approach.
06CG0ZZ	Extirpation of matter from left external iliac vein, open approach.
06CG3ZZ	Extirpation of matter from left external iliac vein, percutaneous approach.
06CG4ZZ	Extirpation of matter from left external iliac vein, percutaneous endoscopic approach.
06CH0ZZ	Extirpation of matter from right hypogastric vein, open approach.
06CH3ZZ	Extirpation of matter from right hypogastric vein, percutaneous approach.
06CH4ZZ	Extirpation of matter from right hypogastric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.07—Continued

ICD–10–PCS code	Code description
06CJ0ZZ	Extirpation of matter from left hypogastric vein, open approach.
06CJ3ZZ	Extirpation of matter from left hypogastric vein, percutaneous approach.
06CJ4ZZ	Extirpation of matter from left hypogastric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.15

ICD–10–PCS code	Code description
02CP0ZZ	Extirpation of matter from pulmonary trunk, open approach.
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach.
02CP4ZZ	Extirpation of matter from pulmonary trunk, percutaneous endoscopic approach.
02CQ0ZZ	Extirpation of matter from right pulmonary artery, open approach.
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach.
02CQ4ZZ	Extirpation of matter from right pulmonary artery, percutaneous endoscopic approach.
02CR0ZZ	Extirpation of matter from left pulmonary artery, open approach.
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach.
02CR4ZZ	Extirpation of matter from left pulmonary artery, percutaneous endoscopic approach.
02CS0ZZ	Extirpation of matter from right pulmonary vein, open approach.
02CS3ZZ	Extirpation of matter from right pulmonary vein, percutaneous approach.
02CS4ZZ	Extirpation of matter from right pulmonary vein, percutaneous endoscopic approach.
02CT0ZZ	Extirpation of matter from left pulmonary vein, open approach.
02CT3ZZ	Extirpation of matter from left pulmonary vein, percutaneous approach.
02CT4ZZ	Extirpation of matter from left pulmonary vein, percutaneous endoscopic approach.
02CV0ZZ	Extirpation of matter from superior vena cava, open approach.
02CV3ZZ	Extirpation of matter from superior vena cava, percutaneous approach.
02CV4ZZ	Extirpation of matter from superior vena cava, percutaneous endoscopic approach.
03C00ZZ	Extirpation of matter from right internal mammary artery, open approach.
03C03ZZ	Extirpation of matter from right internal mammary artery, percutaneous approach.
03C04ZZ	Extirpation of matter from right internal mammary artery, percutaneous endoscopic approach.
03C10ZZ	Extirpation of matter from left internal mammary artery, open approach.
03C13ZZ	Extirpation of matter from left internal mammary artery, percutaneous approach.
03C14ZZ	Extirpation of matter from left internal mammary artery, percutaneous endoscopic approach.
03C20ZZ	Extirpation of matter from innominate artery, open approach.
03C23ZZ	Extirpation of matter from innominate artery, percutaneous approach.
03C24ZZ	Extirpation of matter from innominate artery, percutaneous endoscopic approach.
03C30ZZ	Extirpation of matter from right subclavian artery, open approach.
03C33ZZ	Extirpation of matter from right subclavian artery, percutaneous approach.
03C34ZZ	Extirpation of matter from right subclavian artery, percutaneous endoscopic approach.
03C40ZZ	Extirpation of matter from left subclavian artery, open approach.
03C43ZZ	Extirpation of matter from left subclavian artery, percutaneous approach.
03C44ZZ	Extirpation of matter from left subclavian artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.16

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.16 are shown in Table 6P.1c for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.35

ICD–10–PCS code	Code description
02BP0ZZ	Excision of pulmonary trunk, open approach.
02BP4ZZ	Excision of pulmonary trunk, percutaneous endoscopic approach.
02BQ0ZZ	Excision of right pulmonary artery, open approach.
02BQ4ZZ	Excision of right pulmonary artery, percutaneous endoscopic approach.
02BR0ZZ	Excision of left pulmonary artery, open approach.
02BR4ZZ	Excision of left pulmonary artery, percutaneous endoscopic approach.
02BS0ZZ	Excision of right pulmonary vein, open approach.
02BS4ZZ	Excision of right pulmonary vein, percutaneous endoscopic approach.
02BT0ZZ	Excision of left pulmonary vein, open approach.
02BT4ZZ	Excision of left pulmonary vein, percutaneous endoscopic approach.
02BV0ZZ	Excision of superior vena cava, open approach.
02BV4ZZ	Excision of superior vena cava, percutaneous endoscopic approach.
03B00ZZ	Excision of right internal mammary artery, open approach.
03B04ZZ	Excision of right internal mammary artery, percutaneous endoscopic approach.
03B10ZZ	Excision of left internal mammary artery, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.35—Continued

ICD–10–PCS code	Code description
03B14ZZ	Excision of left internal mammary artery, percutaneous endoscopic approach.
03B20ZZ	Excision of innominate artery, open approach.
03B24ZZ	Excision of innominate artery, percutaneous endoscopic approach.
03B30ZZ	Excision of right subclavian artery, open approach.
03B34ZZ	Excision of right subclavian artery, percutaneous endoscopic approach.
03B40ZZ	Excision of left subclavian artery, open approach.
03B44ZZ	Excision of left subclavian artery, percutaneous endoscopic approach.
05B00ZZ	Excision of azygos vein, open approach.
05B04ZZ	Excision of azygos vein, percutaneous endoscopic approach.
05B10ZZ	Excision of hemiazygos vein, open approach.
05B14ZZ	Excision of hemiazygos vein, percutaneous endoscopic approach.
05B30ZZ	Excision of right innominate vein, open approach.
05B34ZZ	Excision of right innominate vein, percutaneous endoscopic approach.
05B40ZZ	Excision of left innominate vein, open approach.
05B44ZZ	Excision of left innominate vein, percutaneous endoscopic approach.
05B50ZZ	Excision of right subclavian vein, open approach.
05B54ZZ	Excision of right subclavian vein, percutaneous endoscopic approach.
05B60ZZ	Excision of left subclavian vein, open approach.
05B64ZZ	Excision of left subclavian vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.36

ICD–10–PCS code	Code description
04B10ZZ	Excision of celiac artery, open approach.
04B14ZZ	Excision of celiac artery, percutaneous endoscopic approach.
04B20ZZ	Excision of gastric artery, open approach.
04B24ZZ	Excision of gastric artery, percutaneous endoscopic approach.
04B30ZZ	Excision of hepatic artery, open approach.
04B34ZZ	Excision of hepatic artery, percutaneous endoscopic approach.
04B40ZZ	Excision of splenic artery, open approach.
04B44ZZ	Excision of splenic artery, percutaneous endoscopic approach.
04B50ZZ	Excision of superior mesenteric artery, open approach.
04B54ZZ	Excision of superior mesenteric artery, percutaneous endoscopic approach.
04B60ZZ	Excision of right colic artery, open approach.
04B64ZZ	Excision of right colic artery, percutaneous endoscopic approach.
04B70ZZ	Excision of left colic artery, open approach.
04B74ZZ	Excision of left colic artery, percutaneous endoscopic approach.
04B80ZZ	Excision of middle colic artery, open approach.
04B84ZZ	Excision of middle colic artery, percutaneous endoscopic approach.
04B90ZZ	Excision of right renal artery, open approach.
04B94ZZ	Excision of right renal artery, percutaneous endoscopic approach.
04BA0ZZ	Excision of left renal artery, open approach.
04BA4ZZ	Excision of left renal artery, percutaneous endoscopic approach.
04BB0ZZ	Excision of inferior mesenteric artery, open approach.
04BB4ZZ	Excision of inferior mesenteric artery, percutaneous endoscopic approach.
04BC0ZZ	Excision of right common iliac artery, open approach.
04BC4ZZ	Excision of right common iliac artery, percutaneous endoscopic approach.
04BD0ZZ	Excision of left common iliac artery, open approach.
04BD4ZZ	Excision of left common iliac artery, percutaneous endoscopic approach.
04BE0ZZ	Excision of right internal iliac artery, open approach.
04BE4ZZ	Excision of right internal iliac artery, percutaneous endoscopic approach.
04BF0ZZ	Excision of left internal iliac artery, open approach.
04BF4ZZ	Excision of left internal iliac artery, percutaneous endoscopic approach.
04BH0ZZ	Excision of right external iliac artery, open approach.
04BH4ZZ	Excision of right external iliac artery, percutaneous endoscopic approach.
04BJ0ZZ	Excision of left external iliac artery, open approach.
04BJ4ZZ	Excision of left external iliac artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.37

ICD–10–PCS code	Code description
06B00ZZ	Excision of inferior vena cava, open approach.
06B04ZZ	Excision of inferior vena cava, percutaneous endoscopic approach.
06B10ZZ	Excision of splenic vein, open approach.
06B14ZZ	Excision of splenic vein, percutaneous endoscopic approach.
06B20ZZ	Excision of gastric vein, open approach.
06B24ZZ	Excision of gastric vein, percutaneous endoscopic approach.
06B40ZZ	Excision of hepatic vein, open approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.37—Continued

ICD–10–PCS code	Code description
06B44ZZ	Excision of hepatic vein, percutaneous endoscopic approach.
06B50ZZ	Excision of superior mesenteric vein, open approach.
06B54ZZ	Excision of superior mesenteric vein, percutaneous endoscopic approach.
06B60ZZ	Excision of inferior mesenteric vein, open approach.
06B64ZZ	Excision of inferior mesenteric vein, percutaneous endoscopic approach.
06B70ZZ	Excision of colic vein, open approach.
06B74ZZ	Excision of colic vein, percutaneous endoscopic approach.
06B80ZZ	Excision of portal vein, open approach.
06B84ZZ	Excision of portal vein, percutaneous endoscopic approach.
06B90ZZ	Excision of right renal vein, open approach.
06B94ZZ	Excision of right renal vein, percutaneous endoscopic approach.
06BB0ZZ	Excision of left renal vein, open approach.
06BB4ZZ	Excision of left renal vein, percutaneous endoscopic approach.
06BC0ZZ	Excision of right common iliac vein, open approach.
06BC4ZZ	Excision of right common iliac vein, percutaneous endoscopic approach.
06BD0ZZ	Excision of left common iliac vein, open approach.
06BD4ZZ	Excision of left common iliac vein, percutaneous endoscopic approach.
06BF0ZZ	Excision of right external iliac vein, open approach.
06BF4ZZ	Excision of right external iliac vein, percutaneous endoscopic approach.
06BG0ZZ	Excision of left external iliac vein, open approach.
06BG4ZZ	Excision of left external iliac vein, percutaneous endoscopic approach.
06BH0ZZ	Excision of right hypogastric vein, open approach.
06BH4ZZ	Excision of right hypogastric vein, percutaneous endoscopic approach.
06BJ0ZZ	Excision of left hypogastric vein, open approach.
06BJ4ZZ	Excision of left hypogastric vein, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.46

ICD–10–PCS code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.46 are shown in Table 6P.1d for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.47

ICD–10–PCS code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.47 are shown in Table 6P.1e for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

There is not an equivalent ICD–10–PCS code translation for ICD–9–CM procedure code 38.55.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.65

ICD–10–PCS code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.65 are shown in Table 6P.1f for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.66

ICD–10–PCS code	Code description
The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.66 are shown in Table 6P.1g for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*	

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.67

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.67 are shown in Table 6P.1h for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.85

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.85 are shown in Table 6P.1i for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.86

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.86 are shown in Table 6P.1j for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 38.87

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 38.87 are shown in Table 6P.1k for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.0

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.0 are shown in Table 6P.1l for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.1

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.1 are shown in Table 6P.1m for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.21

ICD–10–PCS code	Code description
021V09P	Bypass superior vena cava to pulmonary trunk with autologous venous tissue, open approach.
021V09Q	Bypass superior vena cava to right pulmonary artery with autologous venous tissue, open approach.
021V09R	Bypass superior vena cava to left pulmonary artery with autologous venous tissue, open approach.
021V0AP	Bypass superior vena cava to pulmonary trunk with autologous arterial tissue, open approach.
021V0AQ	Bypass superior vena cava to right pulmonary artery with autologous arterial tissue, open approach.
021V0AR	Bypass superior vena cava to left pulmonary artery with autologous arterial tissue, open approach.
021V0JP	Bypass superior vena cava to pulmonary trunk with synthetic substitute, open approach.
021V0JQ	Bypass superior vena cava to right pulmonary artery with synthetic substitute, open approach.
021V0JR	Bypass superior vena cava to left pulmonary artery with synthetic substitute, open approach.
021V0KP	Bypass superior vena cava to pulmonary trunk with nonautologous tissue substitute, open approach.
021V0KQ	Bypass superior vena cava to right pulmonary artery with nonautologous tissue substitute, open approach.
021V0KR	Bypass superior vena cava to left pulmonary artery with nonautologous tissue substitute, open approach.
021V0ZP	Bypass superior vena cava to pulmonary trunk, open approach.
021V0ZQ	Bypass superior vena cava to right pulmonary artery, open approach.
021V0ZR	Bypass superior vena cava to left pulmonary artery, open approach.
021V49P	Bypass superior vena cava to pulmonary trunk with autologous venous tissue, percutaneous endoscopic approach.
021V49Q	Bypass superior vena cava to right pulmonary artery with autologous venous tissue, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.21—Continued

ICD–10–PCS code	Code description
021V49R	Bypass superior vena cava to left pulmonary artery with autologous venous tissue, percutaneous endoscopic approach.
021V4AP	Bypass superior vena cava to pulmonary trunk with autologous arterial tissue, percutaneous endoscopic approach.
021V4AQ	Bypass superior vena cava to right pulmonary artery with autologous arterial tissue, percutaneous endoscopic approach.
021V4AR	Bypass superior vena cava to left pulmonary artery with autologous arterial tissue, percutaneous endoscopic approach.
021V4JP	Bypass superior vena cava to pulmonary trunk with synthetic substitute, percutaneous endoscopic approach.
021V4JQ	Bypass superior vena cava to right pulmonary artery with synthetic substitute, percutaneous endoscopic approach.
021V4JR	Bypass superior vena cava to left pulmonary artery with synthetic substitute, percutaneous endoscopic approach.
021V4KP	Bypass superior vena cava to pulmonary trunk with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4KQ	Bypass superior vena cava to right pulmonary artery with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4KR	Bypass superior vena cava to left pulmonary artery with nonautologous tissue substitute, percutaneous endoscopic approach.
021V4ZP	Bypass superior vena cava to pulmonary trunk, percutaneous endoscopic approach.
021V4ZQ	Bypass superior vena cava to right pulmonary artery, percutaneous endoscopic approach.
021V4ZR	Bypass superior vena cava to left pulmonary artery, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.22

ICD–10–PCS code	Code description
021W09B	Bypass thoracic aorta to subclavian with autologous venous tissue, open approach).
021W09D	Bypass thoracic aorta to carotid with autologous venous tissue, open approach).
021W0AB	Bypass thoracic aorta to subclavian with autologous arterial tissue, open approach.
021W0AD	Bypass thoracic aorta to carotid with autologous arterial tissue, open approach.
021W0JB	Bypass thoracic aorta to subclavian with synthetic substitute, open approach.
021W0JD	Bypass thoracic aorta to carotid with synthetic substitute, open approach.
021W0KB	Bypass thoracic aorta to subclavian with nonautologous tissue substitute, open approach.
021W0KD	Bypass thoracic aorta to carotid with nonautologous tissue substitute, open approach.
021W0ZB	Bypass thoracic aorta to subclavian, open approach.
021W0ZD	Bypass thoracic aorta to carotid, open approach.
021W49B	Bypass thoracic aorta to subclavian with autologous venous tissue, percutaneous endoscopic approach.
021W49D	Bypass thoracic aorta to carotid with autologous venous tissue, percutaneous endoscopic approach.
021W4AB	Bypass thoracic aorta to subclavian with autologous arterial tissue, percutaneous endoscopic approach.
021W4AD	Bypass thoracic aorta to carotid with autologous arterial tissue, percutaneous endoscopic approach.
021W4JB	Bypass thoracic aorta to subclavian with synthetic substitute, percutaneous endoscopic approach.
021W4JD	Bypass thoracic aorta to carotid with synthetic substitute, percutaneous endoscopic approach.
021W4KB	Bypass thoracic aorta to subclavian with nonautologous tissue substitute, percutaneous endoscopic approach.
021W4KD	Bypass thoracic aorta to carotid with nonautologous tissue substitute, percutaneous endoscopic approach.
021W4ZB	Bypass thoracic aorta to subclavian, percutaneous endoscopic approach.
021W4ZD	Bypass thoracic aorta to carotid, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.23

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.23 are shown in Table 6P.1n for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.25

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.25 are shown in Table 6P.1o for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.26

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.26 are shown in Table 6P.1p for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.52

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.52 are shown in Table 6P.1q for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.54

ICD–10–PCS code	Code description
02QW0ZZ	Repair thoracic aorta, open approach.
02QW3ZZ	Repair thoracic aorta, percutaneous approach.
02QW4ZZ	Repair thoracic aorta, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.72

ICD–10–PCS code	Code description
03LR0DZ	Occlusion of face artery with intraluminal device, open approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS0DZ	Occlusion of right temporal artery with intraluminal device, open approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT0DZ	Occlusion of left temporal artery with intraluminal device, open approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.75

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.75 are shown in Table 6P.1r for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.76

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.76 are shown in Table 6P.1s for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

ICD–10–PCS CODE TRANSLATIONS FOR ICD–9–CM PROCEDURE CODE 39.79

ICD–10–PCS code	Code description

The comparable ICD–10–PCS code translations for ICD–9–CM procedure code 39.79 are shown in Table 6P.1t for this proposed rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

As previously stated, we separated the more complex, more invasive procedures from the less complex, less invasive procedures to continue our evaluation of the procedures assigned to MS–DRGs 237 and 238. Our data analysis showed that the distribution of cases, the average length of stay, and average costs of the more complex, more invasive aortic and heart assist procedures and the less complex, less invasive other cardiovascular procedures would be more appropriately reflected if we classified these distinguishing types of procedures under newly created MS–DRGs, as reflected in the table below.

MAJOR CARDIOVASCULAR PROCEDURES WITH AND WITHOUT MCC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 237 and 238—Combined	50,567	5.8	$29,174

MAJOR CARDIOVASCULAR PROCEDURES WITH AND WITHOUT MCC—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 237 and 238—Cases with more complex, more invasive procedure codes (37.41; 37.49; 37.55; 37.64; 38.04; 38.14; 38.34; 38.44; 38.64; 38.84; 39.24; 39.71, and 39.78)	22,278	4.0	31,729
MS–DRGs 237 and 238—Cases with less complex, less invasive procedure codes (35.00; 35.01; 35.02; 35.03; 35.04; 37.12; 37.24; 37.31; 37.61; 37.67; 37.91; 37.99; 38.05; 38.06; 38.07; 38.15; 38.16; 38.35; 38.36; 38.37; 38.46; 38.47; 38.55; 38.65; 38.66; 38.67; 38.85; 38.86; 38.87; 39.0; 39.1; 39.21; 39.22; 39.23; 39.25; 39.26; 39.52; 39.54; 39.72; 39.75; 39.76; and 39.79)	28,289	7.1	27,162

Our clinical advisors reviewed the results of the analysis and agreed that distinguishing the more complex, more invasive procedures from the less complex, less invasive procedures would result in improved clinical coherence for the various cardiovascular procedures currently assigned to MS–DRGs 237 and 238, as listed previously. Therefore, for FY 2016, we are proposing to delete MS–DRGs 237 and 238. When we applied our established criteria to determine if the creation of a new CC or MCC subgroup within a base MS–DRG is warranted, we determined that a 2-way severity level split (with MCC and without MCC) was justified. Therefore, we are proposing to create two new MS–DRGs that would contain the more complex, more invasive aortic and heart assist procedures currently assigned to MS–DRGs 237 and 238, as listed previously. We are proposing to create MS–DRG 268, entitled ''Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC,'' and MS–DRG 269, entitled ''Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.'' The table below shows the distribution of cases and the average length of stay and average costs of the more complex, more invasive procedures for aortic and heart assistance for the proposed new MS–DRGs 268 and 269.

PROPOSED NEW MS–DRGS FOR AORTIC AND HEART ASSIST PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed New MS–DRG 268 with MCC	4,182	10.03	$45,996
Proposed New MS–DRG 269 without MCC	18,096	2.68	28,431

We are inviting public comments on this proposal and the ICD–10–PCS code translations for these procedures shown earlier in this section, which we also are proposing to assign to proposed new MS–DRGs 268 and 269.

In addition, when we further applied our established criteria to determine if the creation of a new CC or MCC subgroup for the remaining procedures was warranted, we determined that a 3-way severity level split (with MCC, with CC, and without CC/MCC) was justified. Therefore, we are proposing to create three new MS–DRGs that would contain the remaining cardiovascular procedures that were designated as the less complex, less invasive procedures, as listed previously. For FY 2016, we are proposing to create MS–DRG 270, entitled ''Other Major Cardiovascular Procedures with MCC''; MS–DRG 271, entitled ''Other Major Cardiovascular Procedures with CC''; and MS–DRG 272, entitled ''Other Major Cardiovascular Procedures without CC/MCC,'' and to assign the less complex, less invasive cardiovascular procedures shown earlier in this section to these proposed new MS–DRGs. We believe that, as shown in the table below, the distribution of cases and average length of stay and average costs of these procedures would be more appropriately reflected when these types of procedures are classified under these proposed new MS–DRGs.

PROPOSED NEW MS–DRGS FOR OTHER MAJOR CARDIOVASCULAR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
Proposed New MS–DRG 270 with MCC	14,158	9.3	$33,507
Proposed New MS–DRG 271 with CC	9,648	5.99	22,800
Proposed New MS–DRG 272 without CC/MCC	4,483	3.08	16,438

We are inviting public comments on this proposal and the ICD–10–PCS code translations for the less complex, less invasive cardiovascular procedures shown earlier in this section, which we also are proposing to assign to proposed new MS–DRGs 270, 271, and 272.

In summary, for FY 2016, we are proposing to delete MS–DRGs 237 and 238, and to create the following five new MS–DRGs:

- Proposed new MS–DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC);
- Proposed new MS–DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC);
- Proposed new MS–DRG 270 (Other Major Cardiovascular Procedures with MCC);
- Proposed new MS–DRG 271 (Other Major Cardiovascular Procedures with CC); and
- Proposed new MS–DRG 272 (Other Major Cardiovascular Procedures without CC/MCC).

We also are proposing to assign the more complex, more invasive cardiovascular procedures identified in our analysis and the ICD–10–PCS code translations to proposed new MS–DRGs

268 and 269. In addition, we are proposing to assign the less complex, less invasive cardiovascular procedures identified in our analysis and the ICD–10–PCS code translations to proposed new MS–DRGs 270, 271, and 272. We encourage public comments on our proposal to create these proposed new MS–DRGs, as well as the ICD–10–PCS code translations that we are proposing to assign to the corresponding proposed new MS–DRGs.

4. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Revision of Hip or Knee Replacements: Proposed Revision of ICD–10–PCS Version 32 Logic

We received two comments that the logic for ICD–10 MS–DRGs Version 32 does not work the same as it does for the ICD–9–CM based MS–DRGs Version 32 for joint revisions. One of the commenters requested that CMS change the MS–DRG structure for joint revisions within the ICD–10 MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) so that cases that have a spacer removed prior to the insertion of a new joint prosthesis are assigned to MS–DRG 466, 467, and 468, as is the case with the ICD–9–CM MS–DRGs. The other commenter asked that joint revision cases that involve knee revisions with cemented and uncemented qualifiers be assigned to these MS–DRGs. This commenter provided an example of a patient admitted for a knee revision and reported under ICD–10–PCS codes 0SPD0JZ (Removal of synthetic substitute from left knee joint, open approach) and 0SRU0JA (Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach), which should be assigned to MS–DRGs 466, 467, and 468. The requestor stated that revision cases coded with ICD–9–CM codes are assigned to MS–DRGs 466, 467, and 468, but similar cases reported with these ICD–10–PCS codes are not assigned to MS–DRGs 466, 467, and 468 in ICD–10–PCS MS–DRGs Version 32.

We agree that joint revision cases with the removal of a spacer and subsequent insertion of a new joint prosthesis should be assigned to MS–DRGs 466, 467, and 468 as is the case currently with the ICD–9–CM based MS–DRGs Version 32. We also agree that knee revisions that involve cemented and uncemented qualifiers should be assigned to MS–DRGs 466, 467, and 468. Knee revision cases currently reported with ICD–9–CM codes are assigned to MS–DRGs 466, 467, and 468 in the ICD–9–CM based MS–DRGs. We examined joint revision combination codes that are not currently assigned to MS–DRGs 466, 467, and 468 in ICD–10 MS–DRGs Version 32 and identified additional combinations that also should be included so that the joint revision MS–DRGs would have the same logic as the ICD–9–CM MS–DRGs. We are proposing to add the following code combinations which capture the joint revisions to the Version 33 MS–DRG structure for ICD–10 MS–DRGs 466, 467, and 468 that we are proposing to implement effective October 1, 2015.

MS–DRG 466–468 ICD–10–PCS Code Pairs To Be Added to the Version 33 ICD–10 MS–DRGs 466, 467, and 468: Proposed New Hip Revision ICD–10–PCS Combinations

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, pen approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic Substitute, cemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic Substitute, uncemented, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP909Z	Removal of liner from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular Surface with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP90BZ	Removal of resurfacing device from right hip joint, open approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP90JZ	Removal of synthetic substitute from right hip joint, open approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA01A	Replacement of right hip joint, acetabular Surface with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP948Z	Removal of spacer from right hip joint, percutaneous endoscopic approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9019	Replacement of right hip joint with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR901A	Replacement of right hip joint with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR901Z	Replacement of right hip joint with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9029	Replacement of right hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR902A	Replacement of right hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR902Z	Replacement of right hip joint with metal on polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9039	Replacement of right hip joint with ceramic synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR903A	Replacement of right hip joint with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR903Z	Replacement of right hip joint with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR9049	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR904A	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR904Z	Replacement of right hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90J9	Replacement of right hip joint with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90JA	Replacement of right hip joint with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SR90JZ	Replacement of right hip joint with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA009	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA00A	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA00Z	Replacement of right hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA019	Replacement of right hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA01A	Replacement of right hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA01Z	Replacement of right hip joint, acetabular surface with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA039	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA03A	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA03Z	Replacement of right hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0J9	Replacement of right hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0JA	Replacement of right hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRA0JZ	Replacement of right hip joint, acetabular surface with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR019	Replacement of right hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR01A	Replacement of right hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR01Z	Replacement of right hip joint, femoral surface with metal synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR039	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR03A	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR03Z	Replacement of right hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0J9	Replacement of right hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0JA	Replacement of right hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SRR0JZ	Replacement of right hip joint, femoral surface with synthetic substitute, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SU909Z	Supplement right hip joint with liner, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SUA09Z	Supplement right hip joint, acetabular surface with liner, open approach.
0SP94JZ	Removal of synthetic substitute from right hip joint, percutaneous endoscopic approach.	and	0SUR09Z	Supplement right hip joint, femoral surface with liner, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB08Z	Removal of spacer from left hip joint, open approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB09Z	Removal of liner from left hip joint, open approach	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB0BZ	Removal of resurfacing device from left hip joint, open approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB0JZ	Removal of synthetic substitute from left hip joint, open approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB48Z	Removal of spacer from left hip joint, percutaneous endoscopic approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB019	Replacement of left hip joint with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB01A	Replacement of left hip joint with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB01Z	Replacement of left hip joint with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB029	Replacement of left hip joint with metal on polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB02A	Replacement of left hip joint with metal on polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB02Z	Replacement of left hip joint with metal on polyethylene synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB039	Replacement of left hip joint with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB03A	Replacement of left hip joint with ceramic synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB03Z	Replacement of left hip joint with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB049	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB04A	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB04Z	Replacement of left hip joint with ceramic on polyethylene synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0J9	Replacement of left hip joint with synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0JA	Replacement of left hip joint with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRB0JZ	Replacement of left hip joint with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE009	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE00A	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE00Z	Replacement of left hip joint, acetabular surface with polyethylene synthetic substitute, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW HIP REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code description		ICD–10–PCS code	Code description
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE019	Replacement of left hip joint, acetabular surface with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE01A	Replacement of left hip joint, acetabular surface with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE01Z	Replacement of left hip joint, acetabular surface with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE039	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE03A	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE03Z	Replacement of left hip joint, acetabular surface with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0J9	Replacement of left hip joint, acetabular surface with synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0JA	Replacement of left hip joint, acetabular surface with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRE0JZ	Replacement of left hip joint, acetabular surface with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS019	Replacement of left hip joint, femoral surface with metal synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS01A	Replacement of left hip joint, femoral surface with metal synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS01Z	Replacement of left hip joint, femoral surface with metal synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS039	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS03A	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS03Z	Replacement of left hip joint, femoral surface with ceramic synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0J9	Replacement of left hip joint, femoral surface with synthetic substitute, cemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0JA	Replacement of left hip joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SRS0JZ	Replacement of left hip joint, femoral surface with synthetic substitute, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUB09Z	Supplement left hip joint with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUE09Z	Supplement left hip joint, acetabular surface with liner, open approach.
0SPB4JZ	Removal of synthetic substitute from left hip joint, percutaneous endoscopic approach.	and	0SUS09Z	Supplement left hip joint, femoral surface with liner, open approach

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS

ICD–10–PCS code	Code descriptions		ICD–10–PCS code	Code description
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0J9	Replacement of right knee joint with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0JA	Replacement of right knee joint with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRC0JZ	Replacement of right knee joint with synthetic substitute, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code descriptions		ICD–10–PCS code	Code description
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRT0JZ	Replacement of right knee joint, femoral surface with synthetic substitute, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPC09Z	Removal of liner from right knee joint, open approach.	and	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC0JZ	Removal of synthetic substitute from right knee joint, open approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPC4JZ	Removal of synthetic substitute from right knee joint, percutaneous endoscopic approach.	and	0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0J9	Replacement of left knee joint with synthetic substitute, cemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0JA	Replacement of left knee joint with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRD0JZ	Replacement of left knee joint with synthetic substitute, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRU0JZ	Replacement of left knee joint, femoral surface with synthetic substitute, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD09Z	Removal of liner from left knee joint, open approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.

MS–DRG 466–468 ICD–10–PCS CODE PAIRS TO BE ADDED TO THE VERSION 33 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

ICD–10–PCS code	Code descriptions		ICD–10–PCS code	Code description
0SPD0JZ	Removal of synthetic substitute from left knee joint, open approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach.
0SPD4JZ	Removal of synthetic substitute from left knee joint, percutaneous endoscopic approach.	and	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach.

We are inviting public comments on our proposal to add the joint revision code combinations listed above to MS–DRGs 466, 467, and 468.

b. Spinal Fusion

We received a request to revise the titles of MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusion with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs so that they more closely correspond to the terminology used to describe the ICD–10–PCS procedure codes without changing the ICD–10 MS–DRG logic. We agree with the requestor that revising the titles of these MS–DRGs would more appropriately identify the procedures classified under these groupings. Therefore, we are proposing new titles for these three MS–DRGs that would change the reference of ''9+ Fusions'' to ''Extensive Fusions.'' The proposed title revisions to MS–DRGs 456, 457, and 458 for the FY 2016 ICD–10 MS–DRGs Version 33 are as follows:

- MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with MCC)
- MS–DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with CC)
- MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion without CC/MCC).

We are inviting public comments on our proposal.

5. MDC 14 (Pregnancy, Childbirth and the Puerperium): MS–DRG 775 (Vaginal Delivery Without Complicating Diagnosis)

We received a request to modify the logic for ICD–10 MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis) so that the procedure code for the induction of labor with a cervical ripening gel would not group to the incorrect MS–DRG when a normal delivery has occurred. ICD–10–PCS code 3E0P7GC (Introduction of other therapeutic substance into female reproductive, via natural or artificial opening) describes this procedure.

We reviewed how this code is currently classified under the ICD–10 MS–DRGs Version 32 and noted that it is currently designated as an operating room (O.R.) code affecting MS–DRG assignment. We agree with the requestor that the current logic for ICD–10–PCS procedure code 3E0P7GC does not result in the appropriate MS–DRG assignment. The result of our analysis suggests that this code should not be designated as an O.R. code. Our clinical advisors agree that this procedure does not require the intensity or complexity of service and resource utilization to merit an O.R. designation under ICD–10. Therefore, we are proposing to make ICD–10–PCS procedure code 3E0P7GC a non-O.R. code so that cases reporting this procedure code will group to the appropriate MS–DRG assignment. We are inviting public comments on our proposal.

Our analysis of ICD–10–PCS code 3E0P7GC also prompted the review of additional, similar codes that describe the introduction of a substance. We evaluated the following ICD–10–PCS procedure codes:

- 3E0P76Z (Introduction of nutritional substance into female reproductive, via natural or artificial opening);
- 3E0P77Z (Introduction of electrolytic and water balance substance into female reproductive, via natural or artificial opening);
- 3E0P7SF (Introduction of other gas into female reproductive, via natural or artificial opening);
- 3E0P83Z (Introduction of anti-inflammatory into female reproductive, via natural or artificial opening endoscopic);
- 3E0P86Z (Introduction of nutritional substance into female reproductive, via natural or artificial opening endoscopic);
- 3E0P87Z (Introduction of electrolytic and water balance substance into female reproductive, via natural or artificial opening endoscopic);
- 3E0P8GC (Introduction of other therapeutic substance into female reproductive, via natural or artificial opening endoscopic); and
- 3E0P8SF (Introduction of other gas into female reproductive, via natural or artificial opening endoscopic).

From our analysis, we determined that these codes also are currently designated as O.R. codes affecting MS–DRG assignment. Our clinical advisors recommended that these codes should also be designated as non-O.R. because they do not require the intensity or complexity of service and resource utilization to merit an O.R. designation under the ICD–10 MS–DRGs. As a result of our analysis and our clinical advisors' recommendation, we are proposing to designate the above listed ICD–10–PCS procedure codes as non-O.R. codes to ensure that these codes will group to the appropriate MS–DRG assignment.

We are inviting public comments on our proposal.

6. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): CroFab Antivenin Drug

We received a request that CMS change the MS–DRG assignment for antivenom cases from MS–DRG 917 and 918 (Poisoning & Toxic Effects of Drugs with and without MCC, respectively).

For these MS–DRGs, we examined claims data from the December 2014 update of the FY 2014 MedPAR file for ICD–9–CM diagnosis codes of a principal diagnosis 989.5 (Toxic effect of venom), a secondary diagnosis ICD–9–CM E code of E905.0 (Venomous snakes and lizards), and the ICD–9–CM procedure code of 99.16 (Injection of antidote), which is a non-O.R. code and does not impact the MS–DRG assignment.

For the ICD–9–CM diagnosis code 989.5 (Toxic effect of venom), the ICD–10–CM provides more detailed diagnosis codes for these toxic effects of venom cases as shown in the following table:

ICD–10–CM Code Translations for ICD–9–CM Diagnosis Code 989.5

ICD–10–CM code	Code description
T63.001A	Toxic effect of unspecified snake venom, accidental (unintentional), initial encounter.
T63.011A	Toxic effect of rattlesnake venom, accidental (unintentional) initial encounter.
T63.021A	Toxic effect of coral snake venom, accidental (unintentional), initial encounter.
T63.031A	Toxic effect of taipan venom, accidental (unintentional), initial encounter.
T63.041A	Toxic effect of cobra venom, accidental (unintentional), initial encounter.
T63.061A	Toxic effect of venom of other North and South American snake, accidental (unintentional), initial encounter.
T63.71A	Toxic effect of venom of other Australian snake, accidental (unintentional), initial encounter.
T63.081A	Toxic effect of venom of other African and Asian snake, accidental (unintentional), initial encounter.
T63.091A	Toxic effect of venom of other snake, accidental (unintentional), initial encounter.

For the ICD–9–CM Supplementary Classification of External Causes of Injury and Poisoning code E905.0 (Venomous snakes and lizards), ICD–10–CM provides more detailed diagnosis codes for these cases as shown in the following table:

ICD–10–CM Code Translations for ICD–9–CM Code E905.0

ICD–10–CM code	Code description
T63.001A	Toxic effect of unspecified snake venom, accidental (unintentional), initial encounter.
T63.011A	Toxic effect of rattlesnake venom, accidental (unintentional) initial encounter.
T63.021A	Toxic effect of coral snake venom, accidental (unintentional), initial encounter.
T63.031A	Toxic effect of taipan venom, accidental (unintentional), initial encounter.
T63.041A	Toxic effect of cobra venom, accidental (unintentional), initial encounter.
T63.061A	Toxic effect of venom of other North and South American snake, accidental (unintentional), initial encounter.
T63.71A	Toxic effect of venom of other Australian snake, accidental (unintentional), initial encounter.
T63.081A	Toxic effect of venom of other African and Asian snake, accidental (unintentional), initial encounter.
T63.091A	Toxic effect of venom of other snake, accidental (unintentional), initial encounter.

We examined claims data for injections for snake bites reported in MS–DRGs 917 and 918 from the December 2014 update of the FY 2014 MedPAR file. Our findings are displayed in the table below.

Snake Bite With Injections

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 917—All cases	26,393	4.77	$9,983
MS–DRG 917—Cases with principal diagnosis code 989.5 and secondary diagnosis code E905.0 with procedure code 99.16 (non-OR)	0	0	0
MS–DRG 918—All cases	24,557	2.90	4,953
MS–DRG 918—Cases with principal diagnosis code 989.5 and secondary diagnosis code E905.0 with procedure code 99.16 (non-OR)	19	2.16	12,014

As shown in the table above, we identified 19 cases of injections for snake bites reported in MS–DRG 918 only. This small number of cases (19) does not provide justification to create a new MS–DRG. The cases are assigned to the same MS–DRG as are other types of poisonings and toxic effects. We were unable to find another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the clinical nature of this condition. The MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. Basing a new MS–DRG on such a small number of cases (19) could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights.

Our clinical advisors reviewed the data, evaluated these conditions, and recommended that we not change the MS–DRG assignment for CroFab antivenom drug for snake bites because these cases are clinically similar to other poisoning cases currently assigned to

MS–DRGs 917 and 918. Based on the findings in our data analysis and the recommendations of our clinical advisors, we are proposing to maintain the current assignment of diagnosis codes in MS–DRGs 917 and 918. We are not proposing any MS–DRG changes for cases of CroFab antivenom drugs for snake bites. We are inviting public comments on our proposal.

7. MDC 22 (Burns): Additional Severity of Illness Level for MS–DRG 927 (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft)

We received a request to add an additional severity level to MS–DRG 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation 96+ Hours with Skin Graft). The requestor was concerned about payment for severe burn cases that used dermal regenerative grafts. These grafts are captured by procedure code 86.67 (Dermal regenerative graft). The requestor stated that the total cost of these graft cases is significantly greater than the average total costs for all cases in MS–DRG 927. The requestor stated that the dermal regenerative grafts are used to cover large burns where donor skin is not available. The requestor stated that the grafts provide permanent covering of the wound and thus immediate closure of the wound. The requestor asserted that the grafts offer benefits such as the avoidance of infections. The requestor pointed out that MS–DRG 927 is not subdivided into severity of illness levels and recommended an additional severity level be added to address any payment issues for dermal regenerative grafts within MS–DRG 927.

ICD–10–PCS provides more detailed and specific codes for skin grafts. The ICD–10–PCS codes for skin grafts provide specific information on the part of the body receiving the skin graft, the type of graft, and the approach used to apply the graft. These codes can be found in the table labeled ''OHR (Replacement of Skin)'' in the ICD–10 MS–DRG Version 32 Definitions Manual available on the Internet at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* As stated earlier, for the ICD–9–CM codes that result in greater than 50 ICD–10–PCS comparable code translations, we refer readers to Table 6P (ICD–10–PCS Code Translations for Proposed MS–DRG Changes), which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* The table includes the MDC topic, the ICD–9–CM code, and the ICD–10–PCS code translations. In Table 6P.2a, we show the comparable ICD–10–PCS codes for ICD–9–CM code 86.67 (Dermal regenerative graft).

We examined claims data for cases reported in MS–DRG 927 from the December 2014 update of the FY 2014 MedPAR file. The following table shows our findings.

EXTENSIVE BURNS OR FULL THICKNESS BURNS WITH MECHANICAL VENTILATION 96+ HOURS WITH SKIN GRAFT

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 927—All cases	171	29.92	$113,844
MS–DRG 927—Cases with procedure code 86.67	22	33.5	146,903
MS–DRG 927—Cases with procedure code 86.67 and 96.72 (Mechanical ventilation for 96+ hours)	14	38.6	174,372
MS–DRG 927—Cases with procedure code 86.67 and without 96.72 (Mechanical ventilation for 96+ hours)	8	24.6	98,482
MS–DRG 927—All cases with MCC	131	31.51	121,519
MS–DRG 927—All cases with CC	38	25.21	91,910
MS–DRG 927—All cases without CC/MCC	2	15.00	27,872

As shown in the table above, we found a total of 171 cases in MS–DRG 927. Of these 171 cases, there were 131 cases with an MCC, 38 cases with a CC, and 2 cases without a CC or an MCC. The requested new severity level does not meet all of the criteria established in the FY 2008 IPPS final rule (72 FR 47169), and described in section II.G.1.b. of the preamble of this proposed rule, that must be met to warrant the creation of a CC or an MCC subgroup within a base MS–DRG. Specifically, the requested new severity level does not meet the criterion that there are at least 500 cases in the CC or MCC subgroup.

We also point out that the long-term mechanical ventilation cases are driving the costs to a greater extent than the graft cases. We found that the 22 cases that received a graft had average costs of $146,903. The 14 cases that had both 96+ hours of mechanical ventilation and a graft had average costs of $174,372. The 8 cases that had a graft but did not receive 96+ hours of mechanical ventilation had average costs of $98,482.

Our clinical advisors reviewed this issue and recommended making no MS–DRG updates for MS–DRG 927. They advised us that the dermal regenerative graft cases are appropriately assigned to the MS–DRG 927 because they are clinically similar to other cases within MS–DRG 927. Our clinical advisors also agreed that the cases in MS–DRG 927 do not meet the established criterion for creating a new severity level.

Based on the findings of our data analysis, the fact that MS–DRG 927 does not meet the criterion for the creation of an additional severity level, and the recommendations of our clinical advisors, we are not proposing to create a new severity level for MS–DRG 927. We are proposing to maintain the current MS–DRG 927 structure without additional severity levels. We are inviting public comments on our proposal.

8. Proposed Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in section II.G.1.a. of the preamble of this proposed rule, CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS–DRGs Version 32 and the MCE Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/*

Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html. We also prepared a document that described the changes made between Version 31–R to Version 32 to help facilitate a review of the ICD–10 MS–DRGs logic. We produced mainframe and computer software for ICD–10 MS–DRGs Version 32 and MCE Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRG GROUPER and MCE did not accurately reflect the logic and edits found in the ICD–9–CM MS–DRG GROUPER and the MCE.

For FY 2016, in order to be consistent with the ICD–9–CM MS–DRG GROUPER and MCE Version 32, we are proposing to add the ICD–10–PCS codes listed in the table below to the ICD–10 MCE Version 33 of the ''Manifestation codes not allowed as principal diagnosis'' edit. Under the MCE, manifestation codes describe the ''manifestation'' of an underlying disease, not the disease itself. Because these codes do not describe the disease itself, they should not be used as principal diagnoses.

ICD–10–CM Codes Proposed To Be Added to the Version 33 MCE ''Manifestation Codes Not Allowed as Principal Diagnosis'' Edit

ICD–10–CM code	Code description
D75.81	Myelofibrosis.
E08.00	Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC).
E08.01	Diabetes mellitus due to underlying condition with hyperosmolarity with coma.
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma.
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma.
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy.
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease.
E08.29	Diabetes mellitus due to underlying condition with other diabetic kidney complication.
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema.
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema.
E08.321	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema.
E08.329	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema.
E08.331	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema.
E08.339	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema.
E08.341	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema.
E08.349	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema.
E08.351	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema.
E08.359	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema.
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract.
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication.
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified.
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy.
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy.
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy.
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy.
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication.
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene.
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene.
E08.59	Diabetes mellitus due to underlying condition with other circulatory complications.
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy.
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy.
E08.620	Diabetes mellitus due to underlying condition with diabetic dermatitis.
E08.621	Diabetes mellitus due to underlying condition with foot ulcer.
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer.
E08.628	Diabetes mellitus due to underlying condition with other skin complications.
E08.630	Diabetes mellitus due to underlying condition with periodontal disease.
E08.638	Diabetes mellitus due to underlying condition with other oral complications.
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma.
E08.649	Diabetes mellitus due to underlying condition with hypoglycemia without coma.
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia.
E08.69	Diabetes mellitus due to underlying condition with other specified complication.
E08.8	Diabetes mellitus due to underlying condition with unspecified complications.
E08.9	Diabetes mellitus due to underlying condition without complications.

We are inviting public comment on our proposal to add the above list of ICD–10–CM diagnosis codes to the ''Manifestation codes not allowed as principal diagnosis'' edit in the FY 2016 ICD–10 MCE Version 33.

We also are proposing to revise the language describing the ''Procedure inconsistent with LOS (Length of stay)'' edit which lists ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours), effective for the FY 2016 ICD–10 MCE Version 33. Currently, in Version 32 of the ICD–10 MCE, the language describing this ''Procedure inconsistent with LOS (Length of stay)'' edit states: ''The following procedure should only

be coded on claims with a length of stay of four days or greater.'' Because the code description of the ICD–10–PCS code is for ventilation that occurs *greater than* 96 hours, we are proposing to revise the language for the edit to read: ''The following procedure code should only be coded on claims with a length of stay greater than 4 days.'' This proposed revision would clarify the intent of this MCE edit. We are inviting public comments on our proposal.

9. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2016, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2016, as discussed in section II.G.3.e. of the preamble of this FY 2016 IPPS/LTCH PPS proposed rule, we are proposing to revise the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System). Specifically, we are proposing to delete MS–DRG 237 (Major Cardiovascular Procedures with MCC) and MS–DRG 238 (Major Cardiovascular Procedures without MCC) from the surgical hierarchy. We are proposing to sequence proposed new MS–DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC) and proposed new MS–DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC) above proposed new MS–DRG 270 (Other Major Cardiovascular Procedures with MCC), proposed new MS–DRG 271 (Other Major Cardiovascular Procedures with CC), and proposed new MS–DRG 272 (Other Major Cardiovascular Procedures without CC/MCC). We are proposing to sequence proposed new MS–DRGs 270, 271, and 272 above MS–DRG 239 (Amputation for Circulatory System Disorders Except Upper Limb & Toe with MCC). In addition, we are proposing to sequence proposed new MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and proposed new MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) above MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-eluting Stent with MCC or 4+ Vessels/Stents).

We are inviting public comments on our proposals.

10. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2016

a. Major Complications or Comorbidities (MCCs) and Complications or Comorbidities (CC) Severity Levels for FY 2016

A complete updated MCC, CC, and Non-CC Exclusion List is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as follows:

- Table 6I (Complete MCC list);
- Table 6J (Complete CC list); and
- Table 6K (Complete list of CC Exclusions).

b. Coronary Atherosclerosis Due to Calcified Coronary Lesion

We received a request that we change the severity levels for ICD–9–CM diagnosis codes 414.2 (Chronic total occlusion of coronary artery) and 414.4 (Coronary atherosclerosis due to calcified coronary lesion) from non-CCs to MCCs. The ICD–10–CM codes for these diagnoses are I25.82 (Chronic total occlusion of coronary artery) and I25.84 (Coronary atherosclerosis due to calcified coronary lesion), respectively, and both of these codes are currently classified as non-CCs.

This issue was previously discussed in the FY 2014 IPPS/LTCH PPS proposed rule and final rule (78 FR 27522 and 78 FR 50541 through 50542,

respectively), and the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28018 and 28019 and 79 FR 49903 and 49904, respectively).

We examined claims data from the December 2014 update of the FY 2014 MedPAR file for ICD–9–CM diagnosis codes 414.2 and 414.4. The following table shows our findings.

SDX	SDX description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
414.2	Chronic total occlusion of coronary artery.	Non-CC	14,655	1.393	21,222	2.098	20,615	3.046
414.4	Coronary atherosclerosis due to calcified coronary lesion.	Non-CC	1,752	1.412	3,238	2.148	3,244	3.053

We ran the data using the criteria described in the FY 2008 IPPS final rule with comment period (72 FR 47169) to determine severity levels for procedures in MS–DRGs. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC, but none that is an MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC.

The table above shows that the C1 finding is 1.393 for ICD–9–CM diagnosis code 414.2 and the C1 finding is 1.412 for ICD–9–CM diagnosis code 414.4. A value close to 1.0 in the C1 field suggests that the diagnosis produces the same expected value as a non-CC. A value close to 2.0 suggests the condition is more like a CC than a non-CC, but not as significant in resource usage as an MCC. A value close to 3.0 suggests that the condition is expected to consume resources more similar to an MCC than a CC or a non-CC. The C2 finding was 2.098 for ICD–9–CM diagnosis code 414.2, and the C2 finding was 2.148 for ICD–9–CM diagnosis code 414.4. A C2 value close to 2.0 suggests the condition is more like a CC than a non-CC, but not as significant in resource usage as an MCC when there is at least one other secondary diagnosis that is a CC but none that is an MCC. While the C1 value of 1.393 for ICD–9–CM diagnosis code 414.2 and the C1 value of 1.412 for ICD–9–CM diagnosis code 414.4 are above the 1.0 value for a non-CC, these values do not support the reclassification of diagnosis codes 414.2 and 414.4 to MCCs. As stated earlier, a value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or a non-CC. The C2 finding of 2.098 for ICD–9–CM diagnosis code 414.2 and the C2 finding of 2.148 for ICD–9–CM diagnosis code 414.4 also do not support reclassifying these diagnosis codes to MCCs.

Our clinical advisors reviewed the data and evaluated these conditions. They recommended that we not change the severity level of diagnosis codes 414.2 and 414.4 from a non-CC to an MCC. Our clinical advisors do not believe that these diagnoses would increase the severity of illness level of patients. Considering the C1 and C2 ratings of both diagnosis codes 414.2 and 414.4 and the input from our clinical advisors, we are not proposing to reclassify conditions represented by diagnosis codes 414.2 and 414.4 to MCCs. We are proposing to maintain both of these conditions as non-CCs. As stated earlier, the equivalent ICD–10–CM codes for these conditions are codes I25.82 and I25.84, respectively. Therefore, based on the data and clinical analysis, we are proposing to maintain ICD–10–CM diagnosis codes I25.82 and I25.84 as non-CCs. We are inviting public comments on our proposals.

c. Hydronephrosis

Some ICD–10–CM diagnosis codes express conditions that are normally coded in ICD–9–CM using two or more ICD–9–CM diagnosis codes. CMS' goal in developing the ICD–10 MS–DRGs was to ensure that a patient case is assigned to the same MS–DRG, regardless of whether the patient record were to be coded in ICD–9–CM or ICD–10–CM/PCS. When one of the ICD–10–CM combination codes is used as a principal diagnosis, the cluster of ICD–9–CM codes that would be coded on an ICD–9–CM record was evaluated. If one of the ICD–9–CM codes in the cluster is a CC or an MCC, the single ICD–10–CM combination code used as a principal diagnosis also must imply that the CC or MCC is present. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32 includes two lists. Part 1 is the list of principal diagnosis codes where the ICD–10–CM code is its own MCC. Part 2 is the list of principal diagnosis codes where the ICD–10–CM code is its own CC. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32 is available via the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

We received a request that the ICD–10–CM combination codes for hydronephrosis due to ureteral stricture and urinary stone (N13.1 and N13.2) be flagged as principal diagnoses that can act as their own CC for MS–DRG grouping purposes.

In ICD–9–CM, code 591 (Hydronephrosis) is classified as a CC. In ICD–10–CM, hydronephrosis is reported with a combination code if the hydronephrosis is due to a ureteral stricture or urinary stone obstruction of N13.1 (Hydronephrosis with ureteral stricture, not elsewhere classified) and N13.2 (Hydronephrosis with renal and ureteral calculous obstruction). In ICD–10–CM, these two codes (N13.1 and N13.2) are classified as CCs, but these codes are not recognized as principal diagnoses that act as their own CC (they are not included in the Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32).

We agree with the requestor that ICD–10–CM diagnosis codes N13.1 and N13.2 should be flagged as principal diagnosis codes that can act as their own CC for MS–DRG grouping purposes. Therefore, we are proposing that diagnosis codes N13.1 and N13.2 be added to the list of principal diagnoses that act as their own CC in Appendix J of the ICD–10 MS–DRG Definitions Manual Version 32. We are inviting public comments on our proposal.

11. Proposed Complications or Comorbidity (CC) Exclusions List for FY 2016

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we

developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Proposed CC Exclusions List for FY 2016

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[4]

The ICD–10 MS–DRGs Version 32 CC Exclusion List is included as Appendix C in the Definitions Manual available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.*

For FY 2016, we are not proposing any changes to the CC Exclusion List. Because we are not proposing any changes to the ICD–10 MS–DRGs CC Exclusion List for FY 2016, we are not publishing Table 6G (Additions to the CC Exclusion List) or Table 6H (Deletions from the CC Exclusion List). We have developed Table 6K (Complete List of CC Exclusions), which is available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Because of the length of Table 6K, we are not publishing it in the Addendum to this proposed rule. Each of the secondary diagnosis codes for which there is an exclusion is listed in Part 1 of Table 6K. Each of these secondary diagnosis codes is indicated as a CC or an MCC. If the CC or MCC is allowed with all principal diagnoses, the phrase ''NoExcl'' (for no exclusions) follows the CC/MCC indicator. Otherwise, a link is given to a collection of diagnosis codes which, when used as the principal diagnosis, will cause the CC or MCC to be considered as only a non-CC. Part 2 of Table 6K lists codes that are assigned as an MCC only for patients discharged alive. Otherwise, the codes are assigned as a non-CC.

A complete updated MCC, CC, and Non-CC Exclusions List is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Because there are no proposed new, revised, or deleted ICD–10–CM diagnosis codes for FY 2016, we have not developed Table 6A (New Diagnosis Codes), Table 6C (Invalid Diagnosis Codes), or Table 6E (Revised Diagnosis Code Titles), for this proposed rule and they are not published as part of this proposed rule. We have developed Table 6B (New Procedure Codes) for new ICD–10–PCS codes which will be implemented on October 1, 2015. Because there are no proposed revised or deleted procedure codes for FY 2016, we have not developed Table 6D (Invalid Procedure Codes) or Table 6F (Revised Procedure Codes).

We are not proposing any additions or deletions to the MS–DRG MCC List for FY 2016 nor any additions or deletions to the MS–DRG CC List for FY 2016. Therefore, for this proposed rule, we have not developed Tables 6I.1 (Additions to the MCC List), 6I.2 (Deletions to the MCC List), 6J.1 (Additions to the CC List), and 6J.2 (Deletions to the CC List), and they are not published as part of this proposed rule. We have developed Table 6M.1 (Additions to Principal Diagnosis Is Its Own CC) to show the two proposed additions to this list for the two principal diagnosis codes acting as their own CC.

The complete documentation of the ICD–10 MS–DRG Version 32 GROUPER logic, including the current CC

[4] We refer readers to the FY 1989 final rule (53 FR 38485, September 30, 1988) for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989) for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990) for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992) for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993) for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994) for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995) for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996) for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998) for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000) for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001) for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002) for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003) for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004) for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005) for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions; the FY 2009 final rule (73 FR 48510); the FY 2010 final rule (74 FR 43799); the FY 2011 final rule (75 FR 50114); the FY 2012 final rule (76 FR 51542); the FY 2013 final rule (77 FR 53315); the FY 2014 final rule (78 FR 50541), and the FY 2015 final rule (79 FR 49905). In the FY 2000 final rule (64 FR 41490, July 30, 1999), we did not modify the CC Exclusions List because we did not make any changes to the ICD–9–CM codes for FY 2000.

Exclusions List, is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* The complete documentation of the ICD–10 MS–DRG GROUPER logic will be available on the CMS Acute Inpatient PPS Web page after the issuance of the final rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

12. Review of Procedure Codes in MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0 (Incision of prostate);
- 60.12 (Open biopsy of prostate);
- 60.15 (Biopsy of periprostatic tissue);
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue);
- 60.21 (Transurethral prostatectomy);
- 60.29 (Other transurethral prostatectomy);
- 60.61 (Local excision of lesion of prostate);
- 60.69 (Prostatectomy, not elsewhere classified);
- 60.81 (Incision of periprostatic tissue);
- 60.82 (Excision of periprostatic tissue);
- 60.93 (Repair of prostate);
- 60.94 (Control of (postoperative) hemorrhage of prostate);
- 60.95 (Transurethral balloon dilation of the prostatic urethra);
- 60.96 (Transurethral destruction of prostate tissue by microwave thermotherapy);
- 60.97 (Other transurethral destruction of prostate tissue by other thermotherapy); and
- 60.99 (Other operations on prostate).

All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[5]

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we are not proposing to change the procedures assigned among these MS–DRGs.

We are inviting public comments on our proposal.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As noted above, there are no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

We are inviting public comments on our proposal.

b. Reassignment of Procedures Among MS DRGs 981 Through 983, 984 Through 986, and 987 Through 989

(1) Annual Review of Procedures

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS DRGs to another of the three MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment

[5] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962), in the FY 2000 (64 FR 41496), in the FY 2001 (65 FR 47064), or in the FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999), we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, and 2015, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), in the FY 2009 final rule (73 FR 48513), in the FY 2010 final rule (74 FR 43796), in the FY 2011 final rule (75 FR 50122), in the FY 2012 final rule (76 FR 51549), in the FY 2013 final rule (77 FR 53321), in the FY 2014 final rule (78 FR 50545); and in the FY 2015 final rule (79 FR 49906).

illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There are no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2016, we are not proposing to move any procedure codes among these MS–DRGs.

(2) Review of Cases With Endovascular Embolization Procedures for Epistaxis

During the comment period for the FY 2015 IPPS/LTCH PPS proposed rule, we received a public comment expressing concern regarding specific procedure codes that are assigned to MS–DRGs 981 through 983; 984 through 986; and 987 through 989 in relation to our discussion of the annual review of these MS–DRGs in section II.G.12. of that proposed rule (79 FR 28020). The commenter noted that the endovascular embolization of the arteries of the branches of the internal maxillary artery is frequently performed for intractable posterior epistaxis (nosebleed). The commenter stated that, currently, diagnosis code 784.7 (Epistaxis) reported with procedure codes 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils) and 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils) groups to MS–DRGs 981, 982, and 983. The commenter indicated that it also found this grouping with the ICD–10 MS–DRGs Version 31 using ICD–10–CM diagnosis code R04.0 (Epistaxis) reported with artery occlusion procedure codes. The commenter requested that CMS review these groupings and consider the possibility of reassigning these epistaxis cases with endovascular embolization procedure codes into a more specific MS–DRG.

We considered this public comment to be outside of the scope of the FY 2015 IPPS/LTCH PPS proposed rule and, therefore, did not address it in the FY 2015 IPPS/LTCH PPS final rule. However, we indicated that we would consider this public comment for possible proposals in future rulemaking as part of our annual review process.

ICD–10–PCS provides more detailed codes for endovascular embolization or occlusion of vessel(s) of head or neck using bare coils and bioactive coils which are listed in the following table:

ICD–10–PCS Codes for Endovascular Embolization or Occlusion of Vessel(s) of Head or Neck Using Bare Coils and Bioactive Coils

ICD–10–PCS code	Code description
03LG0BZ	Occlusion of intracranial artery with bioactive intraluminal device, open approach.
03LG0DZ	Occlusion of intracranial artery with intraluminal device, open approach.
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH0BZ	Occlusion of right common carotid artery with bioactive intraluminal device, open approach.
03LH0DZ	Occlusion of right common carotid artery with intraluminal device, open approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ0BZ	Occlusion of left common carotid artery with bioactive intraluminal device, open approach.
03LJ0DZ	Occlusion of left common carotid artery with intraluminal device, open approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK0BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, open approach.
03LK0DZ	Occlusion of right internal carotid artery with intraluminal device, open approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL0BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, open approach.
03LL0DZ	Occlusion of left internal carotid artery with intraluminal device, open approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM0BZ	Occlusion of right external carotid artery with bioactive intraluminal device, open approach.
03LM0DZ	Occlusion of right external carotid artery with intraluminal device, open approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN0BZ	Occlusion of left external carotid artery with bioactive intraluminal device, open approach.
03LN0DZ	Occlusion of left external carotid artery with intraluminal device, open approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP0BZ	Occlusion of right vertebral artery with bioactive intraluminal device, open approach.
03LP0DZ	Occlusion of right vertebral artery with intraluminal device, open approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF VESSEL(S) OF HEAD OR NECK USING BARE COILS AND BIOACTIVE COILS—Continued

ICD–10–PCS code	Code description
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ0BZ	Occlusion of left vertebral artery with bioactive intraluminal device, open approach.
03LQ0DZ	Occlusion of left vertebral artery with intraluminal device, open approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VG0BZ	Restriction of intracranial artery with bioactive intraluminal device, open approach.
03VG0DZ	Restriction of intracranial artery with intraluminal device, open approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH0BZ	Restriction of right common carotid artery with bioactive intraluminal device, open approach.
03VH0DZ	Restriction of right common carotid artery with intraluminal device, open approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ0BZ	Restriction of left common carotid artery with bioactive intraluminal device, open approach.
03VJ0DZ	Restriction of left common carotid artery with intraluminal device, open approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK0BZ	Restriction of right internal carotid artery with bioactive intraluminal device, open approach.
03VK0DZ	Restriction of right internal carotid artery with intraluminal device, open approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL0BZ	Restriction of left internal carotid artery with bioactive intraluminal device, open approach.
03VL0DZ	Restriction of left internal carotid artery with intraluminal device, open approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM0BZ	Restriction of right external carotid artery with bioactive intraluminal device, open approach.
03VM0DZ	Restriction of right external carotid artery with intraluminal device, open approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN0BZ	Restriction of left external carotid artery with bioactive intraluminal device, open approach.
03VN0DZ	Restriction of left external carotid artery with intraluminal device, open approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP0BZ	Restriction of right vertebral artery with bioactive intraluminal device, open approach.
03VP0DZ	Restriction of right vertebral artery with intraluminal device, open approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ0BZ	Restriction of left vertebral artery with bioactive intraluminal device, open approach.
03VQ0DZ	Restriction of left vertebral artery with intraluminal device, open approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR0DZ	Restriction of face artery with intraluminal device, open approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS0DZ	Restriction of right temporal artery with intraluminal device, open approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT0DZ	Restriction of left temporal artery with intraluminal device, open approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF VESSEL(S) OF HEAD OR NECK USING BARE COILS AND BIOACTIVE COILS—Continued

ICD–10–PCS code	Code description
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU0DZ	Restriction of right thyroid artery with intraluminal device, open approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV0DZ	Restriction of left thyroid artery with intraluminal device, open approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

We examined claims data from the December 2014 update of the FY 2014 MedPAR file for cases with diagnosis code 784.7 reported with procedure codes 39.75 and 39.76 in MS–DRGs 981, 982, and 983. The following table shows our findings.

ENDOVASCULAR EMBOLIZATION PROCEDURES FOR EPISTAXIS

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—All cases	21,118	12.38	$33,080
MS–DRG 981—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	8	6.50	34,655
MS–DRG 981—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	2	12.50	50,081
MS–DRG 982—All cases	13,657	7.14	19,392
MS–DRG 982—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	22	3.14	17,725
MS–DRG 982—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	2	2.0	11,010
MS–DRG 983—All cases	2,989	3.60	12,760
MS–DRG 983—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.75	5	2.60	10,532
MS–DRG 983—Epistaxis cases with principal diagnosis code 784.7 and procedure code 39.76	4	1.50	16,658

We found only 35 epistaxis cases with procedure code 39.75 reported and 8 cases with procedure code 39.76 reported among MS–DRGs 981, 982, and 983. The use of endovascular embolizations for epistaxis appears to be rare. The average costs for the cases with procedure code 39.75 in MS–DRGs 981, 982, and 983 are similar to the average costs for all cases in MS–DRGs 981, 982, and 983, respectively. The average costs for the cases with procedure code 39.75 in MS–DRGs 981, 982, and 983 were $34,655, $17,725, and $10,532, respectively, compared to $33,080, $19,392, and $12,760 for all cases in MS–DRGs 981, 982, and 983. The average costs for cases with procedure code 39.76 in MS–DRGs 981, 982, and 983 were $50,081, $11,010, and $16,658, respectively, and were significantly greater than all cases in MS–DRGs 981 and 983. However, as stated earlier, there were only 8 cases reported with procedure code 39.76. As explained previously, MS–DRGs 981, 982, and 983 were created for operating room procedures that are unrelated to the principal diagnosis. Because there were so few cases reported, this does not appear to be a common procedure for epistaxis. There were not enough cases to base a change of MS–DRG assignment for these cases.

Our clinical advisors reviewed this issue and did not identify any new MS–DRG assignment that would be more appropriate for these rare cases. They advised us to maintain the current MS–DRG structure within MS–DRGs 981, 982, and 983.

Based on the results of the examination of the claims data and the recommendations from our clinical advisors, we are not proposing to create new MS–DRG assignments for epistaxis cases receiving endovascular embolization procedures. We are proposing to maintain the current MS–DRG structure for epistaxis cases receiving endovascular embolization procedures and are not proposing any updates to MS–DRGs 981, 982, and 983. We are inviting public comments on our proposal.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs, as described above in sections II.G.2. through 7. of the preamble of this proposed rule, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2016. We are inviting public comments on our proposal.

13. Proposed Changes to the ICD–9–CM System

a. ICD–10 Coordination and Maintenance Committee

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was to be made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with

the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM, ICD–10–PCS, and ICD–9–CM coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2016 at a public meeting held on September 23–24, 2014, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2014.

The Committee held its 2015 meeting on March 18–19, 2015. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2015 would be included in the October 1, 2015 update to ICD–10–CM/ICD–10–PCS. For FY 2016, there are no new, revised, or deleted ICD–10–CM diagnosis codes. For FY 2016, there are new ICD–10–PCS procedure codes that are included in Table 6B (New Procedure Codes). However, there are no revised or deleted ICD–10–PCS procedure codes. There also are no new ICD–9–CM diagnosis or procedure codes because ICD–9–CM will be replaced by ICD–10–CM/ICD–10–PCS for services provided on or after October 1, 2015.

Copies of the agenda, handouts, and access to the live stream videos for the procedure codes discussions at the Committee's September 23–24, 2014 meeting and March 18–19, 2015 meeting can be obtained from the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp.* The agenda, handouts and minutes of the diagnosis codes discussions at the September 23–24, 2014 meeting and March 18–19, 2015 meeting are found at: *http://www.cdc.gov/nchs/icd/icd9cm-maintenance.html.* These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *dfp4@cdc.gov.*

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: *patricia.brooks2@cms.hhs.gov.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating ICD–9–CM codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is

published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2015 implementation of a code at the September 23–24, 2014 Committee meeting. Therefore, there were no new codes implemented on April 1, 2015.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at *http://www.cms.gov/Medicare/Coding/ICD10/index.html.* Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/index.html.* Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

b. Code Freeze

In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3340), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

HHS responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, HHS indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. The Committee also considered the delay in implementation of ICD–10 until October 1, 2014. There was an announcement at the September 19, 2012 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes will be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was made on October 1, 2011.
- On October 1, 2012 and October 1, 2013, there were to be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- On October 1, 2014, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Public Law 108–173. There were to be no updates to ICD–9–CM on October 1, 2014.
- On October 1, 2015, one year after the originally scheduled implementation of ICD–10, regular updates to ICD–10 were to begin.

On May 15, 2014, CMS posted an updated Partial Code Freeze schedule on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-9-CM-Coordination-and-Maintenance-Committee-Meetings.html.* This updated schedule provided information on the extension of the partial code freeze until 1 year after the implementation of ICD–10. As stated earlier, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2014-08-04/pdf/2014-18347.pdf.* That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Accordingly, the updated schedule for the partial code freeze is as follows:

- The last regular annual updates to both ICD–9–CM and ICD–10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there were only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 1886(d)(5)(K) of the Act.

• On October 1, 2015, there will be only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by section 1886(d)(5)(K) of the Act. There will be no updates to ICD–9–CM, as it will no longer be used for reporting.

• On October 1, 2016 (1 year after implementation of ICD–10), regular updates to ICD–10 will begin.

The ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 one year after the implementation of ICD–10, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–10 Coordination and Maintenance Committee Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html.* A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html.*

This partial code freeze has dramatically decreased the number of codes created each year as shown by the following information.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR

ICD–9–CM Codes			ICD–10–CM and ICD–10–PCS Codes		
Fiscal Year	Number	Change	Fiscal Year	Number	Change
FY 2009 (October 1, 2008):			FY 2009:		
Diagnoses	14,025	348	ICD–10–CM	68,069	+5
Procedures	3,824	56	ICD–10–PCS	72,589	−14,327
FY 2010 (October 1, 2009):			FY 2010:		
Diagnoses	14,315	290	ICD–10–CM	69,099	+1,030
Procedures	3,838	14	ICD–10–PCS	71,957	−632
FY 2011(October 1, 2010):					
Diagnoses	14,432	117	ICD–10–CM	69,368	+269
Procedures	3,859	21	ICD–10–PCS	72,081	+124
FY 2012 (October 1, 2011):			FY 2012:		
Diagnoses	14,567	135	ICD–10–CM	69,833	+465
Procedures	3,877	18	ICD–10–PCS	71,918	−163
FY 2013 (October 1, 2012):			FY 2013:		
Diagnoses	14,567	0	ICD–10–CM	69,832	−1
Procedures	3,878	1	ICD–10–PCS	71,920	+2
FY 2014 (October 1, 2013):			FY 2014:		
Diagnoses	14,567	0	ICD–10–CM	69,823	−9
Procedures	3,882	4	ICD–10–PCS	71,924	+4
FY 2015 (October 1, 2014):			FY 2015:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
FY 2016 (October 1, 2015):			FY 2016:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,962	+38

As mentioned earlier, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The public has supported only a limited number of new codes during the partial code freeze, as can be seen by data shown above. We have gone from creating several hundred new codes each year to creating only a limited number of new ICD–9–CM and ICD–10 codes.

At the September 23–24, 2014 and March 18–19, 2015 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis and ICD–10–PCS procedure codes that were to be implemented on October 1, 2015. We did not discuss ICD–9–CM codes. The public was given the opportunity to comment on whether or not new ICD–10–CM and ICD–10–PCS codes should be created, based on the partial code freeze criteria. The public was to use the criteria as to whether codes were needed to capture new diagnoses or new technologies. If the codes do not meet those criteria for implementation during the partial code freeze, consideration was to be given as to whether the codes should be created after the partial code freeze ends 1 year after the implementation of ICD–10–CM/PCS. We invited public comments on any code requests discussed at the September 23–24, 2014 and March 18–19, 2015 Committee meetings for implementation as part of the October 1, 2015 update. The deadline for commenting on code proposals discussed at the September 23–24, 2014 Committee meeting was November 21, 2014. The deadline for commenting on code proposals discussed at the March 18–19, 2015 Committee meeting was April 17, 2015.

14. Other Proposed Policy Changes: Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. We specified that if a hospital received a credit for a recalled device equal to 50 percent or more of the cost of the device, we would reduce

a hospital's IPPS payment for those MS–DRGs.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 and 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Request for Clarification on Policy Relating to ''Device-Dependent'' MS–DRGs

After publication of the FY 2015 IPPS/LTCH PPS final rule, we received a request to clarify the list of ''device-dependent'' MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. Specifically, a requestor noted that ICD–9–CM procedure codes that previously grouped to MS–DRGs 216 through 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, without CC/MCC, respectively) and were subject to the policy for payment under the IPPS as ''device-dependent'' MS–DRGs had been reassigned to new MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with MCC and without MCC, respectively). The requestor suggested that MS–DRGs 266 and 267 also should be considered ''device-dependent'' MS–DRGs and added to the list of MS–DRGs subject to the IPPS payment policy for replaced devices offered without cost or with a credit.

As noted by the requestor, as final policy for FY 2015, certain ICD–9–CM procedure codes that previously grouped to MS–DRGs 216 through 221, which are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit, were reassigned to MS–DRGs 266 and 267. We agree that MS–DRGs 266 and 267 should be included in the list of ''device-dependent'' MS–DRGs subject to the IPPS policy. We generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Therefore, we are proposing to add MS–DRGs 266 and 267 to the list of ''device dependent'' MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit.

In addition, as discussed in section II.G.4.e. of the preamble of this proposed rule, for FY 2016, we are proposing to delete MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) and create new MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively), as well as new MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively). Currently, MS–DRGs 237 and 238 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. As stated previously, we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Therefore, if finalized, we also would add proposed new MS–DRGs 268 through 272 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit.

In summary, we are proposing to add MS–DRGs 266 and 267 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit, and if the applicable proposed MS–DRG changes are finalized, to also remove existing MS–DRGs 237 and 238 and add proposed new MS–DRGs 268 through 272. The proposed list of MS–DRGs to be subject to the IPPS policy for replaced devices offered without cost or with a credit for FY 2016 is displayed below.

PROPOSED LIST OF MS–DRGS SUBJECT TO THE IPPS POLICY FOR REPLACED DEVICES OFFERED WITHOUT COST OR WITH A CREDIT

MDC	MS–DRG	MS–DRG Title
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant.
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC.
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC.
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC.
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation.
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC.
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device.
MDC 03	130	Major Head & Neck Procedures without CC/MCC.
MDC 05	215	Other Heart Assist System Implant.
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC.
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC.
MDC 05	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC.
MDC 05	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC.
MDC 05	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC.
MDC 05	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC.
MDC 05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC.
MDC 05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC.
MDC 05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC.
MDC 05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC.
MDC 05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
MDC 05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
MDC 05	242	Permanent Cardiac Pacemaker Implant with MCC.
MDC 05	243	Permanent Cardiac Pacemaker Implant with CC.
MDC 05	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
MDC 05	245	AICD Generator Procedures.
MDC 05	258	Cardiac Pacemaker Device Replacement with MCC.

PROPOSED LIST OF MS–DRGS SUBJECT TO THE IPPS POLICY FOR REPLACED DEVICES OFFERED WITHOUT COST OR WITH A CREDIT—Continued

MDC	MS–DRG	MS–DRG Title
MDC 05	259	Cardiac Pacemaker Device Replacement without MCC.
MDC 05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
MDC 05	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
MDC 05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
MDC 05	265	AICD Lead Procedures.
MDC 05	266	Endovascular Cardiac Valve Replacement with MCC.
MDC 05	267	Endovascular Cardiac Valve Replacement without MCC.
MDC 05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
MDC 05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
MDC 05	270	Other Major Cardiovascular Procedures with MCC.
MDC 05	271	Other Major Cardiovascular Procedures with CC.
MDC 05	272	Other Major Cardiovascular Procedures without CC/MCC.
MDC 08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC.
MDC 08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
MDC 08	466	Revision of Hip or Knee Replacement with MCC.
MDC 08	467	Revision of Hip or Knee Replacement with CC.
MDC 08	468	Revision of Hip or Knee Replacement without CC/MCC.
MDC 08	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC.
MDC 08	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

We are inviting public comments on our proposed list of MS–DRGs to be subject to the IPPS policy for replaced devices offered without cost or with a credit for FY 2016. The final list will be included in the FY 2016 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

H. Recalibration of the Proposed FY 2016 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In developing the proposed FY 2016 system of weights, we used two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2014 MedPAR data used in this proposed rule include discharges occurring on October 1, 2013, through September 30, 2014, based on bills received by CMS through December 31, 2014, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2014 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,638,230 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2014 update of the FY 2014 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2016 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2016 relative weights are based on the ICD–9–CM diagnoses and procedures codes from the MedPAR claims data, grouped through the ICD–9–CM version of the FY 2016 GROUPER (Version 33). The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2014 update of the FY 2013 HCRIS for calculating the proposed FY 2016 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.3. of the preamble of this proposed rule, we calculated the FY 2016 relative weights based on 19 CCRs, as we did for FY 2015. The methodology we used to calculate the proposed FY 2016 MS–DRG cost-based relative weights based on claims data in the FY 2014 MedPAR file and data from the FY 2013 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2016 MS–DRG classifications discussed in sections II.B. and II.G. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2014 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average

cost for each MS–DRG and before eliminating statistical outliers.

• Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.

• At least 92.1 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49911) for the edit threshold related to FY 2015.)

• Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

• Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (that is, as if hospitals were not participating in those models under the BPCI initiative). The BPCI initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For FY 2016, we are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2013 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs.

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Routine Days	Private Room Charges.	011X and 014X	Adults & Pediatrics (General Routine Care).	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi–Private Room Charges.	012X, 013X and 016X–019X.				
	Ward Charges	015X				
Intensive Days	Intensive Care Charges.	020X	Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges.	021X	Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
			Burn Intensive Care Unit.	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
			Surgical Intensive Care Unit.	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
			Other Special Care Unit.	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X.	Intravenous Therapy.	C_1_C5_64	C_1_C6_64 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C6_73 C_1_C7_73	D3_HOS_C2_73
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C6_71 C_1_C7_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294–0299.	DME–Rented	C_1_C5_96	C_1_C6_96 C_1_C7_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME–Sold	C_1_C5_97	C_1_C6_97 C_1_C7_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C6_72 C_1_C7_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C6_66 C_1_C7_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C6_67 C_1_C7_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C6_68 C_1_C7_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy.	C_1_C5_65	C_1_C6_65 C_1_C7_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C6_50 C_1_C7_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C6_51 C_1_C7_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C6_52 C_1_C7_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges	037X	Anesthesiology	C_1_C5_53	C_1_C6_53 C_1_C7_53	D3_HOS_C2_53
Cardiology	Cardiology Charges	048X and 073X	Electro-cardiology	C_1_C5_69	C_1_C6_69 C_1_C7_69	D3_HOS_C2_69
Cardiac Catheterization.		0481	Cardiac Catheterization.	C_1_C5_59	C_1_C6_59 C_1_C7_59	D3_HOS_C2_59
Laboratory	Laboratory Charges	030X, 031X, and 075X.	Laboratory	C_1_C5_60	C_1_C6_60 C_1_C7_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C6_61 C_1_C7_61	D3_HOS_C2_61
		074X, 086X	Electro-Encephalography.	C_1_C5_70	C_1_C6_70 C_1_C7_70	D3_HOS_C2_70
Radiology	Radiology Charges	032X, 040X	Radiology—Diagnostic.	C_1_C5_54	C_1_C6_54 C_1_C7_54	D3_HOS_C2_54
		028X, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58
Emergency Room	Emergency Room Charges.	045X	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038X	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
	Blood Storage/Processing.	039X	Blood Storing, Processing, & Transfusing.	C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge.	0002–0099, 022X, 023X, 024X,052X,053X.				
		055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X.				
	Renal Dialysis	0800X	Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges.	080X and 082X–088X.			C_1_C7_74	
			Home Program Dialysis.	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges.	049X	ASC (Non Distinct Part).	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X			C_1_C7_75	
			Other Ancillary	C_1_C5_76	C_1_C6_76 C_1_C7_76	D3_HOS_C2_76
	Clinic Visit Charges	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	C_1_C6_92.01 C_1_C7_92.01	D3_HOS_C2_92.01
	Professional Fees Charges.	096X, 097X, and 098X.	Other Outpatient Services.	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges.	054X	Ambulance	C_1_C5_95	C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic	C_1_C5_88	C_1_C6_88 C_1_C7_88	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89	D3_HOS_C2_89

We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48462) for a discussion on the revenue codes included in the Supplies and Equipment and Implantable Devices CCRs, respectively.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2013 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost

per case to determine the relative weight.

The proposed FY 2016 cost-based relative weights were then normalized by an adjustment factor of 1.678672 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2016 are as follows:

Group	CCR
Routine Days	0.485
Intensive Days	0.399
Drugs	0.192
Supplies & Equipment	0.299
Implantable Devices	0.344
Therapy Services	0.335
Laboratory	0.125
Operating Room	0.201
Cardiology	0.119
Cardiac Catheterization	0.125
Radiology	0.159
MRIs	0.085
CT Scans	0.041
Emergency Room	0.184
Blood and Blood Products	0.340
Other Services	0.367
Labor & Delivery	0.404
Inhalation Therapy	0.178
Anesthesia	0.108

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. For FY 2016, we are proposing to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2016. Using data from the FY 2014 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed below are for newborns. For FY 2016, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2015 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown below:

Low-volume MS–DRG	MS–DRG Title	Crosswalk to MS–DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
791	Prematurity with Major Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
792	Prematurity without Major Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
794	Neonate with Other Significant Problems	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS DRGs).
795	Normal Newborn	Final FY 2015 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).

We are inviting public comments on this proposal.

4. Solicitation of Public Comments on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

Since 2011, CMS has been working to develop and test models of bundling Medicare payments under the authority of section 1115A of the Act. Through these models, CMS plans to evaluate whether bundled payments result in higher quality and more coordinated care at a lower cost to Medicare. CMS is currently testing the Bundled Payments for Care Improvement (BPCI) initiative. Under this initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care.

The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Episodes of care under the BPCI initiative begin with either (1) an inpatient hospital stay or (2) postacute care services following a qualifying inpatient hospital stay. More information on the four models under the BPCI initiative can be found on the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/bundled-payments/*. We also have included discussions of the BPCI initiative in the annual IPPS/LTCH PPS rulemakings since FY 2013 (77 FR 53341 through 53343).

All four models in the BPCI initiative pay a discounted bundled payment for

a single episode of care as an alternative approach to payment for service delivery under traditional Medicare fee-for-service (FFS). Model 1 participants are paid a discounted bundled payment in lieu of the standard IPPS payment upon submission of claims. In Models 2 and 3, the bundled payment is paid retrospectively through a reconciliation process; participants continue to submit claims and receive payment via the usual Medicare FFS payment systems. In Model 4, the bundled payment is made prospectively to a hospital, and participating physician and nonphysician practitioners submit ''no-pay'' claims to CMS. In all models, participants in the BPCI initiative are permitted to share gains arising from the providers' care redesign efforts under certain circumstances in which such arrangements would not otherwise be permitted under Medicare.

Each of the four models in the BPCI initiative tests bundled payments for a different episode of care:

- Model 1 tests retrospective bundled payments for the acute care hospital stay only. All participants in this model are acute care hospitals, and the episode of care is defined as the inpatient stay in the acute care hospital. The hospital is paid a discounted amount based on the payment rates established under the IPPS used in the original Medicare program. Physicians are paid separately for their services under the Medicare Physician Fee Schedule (MPFS).

While Model 1 makes payments as described above for all MS–DRGs, Models 2, 3, and 4 of the BPCI initiative test 48 episodes (comprised of groupings of related MS–DRGs). These episodes and the groupings of related MS–DRGs that are included in these episodes are listed in the table below.

- In Model 2, the episode of care includes the inpatient stay in an acute care hospital and all related services during the episode, including postacute care services. The episode ends either 30, 60, or 90 days after a hospital discharge.
- Model 3 focuses on postacute care services. In this model, the episode of care is triggered by an acute care hospital stay for an MS–DRG included in the episode and begins at the initiation of postacute care services in a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), long-term care hospital (LTCH), or home health agency (HHA). The episode includes postacute care services, physicians' services, and related services provided during an inpatient hospital readmission, but does not include services provided during the episode-initiating acute care hospital stay. The postacute care services included in the episode must begin within 30 days of discharge from the inpatient hospital stay and may end either 30, 60, or 90 days after the initiation of the episode.
- Model 4 tests prospective single bundled payments for physicians' services and hospital services furnished during an acute care hospitalization and related readmissions. Under this model, a single, prospectively determined bundled payment is made to the participating hospital that encompasses all services furnished during the inpatient stay by the hospital, physicians, and other practitioners. Payments for services furnished in related readmissions for 30 days after the hospital discharge are included in the bundled payment amount.

Model 1 of the BPCI initiative began in April 2013. CMS has allowed for participation in two phases in Models 2, 3, and 4. The first phase is the preparatory phase. In the preparatory phase, participants in the BPCI initiative are provided claims data so that they may analyze patterns of care for episodes in preparation for improving care coordination and quality under bundled payments prior to participation in the second phase, the risk-bearing phase.

In the BPCI initiative, the term ''risk-bearing'' refers to the requirement that certain participants in the BPCI initiative bear financial risk for spending above the target price set by Medicare across the episodes of care in which they participate. By using this term, we do not connote any relationship to insurance; we narrowly define this term and use it only to highlight the following financial responsibilities: In the risk-bearing phase, awardees and awardee conveners in Models 2 and 3 are financially responsible to Medicare if FFS expenditures are higher than a target price established by Medicare for the episode(s) in which they are participating. Awardees assume risk on behalf of themselves; awardee conveners assume risk on behalf of others and, in some cases, themselves (as described below). Medicare will recoup the difference between the target price and the actual FFS expenditures from awardees and awardee conveners for all services included in the episode of care if the target price is exceeded. Medicare will pay awardees and awardee conveners the difference if actual FFS expenditures are below the target price. Awardees and awardee conveners in Model 4 who have assumed risk on behalf of themselves and/or others bear risk in that they assume financial responsibility if the bundled prospective payment from Medicare does not cover the services included in the episode of care. Awardees and all participants under awardee conveners in Models 2, 3, and 4 must move to the risk-bearing phase by July 1, 2015.

There are several entity types currently participating in the two phases included in the BPCI initiative's Models 2, 3, and 4. Episode initiators, defined as the entities that initiate episodes of care in Models 2, 3, and 4, are provided claims data in the preparatory phase so that they may establish a structure for bundled payments prior to participation in the risk-bearing phase of the initiative. The entities that initiate episodes of care vary by model: In Model 4, episode initiators are acute care hospitals only; in Model 2, episode initiators are acute care hospitals and physician group practices; and in Model 3, episode initiators are SNFs, HHAs, LTCHs, IRFs, and physician group practices.

To move into the risk-bearing phase, participants must be selected by CMS following a comprehensive review and enter into an agreement with CMS. In the risk-bearing phase, episode initiators participate through one of two options. The first option is that the episode initiator may be an awardee and sign an agreement directly with CMS containing a risk-bearing financial arrangement. While not required, risk-bearing episode initiators may be associated with a ''facilitator convener,'' an entity that convenes multiple health care providers and supports the episode initiators in implementing the BPCI initiative but does not itself bear any risk. Alternatively, through the second option, the episode initiator may participate in the BPCI initiative under an awardee convener, which is an organization that may or may not be a Medicare provider that assumes financial risk on behalf of the episode initiator. In the second option, the awardee convener signs an agreement with CMS containing the terms of participation in the model, including a risk-bearing financial arrangement. Participation through an awardee convener allows episode initiators to mitigate their financial risk, and participation through an awardee or facilitator convener allows episode initiators to benefit in many cases from the convener's resources, such as enhanced technology and administrative assistance.

As of April 2015, the participation in the risk-bearing phase of the BPCI initiative is as follows: Model 2 is testing 2,053 episodes among 345 episode initiators located in 45 States;

Model 3 is testing 3,407 episodes among 318 episode initiators located in 29 States. Model 4 is testing 16 episodes among 9 episode initiators located in 7 States. There are 49 facilitator conveners and awardee conveners across the four models. In addition to the entities in the risk-bearing phase, several thousand entities in the preparatory phase are still considering whether to enter the performance phase, upon successful completion of screening and review by CMS.

The episodes of care and the associated MS–DRGs that define the episodes that are being tested in Models 2, 3, and 4 of the BPCI initiative are listed in the table below. This table is based on FY 2015 IPPS MS–DRGs and does not account yet for proposed FY 2016 changes to the MS–DRGs.

EPISODES OF CARE AND MS–DRG GROUPINGS UNDER THE BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE FOR MODELS 2, 3, AND 4

Episode of care	MS–DRGs
Acute myocardial infarction	280, 281, 282.
AICD generator or lead	245, 265.
Amputation	239, 240, 241, 255, 256, 257, 474, 475, 476, 616, 617, 618.
Atherosclerosis	302, 303.
Back and neck except spinal fusion	518, 519, 520.
Coronary artery bypass graft	231, 232, 233, 234, 235, 236.
Cardiac arrhythmia	308, 309, 310.
Cardiac defibrillator	222, 223, 224, 225, 226, 227.
Cardiac valve	216, 217, 218, 219, 220, 221, 266, 267.
Cellulitis	602, 603.
Cervical spinal fusion	471, 472, 473.
Chest pain	313.
Combined anterior posterior spinal fusion	453, 454, 455.
Complex noncervical spinal fusion	456, 457, 458
Congestive heart failure	291, 292, 293.
Chronic obstructive pulmonary disease, bronchitis, asthma	190, 191, 192, 202, 203.
Diabetes	637, 638, 639.
Double joint replacement of the lower extremity	461, 462.
Esophagitis, gastroenteritis, and other digestive disorders	391, 392.
Fractures of the femur and hip or pelvis	533, 534, 535, 536.
Gastrointestinal hemorrhage	377, 378, 379.
Gastrointestinal obstruction	388, 389, 390.
Hip and femur procedures except major joint	480, 481, 482.
Lower extremity and humerus procedure except hip, foot, femur	492, 493, 494.
Major bowel procedures	329, 330, 331.
Major cardiovascular procedure	237, 238.
Major joint replacement of the lower extremity	469, 470.
Major joint replacement of the upper extremity	483.
Medical noninfectious orthopedic	537, 538, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563.
Medical peripheral vascular disorders	299, 300, 301.
Nutritional and metabolic disorders	640, 641.
Other knee procedures	485, 486, 487, 488, 489.
Other respiratory	189, 204, 205, 206, 207, 208, 186, 187, 188.
Other vascular surgery	252, 253, 254.
Pacemaker	242, 243, 244.
Pacemaker device replacement or revision	258, 259, 260, 261, 262.
Percutaneous coronary intervention	246, 247, 248, 249, 250, 251.
Red blood cell disorders	811, 812.
Removal of orthopedic devices	495, 496, 497, 498, 499.
Renal failure	682, 683, 684.
Revision of the hip or knee	466, 467, 468.
Sepsis	870, 871, 872.
Simple pneumonia and respiratory infections	177, 178, 179, 193, 194, 195.
Spinal fusion (noncervical)	459, 460.
Stroke	61, 62, 63, 64, 65, 66.
Syncope and collapse	312.
Transient ischemia	69.
Urinary tract infection	689, 690.

b. Considerations for Potential Model Expansion

In this FY 2016 IPPS/LTCH PPS proposed rule, we are soliciting public comments regarding policy and operational issues related to a potential expansion of the BPCI initiative in the future. Section 1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the BPCI initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare

spending without reducing the quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. The decision of whether or not to expand will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act.

Evaluation of the BPCI initiative for expansion is expected to include analyses based on a combination of qualitative and quantitative sources, including Medicare claims, patient surveys, awardee reports, interviews, and site visits. Given that further evaluation of the BPCI initiative is needed to determine its impact on both Medicare cost and quality of care, at this time, we are not proposing an expansion of any models within the initiative or any policy changes associated with it. Instead, we are requesting public comments on issues surrounding a potential expansion of the BPCI initiative so that we can be prepared in the event that the Secretary determines that findings from the evaluation of the initiative demonstrate that it meets all criteria for expansion, consistent with the requirements of section 1115A(c) of the Act, and that, based on these findings and other pertinent factors, expansion is warranted.

CMS is committed to testing new payment and service delivery models, evaluating results and advancing best practices, and engaging stakeholders. These three priorities are crucial to the BPCI initiative. As we initiate discussions about potential expansion, we continue to value stakeholder engagement within the framework of CMS' priorities for the BPCI initiative. Consistent with its ongoing commitment to develop new models and refine existing models based on additional information and experience, CMS may modify existing models or test additional models under its testing authority under section 1115A of the Act. It may possibly do so, taking into consideration stakeholder input, including feedback received through the public comments submitted in response to the discussion in this section. However, the primary goal for this solicitation of public comments is to receive information about a potential expansion of the BPCI initiative. Therefore, we are requesting that public comments on the discussion in this section consider how expanded episode payment could continue to encourage high-quality, high-value care during Medicare beneficiaries' episodes of care, while allowing for accurate payments to providers, encouraging coordination of care among providers, and ensuring access to care and freedom of choice for all Medicare beneficiaries, regardless of their severity of illness. The following list is not an exhaustive list of issues on which we are requesting public comments, and the inclusion of the list of issues is not, in any way, meant to imply that any or all of these issues would be addressed in any expanded model. The solicitation of public comments is for planning purposes, and as mentioned above, we would use additional rulemaking if we decide to expand any of the models.

We are seeking public comments on the following issues:

- *Breadth and scope of an expansion.* For example, whether model expansion should focus on one or more of the four models or one or more specific episodes, or should target specific geographic regions of the country. Further, would the model best be expanded with voluntary participation or be most effective if participation were required within the chosen models, episodes, and regions.
- *Episode definitions.* We are seeking public comments on the current BPCI initiative episode definitions as part of an expansion, including the MS–DRGs, other bundled services (such as hospital readmissions), exclusions, and the duration of the episodes. The BPCI initiative uses broadly defined episodes, and these episodes include MS–DRGs that account for approximately 80 percent of Medicare hospital discharges. Depending on the model, lengths of episodes may be 30, 60, or 90 days. Under all models within the BPCI initiative, these episode definitions have been standardized across models for episodes that relate to an acute care hospital stay. An expansion might target episodes beginning with inpatient hospital care or postacute care. We are seeking public comments regarding whether episode definition refinements should be made; for example, refinements potentially could be made for episodes that begin with postacute care to incorporate the findings from standardized patient assessments at postacute care initiation, rather than tying the episode to the hospital discharge diagnosis.
- *Models for expansion.* We are seeking public comments on whether we should consider one or more of the current BPCI initiative models as the first candidates for expansion. For example, under a model expansion, we potentially could expand several or all of the models that include postacute care on a similar timeframe or one model at a time.
- *Roles of organizations and relationships necessary or beneficial to care transformation.* We are seeking public comments on the roles that organizations, including health care providers and suppliers and other entities, should serve under an expanded model. Within this category, we are seeking public comments specifically on the types of relationships and arrangements, financial or otherwise, that would assist participants with care transformation in an expanded model. We would appreciate any public comments on whether relationships encouraged under an expansion could have unintended consequences and what those consequences might be.
- *Setting bundled payment amounts.* We are seeking public comments on approaches to setting bundled payments under model expansion. For participants in the BPCI initiative, bundled payments are related to the historical episode experience of episode initiators based on data from 2009 through 2012. In the BPCI initiative, only Model 4 rates are set prospectively, while Models 2 and 3 involve trending of target amounts following the conclusion of episodes. We potentially could base payments on regional episode experience or set all payments prospectively under model expansion. We potentially could apply the same episode discount percentages to all episodes or vary these discount percentages based on care redesign opportunity in the specific episode. We potentially could rebase payments annually or on another timeframe. In the case of setting payment amounts via a specified discount percentage, we are seeking public comments on methodologies that could be used to determine the discount percentages. We also are seeking public comments on any other methodologies that could be considered for the purposes of setting bundled payment amounts.
- *Mitigating risk of high-cost cases.* Depending on the breadth and scope of an expansion, the potential financial impact of high-cost episode cases could be an issue for some providers. Currently, under the BPCI initiative, we apply a variety of approaches to risk mitigation, including allowing participants to select risk corridors that limit the inclusion of high-cost cases in episodes. We are seeking public comments on strategies to mitigate the

risk of high-cost cases to ensure appropriate payment for these episodes under model expansion, such as through outlier or other policies, while encouraging high-value, coordinated care for these cases as well. For example, under model expansion, we potentially could establish an outlier pool with specific payment policies, similar to approaches under the IPPS and the OPPS.

• *Administering bundled payments.* We are seeking public comments on the issues related to prospective or retrospective payment under model expansion. Currently, Model 4 under the BPCI initiative makes a single bundled payment, while Models 2 and 3 utilize routine Medicare FFS payments to all providers and supplies with retrospective reconciliation for the awardee. We are interested in public comments on the feasibility of different payment approaches under the various models, including the administrative capacity and feasibility for some organizations to pay others for care during episodes or to share payments at reconciliation. For example, under model expansion, we potentially could make a single bundled payment in all models, but we would need to identify the entity to receive the payments and engage in widespread changes to the shared systems to accommodate all payment systems. Under the BPCI initiative, we have agreements with multiple types of entities, including awardee conveners, that may not be Medicare providers or suppliers. We are requesting comments on the possibility of paying an awardee convener the bundled payment when that entity did not actually deliver health care services to the beneficiaries in episodes in an expanded model. Specifically, we would like to know what operational and policy considerations would need to be addressed. A retrospective reconciliation would have different concerns than a prospective payment.

• *Data needs.* We are seeking public comments on the types of data and functionality needed in the marketplace in order to expand this type of model (for example, EHRs and quality measurement, among others). We currently provide monthly episode claims data to BPCI initiative participants for purposes of health care operations and periodic monitoring reports. Under model expansion, providers that are not fully integrated may need to develop approaches to sharing information regarding patients initiating and participating in episodes. Real-time information may improve the coordination of care.

• *Use of health information technology.* We are seeking public comments on how the use of health information technology can be used and encouraged in coordinating care across care settings, including postacute care. Health information technology and health information exchange may be used to support these models by sharing summaries of care, problem lists, physician orders, prescription lists, and care plans across the care continuum. We welcome public comments on how to include SNFs, LTCHs, IRFs, and HHAs that do not currently utilize health information technology and health information exchange at an advanced level without compromising the coordination of care among acute care hospitals and postacute care providers.

• *Quality measurement and payment for value.* We are seeking public comments on the quality measures that could be applied to episodes and approaches to incorporating value-based payment in the BPCI initiative. For example, under model expansion, we potentially could apply the same quality measures to all episodes or develop episode-specific quality measures. We potentially could incorporate value-based payment under model expansion by reducing the discount percentage for high quality care or increasing the discount percentage for low quality care.

• *Transition from Medicare FFS payments to bundled payments.* We are seeking public comments on the need for and parameters of a transition period from Medicare FFS payment to bundled payment under an expanded model. We are seeking public comments regarding the length of any transition and how such a transition would be made.

• *Other issues.* We are seeking public comments on any other issues the public believes are important for us to consider.

Consistent with our continuing commitment to engaging stakeholders in CMS' work, we are seeking public comments on these issues to broaden and deepen our understanding of the important issues and challenges regarding bundled payments in the current health care marketplace. These public comments also will assist us in planning for expansion if a decision is made to expand the BPCI initiative in the future.

I. Proposed Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.'' We note that beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we explained our policy

regarding substantial similarity in detail.

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2015 IPPS/LTCH PPS final rule contains the final thresholds that we use to evaluate applications for new technology add-on payments for FY 2016. We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2015-IPPS-Final-Rule-Home-Page-Items/FY2015-Final-Rule-Tables.html* to download and view Table 10. We note that later in this section under the discussion of the WATCHMAN® Left Atrial Appendage (LAA) Closure technology, we are soliciting public comments on the use of supplemental threshold values when the coding to identify a new technology is reassigned to a new MS–DRG that does not have a threshold value displayed in the most recent version of Table 10.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents ''an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.'' For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2017 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2017, the CMS Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2016 prior to publication of the FY 2016 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 21, 2014 (79 FR 69490), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 3, 2015. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2016 new medical service and technology add-on payment applications before the publication of the FY 2016 IPPS/LTCH PPS proposed rule.

Approximately 95 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: *https://www.youtube.com/watch?v=dn-R5KGQu-M.* We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of January 19, 2015, in our evaluation of the new technology add-on payment applications for FY 2016 in this proposed rule.

In response to the published notice and the New Technology Town Hall meeting, we received written comments regarding the applications for FY 2016 new technology add-on payments. We summarize these comments in the preamble of this proposed rule or, if applicable, indicate that there were no comments received, at the end of each discussion of the individual applications in this proposed rule.

One commenter provided comments that were unrelated to the ''substantial clinical improvement'' criterion. As explained above and in the **Federal Register** notice announcing the New Technology Town Hall meeting (79 FR 69490 through 69492), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2016. Therefore, we are not summarizing the commenter's comments in this proposed rule. The commenter is welcome to resubmit its comments in response to proposals presented in this proposed rule.

Comment: One commenter stated that antibiotics are unique because their development and use present many challenges that are not applicable to other drugs or devices seeking approval for new technology add-on payments. The commenter urged CMS to utilize the expertise of the infectious diseases community when determining how to evaluate applications for new antibiotics for new technology add-on payments.

The commenter further stated that because superiority studies cannot be conducted for most serious infections, the most appropriate evaluation of superiority for many new antibiotics is a ''noninferiority'' clinical trial, which is designed to determine if the experimental drug is similar in efficacy to a standard drug currently available on the market. The commenter noted that, recently, the FDA has demonstrated increased willingness to consider approving new antibiotics if efficacy can be proven based on achieved, well-defined, and statistically validated noninferiority margins. The commenter encouraged CMS to consider the proven efficacy of these antibiotics based on these criteria when determining whether to approve a new antibiotic for new technology add-on payment. The commenter also urged CMS to consider carefully analyzed and peer-reviewed safety, utilization, and economics data when such data are available to support the approval of a new antibiotic for new technology add-on payment. The commenter believed that these considerations could increase the types of information that would be used to support the approval of new drugs for which superiority trials are inappropriate or not feasible or both.

The commenter also believed it is critical that CMS maintain an ongoing dialogue with the FDA as well as nongovernment experts in antibiotic resistance and antibiotic drug development in order to more fully understand the highly complex and unique issues regarding the type of data available for the study and approval of new antibiotics.

Response: In our evaluation of new technology applications, we rely on the recommendations of our clinical advisors. We also consider all clinical

data provided by the applicant in our determination of whether a technology is eligible for new technology add-on payments. In addition, we summarize each application and invite the public to provide their comments and expertise on any new technology application under consideration during the comment period for the proposed rule. We also work with the FDA in instances where guidance is necessary to understand the complexities of a new technology. We appreciate the commenter's input, and we will further consider these comments in future rulemakings.

We note that the commenter provided comments that were unrelated to the substantial clinical improvement criterion. As noted above, the purpose of the new technology town hall meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2016. Therefore, we are not summarizing these comments in this proposed rule. The commenter is welcome to resubmit its comments in response to proposals presented in this proposed rule.

3. Implementation of ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies for FY 2016

As discussed in section II.G.1.a. of the preamble of this proposed rule, health plans and providers are required, as of October 1, 2015, to use the ICD–10 coding system (ICD–10–PCS codes for procedures and ICD–10–CM codes for diagnosis), instead of the ICD–9–CM coding system, to report diagnoses and procedures for Medicare hospital inpatient services provided to Medicare beneficiaries as classified under the MS–DRG system and paid for under the IPPS. HIPAA covered entities will continue to use ICD–9–CM coding practices and principles through September 30, 2015. We refer readers to section II.G.1.a. of the preamble of this proposed rule for a complete discussion of the adoption of the ICD–10 coding system.

As part of the transition to the ICD–10–CM/PCS coding system, at the September 23–24, 2014 ICD–10 Coordination and Maintenance Committee meeting, CMS received a request to create a new section within the ICD–10–PCS to capture new medical services and technologies that might not appropriately align with the current structure of the ICD–10–PCS codes. Examples of these types of new medical services and technologies included drugs, biologicals, and newer medical devices being tested in clinical trials that are not currently captured within the ICD–9–CM or the ICD–10–PCS. The requestor indicated that there may be a need to identify and report these technologies and inpatient services for purposes of approving new technology add-on payment applications and initiating subsequent new technology add-on payments based on approval or tracking and analyzing the use of these new technologies and services. Although several commenters have opposed including these types of technologies and services within the current structure of the ICD–10–PCS codes during past ICD–10 Coordination and Maintenance Committee meetings, as well as in public comments, CMS has evaluated these suggestions and considered them to be valid. As a result, CMS has created a new component within the ICD–10–PCS codes, labeled Section ''X'' codes, to identify and describe these new technologies and services. The new Section ''X'' codes identify new medical services and technologies that are not usually captured by coders, or that do not usually have the desired specificity within the current ICD–10–PCS structure required to capture the use of these new services and technologies. As mentioned earlier, examples of these types of services and technologies include specific drugs, biologicals, and newer medical devices being tested in clinical trials. The new Section ''X'' codes within the ICD–10–PCS structure will be implemented on October 1, 2015, and will be used to identify new technologies and medical services approved under the new technology add-on payment policy for payment purposes beginning October 1, 2015. An overview of Section ''X'' codes was provided at the March 18–19, 2015 ICD–10 Coordination and Maintenance Committee meeting. Further information regarding the new Section ''X'' codes and their use within the ICD–10–PCS can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html* through the ''CMS Coordination and Maintenance Committee Meeting'' link.

The ICD–10–PCS includes a new section containing the new Section ''X'' codes, which will be used beginning FY 2016. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. The FY 2016 ICD–10–PCS Section ''X'' codes will be posted in June 2015 on the Internet via the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html* under the links on the left side of the Web page.

4. Proposed FY 2016 Status of Technologies Approved for FY 2015 Add-On Payments

a. Glucarpidase (Voraxaze®)

BTG International, Inc. submitted an application for new technology add-on payments for Glucarpidase (Voraxaze®) for FY 2013. Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as of result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Voraxaze® was approved by the FDA on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment use to Voraxaze® as an investigational drug. Since 2007, the applicant has been authorized to recover the costs of making Voraxaze® available through its expanded access program. We describe expanded access for treatment use of investigational drugs and authorization to recover certain costs of investigational drugs in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53346 through 53350). Voraxaze® was available on the market in the United States as a commercial product to the larger population as of April 30, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27936 through 27939), we expressed concerns about whether Voraxaze® could be considered new for FY 2013. After consideration of all of the public comments received, in the FY 2013 IPPS/LTCH PPS final rule, we stated that we considered Voraxaze® to be ''new'' as of April 30, 2012, which is the date of market availability.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for Voraxaze® and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved Voraxaze® for new technology add-on payments for FY 2013. Cases of Voraxaze® are identified with ICD–9–CM procedure code 00.95 (Injection or

infusion of glucarpidase). As stated in the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59679), the cost of Voraxaze® is $23,625 per vial. The applicant stated that an average of four vials is used per Medicare beneficiary. Therefore, the average cost per case for Voraxaze® is $94,500 ($23,625 × 4). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for Voraxaze® is $47,250 per case.

As stated above, the new technology add-on payment regulations provide that ''a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology'' (§ 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Voraxaze®, we considered the beginning of the newness period to commence when Voraxaze® was first made available on the U.S. market on April 30, 2012. Because the 3-year anniversary date for Voraxaze® occurred in the latter half of FY 2015 (April 30, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49918). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (April 30, 2015) occurs prior to the beginning of FY 2016. Therefore, we are proposing to discontinue new technology add-on payments for Voraxaze® for FY 2016. We are inviting public comments on this proposal.

b. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. The applicant stated that the current treatment for patients who have had an AAA is an endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53360 through 53365), we stated that because the Zenith® F. Graft was approved by the FDA on April 4, 2012, we believed that the Zenith® F. Graft met the newness criterion as of that date.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the Zenith® F. Graft and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved the Zenith® F. Graft for new technology add-on payments for FY 2013. Cases involving the Zenith® F. Graft that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). In the application, the applicant provided a breakdown of the costs of the Zenith® F. Graft. The total cost of the Zenith® F. Graft utilizing bare metal (renal) alignment stents was $17,264. Of the $17,264 in costs for the Zenith® F. Graft, $921 is for components that are used in a standard Zenith AAA Endovascular Graft procedure. Because the costs for these components are already reflected within the MS–DRGs (and are no longer ''new''), in the FY 2013 IPPS/LTCH PPS final rule, we stated that we do not believe it is appropriate to include these costs in our calculation of the maximum cost to determine the maximum add-on payment for the Zenith® F. Graft. Therefore, the total maximum cost for the Zenith® F. Graft is $16,343 ($17,264–$921). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the Zenith® F. Graft is $8,171.50.

With regard to the newness criterion for the Zenith® F. Graft, we considered the beginning of the newness period to commence when the Zenith® F. Graft was approved by the FDA on April 4, 2012. Because the 3-year anniversary date of the entry of the Zenith® F. Graft on the U.S. market occurred in the second half of FY 2015 (April 4, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49922). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (April 4, 2015) occurs prior to the beginning of FY 2016. Therefore, we are proposing to discontinue new technology add-on payments for the Zenith® F. Graft for FY 2016. We are inviting public comments on this proposal.

c. Kcentra™

CSL Behring submitted an application for new technology add-on payments for Kcentra™ for FY 2014. Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Kcentra™ contains the Vitamin K dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S. Factor IX is the lead factor for the potency of the preparation. The product is a heat-treated, non-activated, virus filtered and lyophilized plasma protein concentrate made from pooled human plasma. Kcentra™ is available as a lyophilized powder that needs to be reconstituted with sterile water prior to administration via intravenous infusion. The product is dosed based on Factor IX units. Concurrent Vitamin K treatment is recommended to maintain blood clotting factor levels once the effects of Kcentra™ have diminished.

Kcentra™ was approved by the FDA on April 29, 2013. In the FY 2014 IPPS/LTCH PPS final rule, we finalized new ICD–9–CM procedure code 00.96 (Infusion of 4-Factor Prothrombrin Complex Concentrate) which uniquely identifies Kcentra™.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27538), we noted that we were concerned that Kcentra™ may be substantially similar to FFP and/or Vitamin K therapy. In the FY 2014 IPPS/LTCH PPS final rule, in response to comments submitted by the manufacturer, we stated that we agree that Kcentra™ may be used in a patient population that is experiencing an acquired coagulation factor deficiency due to Warfarin and who are

experiencing a severe bleed currently but are ineligible for FFP, particularly for use by IgA deficient patients and other patient populations that have no other treatment option to resolve severe bleeding in the context of an acquired Vitamin K deficiency. In addition, FFP is limited because it requires special storage conditions while Kcentra™ is stable for up to 36 months at room temperature thus allowing hospitals that otherwise would not have access to FFP (for example, small rural hospitals as discussed by the applicant in its comments) to keep a supply of Kcentra™ and treat patients who would possibly have no access to FFP. We noted that FFP is considered perishable and can be scarce by nature (due to production and other market limitations) thus making some hospitals unable to store FFP, which limits access to certain patient populations in certain locations. Therefore, we stated that we believe that Kcentra™ provides a therapeutic option for a new patient population and is not substantially similar to FFP. Also, we gave credence to the information presented by the manufacturer that Kcentra™ provides a simple and rapid repletion relative to FFP and reduces the risk of a transfusion reaction relative to FFP because it does not contain ABO antibodies and does not require ABO typing. As a result, we concluded that Kcentra™ is not substantially similar to FFP, and that it meets the newness criterion.

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). Cases involving Kcentra™ that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 00.96. In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of $635 per vial. Therefore, cases of Kcentra™ would incur an average cost per case of $3,175 ($635 × 5). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case of Kcentra™ was $1,587.50 for FY 2014.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that new technology add-on payments for Kcentra™ would not be available with respect to discharges for which the hospital received an add-on payment for a blood clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. Under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is ''the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section)'' for discharges on or after April 1, 1988. Section 1886(a)(4) of the Act excludes from the term ''operating costs of inpatient hospital services'' the costs with respect to administering blood clotting factors to individuals with hemophilia. The costs of administering a blood clotting factor to a Medicare beneficiary who has hemophilia and is a hospital inpatient are paid separately from the IPPS. (For information on how the blood clotting factor add-on payment is made, we refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual, which can be downloaded from the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*.) In addition, we stated that if Kcentra™ is approved by the FDA as a blood clotting factor, we believed that it may be eligible for blood clotting factor add-on payments when administered to Medicare beneficiaries with hemophilia. We make an add-on payment for Kcentra™ for such discharges in accordance with our policy for payment of a blood clotting factor, and the costs would be excluded from the operating costs of inpatient hospital services as set forth in section 1886(a)(4) of the Act.

Section 1886(d)(5)(K)(i) of the Act requires the Secretary to ''establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection'' beginning with discharges on or after October 1, 2001. We believe that it is reasonable to interpret this requirement to mean that the payment mechanism established by the Secretary recognizes only costs for those items that would otherwise be paid based on the prospective payment system (that is, ''the payment system established under this subsection''). As noted above, under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is the amount of payment for the operating costs of inpatient hospital services, as defined in section 1886(a)(4) of the Act, for discharges on or after April 1, 1988. We understand this to mean that a new medical service or technology must be an operating cost of inpatient hospital services paid based on the prospective payment system, and not excluded from such costs, in order to be eligible for the new technology add-on payment. We pointed out that new technology add-on payments are based on the operating costs per case relative to the prospective payment rate as described in § 412.88. Therefore, we believe that new technology add-on payments are appropriate only when the new technology is an operating cost of inpatient hospital services and are not appropriate when the new technology is excluded from such costs.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that we believe that hospitals may only receive new technology add-on payments for discharges where Kcentra™ is an operating cost of inpatient hospital services. In other words, a hospital would not be eligible to receive the new technology add-on payment when it is administering Kcentra™ in treating a Medicare beneficiary who has hemophilia. In those instances, Kcentra™ is specifically excluded from the operating costs of inpatient hospital services in accordance with section 1886(a)(4) of the Act and paid separately from the IPPS. However, when a hospital administers Kcentra™ to a Medicare beneficiary who does not have hemophilia, the hospital would be eligible for a new technology add-on payment because Kcentra™ would not be excluded from the operating costs of inpatient hospital services. Therefore, discharges where the hospital receives a blood clotting factor add-on payment are not eligible for a new technology add-on payment for the blood clotting factor. We refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual for a complete discussion on when a blood clotting factor add-on payment is made. The manual can be downloaded from the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*.

With regard to the newness criterion for Kcentra™, we considered the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because the 3-year anniversary date of the entry of Kcentra™ on the U.S. market will occur in the second half of FY 2016 (April 29, 2016), we are proposing to continue new technology add-on payments for this technology for

FY 2016. We are inviting public comments on this proposal.

Because we are adopting the ICD–10 coding system, effective October 1, 2015, as discussed in section II.G.1.a. of the preamble of this proposed rule, for FY 2016, we are proposing to identify and make new technology add-on payments for cases involving the Kcentra™ technology with ICD–10–PCS procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach). As stated above, new technology add-on payments for Kcentra™ would not be available with respect to discharges for which the hospital received an add-on payment for a blood clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. For information on how the blood clotting factor add-on payment is made (including a list of ICD–10 diagnosis codes that would negate the eligibility of a case for new technology add-on payments, if reported in combination with the proposed ICD–10 procedure code used to identify cases involving the Kcentra™ technology), we refer readers to Section 20.7.3, Chapter 3, of the Medicare Claims Processing Manual, which can be downloaded from the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*. The maximum new technology add-on payment for a case involving the Kcentra™ technology would remain at $1,587.50 for FY 2016. We are inviting public comments on this proposal.

d. Argus® II Retinal Prosthesis System

Second Sight Medical Products, Inc. submitted an application for new technology add-on payments for the Argus® II Retinal Prosthesis System (Argus® II System) for FY 2014. The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). These patients have bare or no light perception in both eyes. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera. The Argus® II implant is intended to be implanted in a single eye, typically the worse-seeing eye. Currently, bilateral implants are not intended for this technology. According to the applicant, the surgical implant procedure takes approximately 4 hours and is performed under general anesthesia.

The Argus® II System consists of three primary components: (1) An implant which is an epiretinal prosthesis that is fully implanted on and in the eye (that is, there are no percutaneous leads); (2) external components worn by the user; and (3) a ''fitting'' system for the clinician that is periodically used to perform diagnostic tests with the system and to custom-program the external unit for use by the patient. We describe these components more fully below.

- *Implant:* The retinal prosthesis implant is responsible for receiving information from the external components of the system and electrically stimulating the retina to induce visual perception. The retinal implant consists of: (a) A receiving coil for receiving information and power from the external components of the Argus® II System; (b) electronics to drive stimulation of the electrodes; and (c) an electrode array. The receiving coil and electronics are secured to the outside of the eye using a standard scleral band and sutures, while the electrode array is secured to the surface of the retina inside the eye by a retinal tack. A cable, which passes through the eye wall, connects the electronics to the electrode array. A pericardial graft is placed over the extra-ocular portion on the outside of the eye.
- *External Components:* The implant receives power and data commands wirelessly from an external unit of components, which include the Argus II Glasses and Video Processing Unit (VPU). A small lightweight video camera and transmitting coil are mounted on the glasses. The telemetry coils and radio-frequency system are mounted on the temple arm of the glasses for transmitting data from the VPU to the implant. The glasses are connected to the VPU by a cable. This VPU is worn by the patient, typically on a belt or a strap, and is used to process the images from the video camera and convert the images into electrical stimulation commands, which are transmitted wirelessly to the implant.
- *''Fitting System'':* To be able to use the Argus® II System, a patient's VPU needs to be custom-programmed. This process, which the applicant called ''fitting'', occurs in the hospital/clinic shortly after the implant surgery and then periodically thereafter as needed. The clinician/physician also uses the ''Fitting System'' to run diagnostic tests (for example, to obtain electrode and impedance waveform measurements or to check the radio-frequency link between the implant and external unit). This ''Fitting System'' can also be connected to a ''Psychophysical Test System'' to evaluate patients' performance with the Argus® II System on an ongoing basis.

These three components work together to stimulate the retina and allow a patient to perceive phosphenes (spots of light), which they then need to learn to interpret. While using the Argus® II System, the video camera on the patient-worn glasses captures a video image. The video camera signal is sent to the VPU, which processes the video camera image and transforms it into electrical stimulation patterns. The electrical stimulation data are then sent to a transmitter coil mounted on the glasses. The transmitter coil sends both data and power via radio-frequency (RF) telemetry to the implanted retinal prosthesis. The implant receives the RF commands and delivers stimulation to the retina via an array of electrodes that is secured to the retina with a retinal tack.

In patients with RP, the photoreceptor cells in the retina, which normally transduce incoming light into an electro-chemical signal, have lost most of their function. The stimulation pulses delivered to the retina via the electrode array of the Argus® II System are intended to mimic the function of these degenerated photoreceptors cells. These pulses induce cellular responses in the remaining, viable retinal nerve cells that travel through the optic nerve to the visual cortex where they are perceived as phosphenes (spots of light). Patients learn to interpret the visual patterns produced by these phosphenes.

With respect to the newness criterion, according to the applicant, the FDA designated the Argus® II System a Humanitarian Use Device in May 2009 (HUD designation #09–0216). The applicant submitted a Humanitarian Device Exemption (HDE) application (#H110002) to the FDA in May 2011 to obtain market approval for the Argus® II System. The HDE was referred to the Ophthalmic Devices Panel of the FDA's Medical Devices Advisory Committee for review and recommendation. At the Panel's meeting held on September 28, 2012, the Panel voted 19 to 0 that the probable benefits of the Argus® II System outweigh the risks of the system for the proposed indication for use. The applicant received the HDE approval from the FDA on February 14, 2013. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49924 through 49925), we discussed comments we had received informing CMS that the Argus® II System was not available on the U.S. market until December 20, 2013. The applicant explained that, as part of the lengthy approval process, it was

required to submit a request to the Federal Communications Commission (FCC) for a waiver of section 15.209(a) of the FCC rules that would allow the applicant to apply for FCC authorization to utilize this specific RF band. The FCC approved the applicant's waiver request on November 30, 2011. After receiving the FCC waiver of the section 15.209(a) rules, the applicant requested and obtained a required Grant of Equipment Authorization to utilize the specific RF band, which the FCC issued on December 20, 2013. Therefore, the applicant stated that the date the Argus® II System first became available for commercial sale in the United States was December 20, 2013. We agreed with the applicant that, due to the delay, the date of newness for the Argus® II System was December 20, 2013, instead of February 14, 2013.

Currently there are no other approved treatments for patients diagnosed with severe to profound RP. The Argus® II System has an IDE number of G050001 and is a Class III device. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50580 through 50583), we finalized new ICD–9–CM procedure code 14.81 (Implantation of epiretinal visual prosthesis), which uniquely identifies the Argus® II System. The other two codes finalized by CMS are for removal, revision, or replacement of the device.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus® II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments currently are identified by ICD–9–CM procedure code 14.81. We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology. In the application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is $144,057.50. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the Argus® II System for FY 2014 was $72,028.75.

With regard to the newness criterion for the Argus® II System, we considered the beginning of the newness period to commence when the Argus® II System became available on the U.S. market on December 20, 2013. Because the 3-year anniversary date of the entry of the Argus® II System on the U.S. market will occur in the first half of FY 2017 (December 23, 2016), we are proposing to continue new technology add-on payments for this technology for FY 2016. We are inviting public comments on this proposal.

Because we are adopting the ICD–10 coding system, effective October 1, 2015, as discussed in section II.G.1.a. of the preamble of this proposed rule, for FY 2016, we are proposing to identify and make new technology add-on payments for cases involving the Argus® II System when one of the following ICD–10–PCS procedure codes is reported: 08H005Z (Insertion of epiretinal visual prosthesis into right eye, open approach) or 08H105Z (Insertion of epiretinal visual prosthesis into left eye, open approach). The maximum new technology add-on payment for a case involving the Argus® II System would remain at $72,028.75 for FY 2016. We are inviting public comments on this proposal.

e. Zilver® PTX® Drug Eluting Peripheral Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Peripheral Stent (Zilver® PTX®) for FY 2014. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above–the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into the artery(s), usually by accessing the common femoral artery in the groin. The applicant stated that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicated that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures.

The applicant received FDA approval on November 15, 2012, for the Zilver® PTX®. The applicant maintains that the Zilver® PTX® is the first drug-eluting stent used for superficial femoral arteries. The technology is currently described by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50583 through 50585), after evaluation of the new technology add-on payment application and consideration of the public comments received, we approved the Zilver® PTX® for new technology add-on payments in FY 2014. Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.60. As explained in the FY 2014 IPPS/LTCH PPS final rule, to determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study. The applicant stated in its application that the anticipated cost per stent is approximately $1,795. Therefore, cases of the Zilver® PTX® would incur an average cost per case of $3,410.50 ($1,795 × 1.9). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case of the Zilver® PTX® was $1,705.25 for FY 2014.

With regard to the newness criterion for the Zilver® PTX®, we considered the beginning of the newness period to commence when the Zilver® PTX® was approved by the FDA on November 15, 2012. Because the 3-year anniversary date of the entry of the Zilver® PTX® on the U.S. market occurred after FY 2015 (November 15, 2015), in the FY 2015 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2015 (79 FR 49925). However, for FY 2016, the 3-year anniversary date of the product's entry on the U.S. market (November 15, 2015) occurs in the first half of FY 2016. Therefore, we are proposing to discontinue new technology add-on payments for the Zilver® PTX® for FY 2016. We are inviting public comments on this proposal.

f. CardioMEMS™ HF (Heart Failure) Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2015 for the CardioMEMS™ HF (Heart Failure) Monitoring System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF Monitoring System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

The applicant believed that a large majority of patients receiving the sensor would be admitted as an inpatient to a hospital with a diagnosis of acute or chronic heart failure, which is typically described by ICD–9–CM diagnosis code 428.43 (Acute on chronic combined systolic and diastolic heart failure) and the sensor would be implanted during the inpatient stay. The applicant stated that for safety considerations, a small portion of these patients may be discharged and the sensor would be implanted at a future date in the hospital outpatient setting. In addition, there would likely be a group of patients diagnosed with chronic heart failure who are not currently hospitalized, but who have been hospitalized in the past few months for which the treating physician believes that regular pulmonary artery pressure readings are necessary to optimize patient management. Depending on the patient's status, the applicant stated that these patients may have the sensor implanted in the hospital inpatient or outpatient setting.

The applicant received FDA approval on May 28, 2014. The CardioMEMS™ HF Monitoring System is currently described by ICD–9–CM procedure code 38.26 (Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 38.26 (Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring), which was effective October 1, 2011. With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System is $8,875.

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System on the U.S. market will occur in FY 2017 (May 28, 2017), we are proposing to continue new technology add-on payments for this technology for FY 2016. We are inviting public comments on this proposal.

Because we are adopting the ICD–10 coding system, effective October 1, 2015, as discussed in section II.G.1.a. of the preamble of this proposed rule, for FY 2016, we are proposing to identify and make new technology add-on payments for cases involving the CardioMEMS™ HF Monitoring System using either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). The maximum payment for a case involving the CardioMEMS™ HF Monitoring System would remain at $8,875 for FY 2016. We are inviting public comments on this proposal.

g. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

Mitral regurgitation (MR), also referred to as mitral insufficiency or mitral incompetence, occurs when the mitral valve fails to close completely causing the blood to leak or flow backwards (regurgitate) into the left ventricle. If the amount of blood that leaks backwards into the left ventricle is minimal, then intervention is usually not necessary. However, if the amount of blood that is regurgitated becomes significant, this can cause the left ventricle to work harder to meet the body's need for oxygenated blood. Severity levels of MR can range from grade 1+ through grade 4+. If left untreated, severe MR can lead to heart failure and death. The American College of Cardiology (ACC) and the American Heart Association (AHA) issued practice guidelines in 2006 that recommended intervention for moderate/severe or severe MR (grade 3+ to 4+). The applicant stated that the MitraClip® System is ''indicated for percutaneous reduction of significant mitral regurgitation . . . in patients who have been determined to be at prohibitive risk for mitral value surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and in whom existing comorbidities would not preclude the

expected benefit from correction of the mitral regurgitation.''

The MitraClip® System mitral valve repair procedure is based on the double-orifice surgical repair technique that has been used as a surgical technique in open chest, arrested-heart surgery for the treatment of MR since the early 1990s. According to the applicant, in utilizing ''the double-orifice technique, a portion of the anterior leaflet is sutured to the corresponding portion of the posterior leaflet using standard techniques and forceps and suture, creating a point of permanent cooptation (''approximation'') of the two leaflets. When the suture is placed in the middle of the valve, the valve will have a functional double orifice during diastole.''

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated ''for the percutaneous reduction of significant symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.'' The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Effective October 1, 2010, ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant) was created to identify and describe the MitraClip® System technology.

On August 7, 2014, CMS issued a National Coverage Decision (NCD) concerning Transcatheter Mitral Valve Repair procedures. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=273* for information related to this NCD.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the MitraClip® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the MitraClip® System for new technology add-on payments for FY 2015 (79 FR 49946). As discussed in the FY 2015 IPPS/LTCH PPS final rule, this approval is on the basis of using the MitraClip® consistent with the NCD. Cases involving the MitraClip® System that are eligible for the new technology add-on payments are currently identified by ICD–9–CM procedure code 35.97. The average cost of the MitraClip® System is reported as $30,000. Under section 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the MitraClip® System is $15,000 for FY 2015.

With regard to the newness criterion for the MitraClip® System, we considered the beginning of the newness period to commence when the MitraClip® System was approved by the FDA on October 24, 2013. Because the 3-year anniversary date of the entry of the MitraClip® System on the U.S. market will occur in FY 2017 (October 24, 2016), we are proposing to continue new technology add-on payments for this technology for FY 2016. We are inviting public comments on this proposal.

Because we are adopting the ICD–10 coding system, beginning October 1, 2015, as discussed in section II.G.1.a, of the preamble of this proposed rule, for FY 2016, we are proposing to identify and make new technology add-on payments for cases involving the MitraClip® System using ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). The maximum payment for a case involving the MitraClip® System would remain at $15,000 for FY 2016. We are inviting public comments on this proposal.

h. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures occur when brain function is disrupted by abnormal electrical activity. Epilepsy is a brain disorder characterized by recurrent, unprovoked seizures. According to the applicant, the RNS® System is the first implantable medical device (developed by NeuroPace, Inc.) for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The applicant further stated that, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns. Stimulation is delivered only when abnormal electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day. The RNS® System incorporates remote monitoring, which allows patients to share information with their physicians remotely.

With respect to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval on November 14, 2013.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the RNS® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the RNS® System for new technology add-on payments for FY 2015 (79 FR 49950). Cases involving the RNS® System that are eligible for new technology add-on payments are currently identified using the following ICD–9–CM procedure codes: 01.20 (Cranial implantation or replacement of neurostimulator pulse

generator) in combination with 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)). According to the applicant, cases using the RNS® System would incur an anticipated cost per case of $36,950. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited to the lesser of 50 percent of the average costs of the device or 50 percent of the costs in excess of the MS–DRG payment rate for the case. As a result, the maximum new technology add-on payment for cases involving the RNS® System is $18,475.

With regard to the newness criterion for the RNS® System, we considered the beginning of the newness period to commence when the RNS® System was approved by the FDA on November 14, 2013. Because the 3-year anniversary date of the entry of the RNS® System on the U.S. market will occur in FY 2017 (November 14, 2016), we are proposing to continue new technology add-on payments for this technology for FY 2016. We are inviting public comments on this proposal.

Because we are adopting the ICD–10 coding system effective October 1, 2015, as discussed in section II.G.1.a. of the preamble of this proposed rule, we are proposing to identify and make new technology add-on payments for cases involving the RNS® System using the following ICD–10–PCS procedure code combination: 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). The maximum payment for a case involving the RNS® System would remain at $18,475 for FY 2016. We are inviting public comments on this proposal.

5. FY 2016 Applications for New Technology Add-On Payments

We received applications for nine new technology add-on payments for FY 2016. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. A discussion of the applications is presented below.

a. Angel Medical Guardian® Ischemic Monitoring Device

Angel Medical Systems, Inc. submitted an application for new technology add-on payments for the Angel Medical Guardian® Ischemic Monitoring Device (hereinafter referred to as the Guardian®). The Guardian® implantable ischemia detection system is designed to provide early detection and patient alerts for ischemic and other cardiac events experienced by ambulatory patients. The device consists of an implantable monitoring device (IMD) that communicates with an external device (EXD) via telemetry. The IMD monitors the patient's current cardiac data and compares these data to the patient's historical baseline using thresholds that reflect the normal ischemic range for each individual. Upon detection of a cardiac anomaly, the implanted IMD vibrates and provides one of two distinguishable alerts, ''emergency alarms'' and ''see doctor alerts,'' which prompt the patient to initiate emergency and/or preventative actions. The system also includes a program that allows physicians to adjust the settings for event detection and subsequent alerts.

With respect to the newness criterion, the applicant anticipates FDA premarket approval during June 2015. The Guardian® technology is a Class III device that has obtained an investigational device exemption (IDE) from the FDA under IDE number G060259. Effective October 1, 2006 (FY 2007), ICD–9–CM procedure codes 00.56 (Insertion or replacement of implantable pressure sensor (lead) for intracardiac hemodynamic monitoring) and 00.57 (Implantation or replacement of subcutaneous device for intracardiac hemodynamic monitoring) were created to describe specific types of cardiac procedures. There have been minor revisions to each of the procedure codes' title and description over the years to better differentiate procedures being performed with various technologies. As of October 1, 2011 (FY 2012), these codes distinguish procedures using the Guardian® technology from other similar procedures that use various technologies. The current ICD–9–CM procedure code titles are as follows: 00.56 (Insertion or replacement of implantable pressure sensor with lead for intracardiac or great vessel hemodynamic monitoring), and 00.57 (Implantation or replacement of subcutaneous device for intracardiac or great vessel hemodynamic monitoring). As stated earlier in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. Under ICD–10, procedure code 02HK32Z (Insertion of monitoring device into right ventricle, percutaneous approach) is the comparable translation for ICD–9–CM procedure code 00.56, and procedure code 0JH602Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach) is the comparable translation for ICD–9–CM procedure code 00.57, which specifically describe procedures involving the Guardian® technology. We note that, in accordance with § 412.87(c), in order for a technology to be considered for new technology add-on payments for a particular fiscal year, the technology must be approved by the FDA by July 1 prior to the particular fiscal year for which add-on payments are requested. According to the applicant, there are no other treatment modalities that perform the same function as the Guardian® technology. Therefore, the applicant believed that the Guardian® technology is not substantially similar to any other currently approved technology. We are inviting public comments on whether the Guardian® technology meets the newness criterion.

With respect to the cost criterion, the applicant determined that cases involving the Guardian® technology map to MS–DRG 264 (Other Circulatory System O.R. Procedures). The applicant initially provided a sensitivity analysis performed using all of the cases assigned to MS–DRG 264, without isolating a subset of cases that would be eligible for treatment using the Guardian® technology. In follow up to our request for a more focused analysis that calculates an average case-weighted standardized charge per case for cases involving the Guardian® technology assigned to MS–DRG 264, the applicant submitted a revised analysis that used data from a subset of cases representing patients who received treatment involving the implantation of pacemakers that mapped to MS–DRG 243 (Pacemaker Implant with CC). The applicant searched the Healthcare Cost and Utilization Project (HCUP) database for patient profiles that indicated prior myocardial infarction with comorbidities such as malignant hypertension (reported using ICD–9–CM diagnosis code 401.0), other acute and subacute forms of ischemic disease (reported using ICD–9–CM diagnosis code 411.89), and intermediate coronary syndrome (that is, unstable angina reported using ICD–9–CM diagnosis code 411.1). According to the applicant, all of the patients enrolled in the ALERTS pivotal clinical study exhibited at least one or more of these comorbidities, similar to many of the patients represented by cases assigned to MS–DRG 243. The applicant asserted that the results from the revised search of the HCUP database revealed patient profiles that were similar to the patients who would have likely been recommended for treatment using the

Guardian® technology, which are represented by the cases assigned to MS–DRG 264. The applicant identified 843 cases assigned to MS–DRG 243, which represents patients treated with pacemaker implantations by the hospitals that participated in the Guardian® ALERTS clinical study.

The applicant used data from multiple sources to compute an average case-weighted standardized charge per case for procedures involving the Guardian® technology. The applicant began by determining the specific FY 2015 Medicare IPPS Federal rate for cases assigned to MS–DRG 243 that were treated by each hospital that participated in the Guardian® ALERTS clinical study. The applicant then adjusted this amount by a factor of 1.057, which was derived from the March 2014 MedPAC Report to Congress on Medicare payment policies, to convert the Medicare payment to actual costs incurred by each hospital for each case. Specifically, the applicant determined this adjustment factor by subtracting the average industry wide margin of −5.4 percent, or −0.054 percent, for hospitals during 2012, which was reflected in the March 2014 Report to Congress, from a factor of 1, which results in the percentage of inpatient costs that Medicare paid (1 − 0.054 = 94.6), and then divided this amount by 100 (100/94.6 = 1.057). To convert the adjusted Medicare payment amount to charges, the applicant applied hospital-specific CCRs found in the FY 2015 IPPS final rule impact file. The applicant computed an average case-weighted standardized charge per case by weighting the number of implants performed using the Guardian® technology performed by each hospital participating in the Guardian® ALERTS clinical study to the overall number of implants performed and represented by cases assigned to MS–DRG 243. This resulted in an average case-weighted standardized charge per case of $75,010. The applicant then deducted device-related charges for a pacemaker based on data obtained from the FY 2015 After Outliers Removed (AOR) File to determine the nonimplant resources used during these types of procedures, and added the device-related charges for the Guardian® technology, which resulted in an adjusted average case-weighted charge per case of $89,050. Because this adjusted average case-weighted standardized charge per case exceeds the average case-weighted threshold amount of $65,544 for MS–DRG 264 as displayed in Table 10 of the FY 2015 IPPS/LTCH PPS final rule, the applicant maintained that the Guardian® technology meets the cost criterion.

We have several concerns regarding the applicant's cost analysis. We do not believe that it is appropriate to convert Medicare payments for discharges to actual costs incurred by hospitals by applying a margin adjustment factor and hospital-specific CCRs to determine an average case-weighted standardized charge for specific cases. According to the regulations under 42 CFR 412.2(b)(1), the prospective payment amount paid for inpatient hospital services is the total Medicare payment for the inpatient operating costs and the inpatient capital-related costs incurred in furnishing services covered by the Medicare program. The prospective payment amount represents a payment amount for the total cost of inpatient hospital services incurred by hospitals participating in the Medicare program, but does not represent a measure of the actual costs per case. For example, two hospitals in the same CBSA will be paid the same prospective payment amount for a case assigned to the same MS–DRG. The fact that these hospitals are paid the same prospective payment amount does not imply that the hospitals incurred the same amount of costs per case. On the contrary, the hospitals probably incurred very different costs for each case and the prospective payment amount is simply a payment for the inpatient costs covered by Medicare. Therefore, we are concerned about the methodology used by the applicant to determine an average case-weighted standardized charge per case, and do not believe that the calculation of this amount determined by the applicant is accurate. Moreover, we are concerned that the applicant assumed that the patient profiles for patient treated with pacemaker implantations and patients treated using the Guardian® technology are similar enough to warrant the inclusion of cases assigned to MS–DRG 243 in the analysis and then to depend upon the results of that analysis as a basis to demonstrate that the technology meets the cost criterion. In addition, we do not believe that it is appropriate to assume that the resources used during procedures involving pacemaker implantations and procedures involving the Guardian® technology would be the same, and the applicant does not provide a rationale for assuming such similarities. Because of these concerns, we are unable to determine if the technology meets the cost criterion. We are inviting public comments on whether the Guardian® technology meets the cost criterion, particularly with respect to the concerns we have raised.

With respect to the substantial clinical improvement criterion, the applicant asserted that this technology provides a more rapid beneficial resolution to ischemic and other cardiac events in ambulatory patients that reduces mortality and morbidity, and facilitates a faster patient presentation time to initiate treatment for these types of disorders. The applicant also believed that this technology fulfills an unmet clinical need for early diagnoses and preventative treatment options for a patient population that experiences silent, asymptomatic ischemia. The applicant included data from its pivotal ALERTS clinical trial, a randomized study expanding over a 6-month period of patients who were treated using the Guardian® technology and with the alarm function turned on (which represented the treatment group) or the alarm function turned off (which represented the control group). The primary efficacy endpoint was a composite variable that considered cardiac or unexplained death, new death Q-wave MI, or delayed presentation (time to door >2 hours) for a documented coronary occlusion event. The primary safety outcome measure was device-related complications. According to the applicant, the following findings demonstrate that the Guardian® technology represents a substantial clinical improvement in regard to currently available treatment options for Medicare beneficiaries:

- The treatment group showed statistically significant clinical improvement over the control group using a composite outcome variable;
- 97 percent of patients treated with implantations using the Guardian® technology were free from system-related complications at 6 months post programming;
- A reduced proportion of patients having pre-hospital delays over 2 hours for a confirmed thrombotic coronary occlusive event;
- A reduction in the median time-to-door for patients treated using the Guardian® technology alert system turned on (51 minutes) versus patients treated using the Guardian® technology alert system turned off (1,808 minutes); and
- An improvement in the overall quality of life, and greater control over the condition, including feeling safer, for patients who were enrolled in the ALERTS trial and participated in a 2012 quality of life study that were treated with the Guardian® technology when the alarm system was activated.

We are concerned that the outcome measures, including the quality of life measures, are based on and reflective of factors other than the efficacy of the device. For instance, any benefit from using the Guardian® technology depends entirely upon the patient heeding the alarms and alerts and seeking emergency medical care without delay. Moreover, we are concerned that the ALERTS pivotal trial uses inherently different methods of ascertainment of ''delayed presentation'' for the treatment group and the control group after an ischemic event, which implies a serious bias in regard to the clinical trial results. We believe that this bias questions the validity of the primary efficacy endpoint. An additional concern is that the ALERTS pivotal trial uses a very broad definition of a ''confirmed thrombotic event.'' Although the pivotal trial used four different criteria to determine whether such an event occurred, only two of them are actually evidence of an acute coronary event for which timely patient presentation for medical care might improve outcomes. The applicant did indicate how many confirmed events met each of the four criteria.

We are inviting public comments on if, and how, the Guardian® technology meets the substantial clinical improvement criterion, particularly with respect to the concerns we have raised.

Below we summarize and respond to the comments submitted on the Guardian® technology at the Town Hall meeting.

Comment: Several participants in the ALERTS clinical trial submitted comments supporting the approval of new technology add-on payments for the Guardian® technology. According to the commenters, use of the Guardian® technology is associated with substantial clinical improvement of patients at high risk for a repeat myocardial infarction. The commenters stated that experiences as part of the ALERTS study have been positive. In addition, the commenters agreed with the applicant that patients implanted with an active Guardian® device who were alerted to a confirmed myocardial infarction event arrived at a medical facility significantly faster than those generally treated using the regular standard of care. Moreover, the commenters agreed with the applicant that patients are reassured by the effectiveness of the Guardian® device as a means of monitoring and protection. The commenters believed that the Guardian® device provides patients and providers with an important tool for helping to recognize when a significant ischemic event occurs and when to seek prompt medical treatment, which result in reduced morbidity and mortality, fewer visits to the emergency room and unnecessary hospitalizations, and reduced health care expenditures. The commenters believed that the Guardian® device meets the substantial clinical improvement criterion because the device offers a more rapid and beneficial resolution for treating patients by its capability to diagnose a medical condition in a patient population where the condition is currently undetectable as well as offers a treatment option to a patient population unresponsive to currently available treatments.

One commenter, a principal investigator in the ALERTS study, further reported that treatment using the Guardian® device tended to reduce the incidence of Q waves, a primary clinical endpoint that has important ramifications in both morbidity and mortality rates. The commenter also noted that, based on the results of the ALERTS study, asymptomatic thrombotic events were recognized in 21 of 451 (4.6 percent) of patients in the Guardian® treatment arm, and that the vast majority of these patients arrived to a medical facility within an hour of the onset of the event. In contrast, patients in the control arm who experienced asymptomatic ischemic events recorded by the Guardian® device arrived to a medical facility between 10 and 77 days after the event. According to the commenter, many of these patients experienced a silent myocardial infarction, which occurs over time in a significant number of patients and can lead to higher mortality rates. The commenter believed that the Guardian® device provides a significant benefit to a patient population that experiences asymptomatic ischemic events and does not receive any physical warnings of their condition, and who would otherwise not seek treatment for a longer period of time than what is recommended in the medical community, if treatment is sought at all.

Another commenter provided additional information on the opportunity for improvement upon time to treatment for patients at high risk for a recurrent myocardial infarction, which would in turn lead to improved clinical outcomes, particularly for the patient population experiencing asymptomatic ischemia. According to the commenter, approximately 50 percent of patients experiencing myocardial infarction have no symptoms at all or symptoms that may not be recognized, and often do not receive any acute therapy to avert or mitigate the impact of the infarction. The commenter stated that the current standard of care requires patients to recognize symptoms of heart attack and seek medication immediately, and, for every 30 minute delay in treatment, there is an associated 8.5 percent increased risk of developing an ejection fraction of less than 30 percent, which is highly correlated with subsequent heart failure, and an associated 7.5 percent relative risk increase in 1 year mortality. Therefore, the commenter believed that the Guardian® device presents a significant opportunity to address improvement in the timing of treatment for patients at high risk for a recurrent myocardial infarction.

Response: We appreciate the commenters' input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for the Guardian® device.

b. Blinatumomab (BLINCYTO™)

Amgen, Inc. submitted an application for new technology add-on payments for Blinatumomab (BLINCYTO™), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with ALL in the United States each year, and approximately 2,400 individuals, which represents 30 percent of all new cases, are adults. ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally throughout the body. As a bi-specific T-cell engager, the BLINCYTO™ technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO™ technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell.

BLINCYTO™ is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle followed by 2 weeks without treatment prior to administering any further

treatments. A course of treatment consists of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments given after remission has been achieved to prolong the duration. During phase 1 of a single treatment course, up to two cycles of BLINCYTO™ are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO™ administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With respect to the newness criterion, the BLINCYTO™ technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014. As stated in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. We note that the applicant submitted a request for unique ICD–10–PCS codes that was presented at the March 18, 2015 ICD–10 Coordination and Maintenance Committee meeting. If approved, the codes will be effective on October 1, 2015 (FY 2016). More information on this request can be found on the CMS Web site located at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

According to the applicant, the BLINCYTO™ technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA. However, we are concerned that BLINCYTO™ may be substantially similar to other bi-specific T-cell engagers. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

With regard to the first criterion, we are concerned that the mechanism of action of the BLINCYTO™ technology does not appear to differ from those of other bi-specific T-cell engagers, which also attract the cancerous cell within close proximity of a normal T-cell with the intent of allowing the cell to get close enough to inject toxins to destroy the cancerous cell. There are several other BiTEs currently under investigation, including MT110 that are used for the treatment of patients diagnosed with gastrointestinal and lung cancers and are directed towards the EpCAM antigen, as well as MCSP-specific and CD33-specific BiTEs used for treating patients diagnosed with melanoma and acute myeloid leukemia, respectively. We believe that the feature that distinguishes the BLINCYTO™ technology from these other bi-specific T-cell engagers is that it specifically targets the CD19 cell. However, we are concerned that the specificity of the mechanism of action may not be sufficient to distinguish the BLINCYTO™ technology from other bi-specific T-cell engagers and, therefore, the technology bears substantial similarity to these other BiTEs used as current treatment options for Medicare beneficiaries. Further, we are concerned that determining that the BLINCYTO™ technology meets the newness criterion based on the specificity of the mechanism of action would set a precedent that a drug employing the same mechanism of action could be considered ''new'' based on such specificity when evaluated under the substantial similarity criterion.

With respect to the second criterion, the applicant maintained that ICD–9–CM diagnosis codes 204.00 (Acute lymphoid leukemia, without mention of having achieved remission) and 204.02 (Acute lymphoid leukemia in relapse) are used to identify patients who may potentially be eligible for treatment using the BLINCYTO™ technology. Using these diagnosis codes, the applicant researched claims data from the FY 2013 MedPAR file and found cases across a wide spectrum of MS–DRGs, not all of which are related to acute lymphoblastic leukemia. According to the applicant, 42.1 percent of all cases representing patients diagnosed with ALL were assigned to 238 MS–DRGs. Therefore, we believe that potential cases involving the BLINCYTO™ technology may be assigned to the same MS–DRG(s) as other cases involving bi-specific T-cell engagers used to treat patients with leukemia.

With respect to the third criterion, according to the applicant, the standard treatment for patients diagnosed with ALL currently requires the use of multiple, intensive chemotherapy treatment drugs in combination to induce remission in order to allow the patient the opportunity to proceed to allogenic hematopoietic stem cell transplant (alloHSCT), which is the next stage in the course of treatment and the only known curative option. The applicant asserted that the BLINCYTO™ technology is not substantially similar to other treatment options because it does not involve the treatment of the same, or similar, type of diseases or the same, or similar, patient population. The commenter stated that, although chemotherapy is a successful treatment option to induce remission in patients diagnosed with R/R ALL, many of these patients relapse or stop responding to this standard treatment and, therefore, are be unable to proceed to alloHSCT, the next stage of treatment. Moreover, chemotherapy toxicities can be cumulative. Therefore, the commenter stated, patients who have received intensive treatments may not be eligible for further intensive chemotherapy treatments and, therefore, are unable to proceed to alloHSCT. The applicant asserted that the BLINCYTO™ technology is an anti-cancer immunotherapy that has shown to be effective in the treatment of a patient population in which chemotherapy has not been successful. Moreover, the applicant asserted that, as an anti-cancer immunotherapy, the BLINCYTO™ technology does not demonstrate the cumulative side-effects typically associated with chemotherapy treatments and, therefore, is a treatment option available to patients who are not eligible for further chemotherapy treatments based on the risks associated with cumulative toxicities. However, we are concerned that this specific patient population is not necessarily distinguishable from the overall patient population of individuals diagnosed with ALL, and we are unsure how to identify these patients using administrative claims data.

We believe that the BLINCYTO™ technology may be similar to other approved technologies currently available to treat the same patient

population and medical disorders and, therefore, may not meet the newness criterion. In addition, we do not believe that the specific patient population targeted by the applicant is sufficiently distinguishable from the overall patient population that may be eligible for treatment using options that are currently available for these types of medical disorders. We are seeking public comments on if, and how, the BLINCYTO™ technology meets the newness criterion.

With respect to the cost criterion, the applicant researched claims data in the FY 2013 MedPAR file, which contained inpatient hospital discharges from October 1, 2012, to September 30, 2013, and identified cases reporting ICD–9–CM diagnosis codes 204.00 (Acute lymphoid leukemia, without mention of having achieved remission) and 204.02 (Acute lymphoid leukemia in relapse), which represent patients who may potentially be eligible for treatment using the BLINCYTO™ technology. The applicant found 2,649 cases across 246 MS–DRGs, including MS–DRGs 834 through 836 (Acute Leukemia without Major Operating Room Procedure, with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 837 through 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis, with MCC, with CC, and without CC/MCC, respectively), which represent approximately 48.1 percent of all cases with patients diagnosed with ALL. The applicant also found that MS–DRG 809 (Major Hematological and Immunologic Diagnoses Except Sickle Cell Crisis and Coagulations Disorders with CC) and MS–DRG 871 (Septicema or Severe Sepsis without Mechanical Ventilation 96+ Hours with CC) contained cases that further represent 9.8 percent of all cases representing patients diagnosed with ALL. The cases assigned to the remaining 238 MS–DRGs represent a combined 42.1 percent of all cases representing patients diagnosed with ALL, with no single MS–DRG containing cases representing more than 2.0 percent of all cases representing patients diagnosed with ALL. The applicant also noted that when identifying cases that may be eligible for the BLINCYTO™ technology, it excluded any claims for discharges paid by Medicare Advantage plans, as well as any claims submitted by Medicare PPS-exempt cancer hospitals.

Because the applicant was unable to provide a single estimate of the charges that would be avoided by using the BLINCYTO™ technology (that is, additional charges incurred during treatment using other technologies), the applicant conducted its own cost analysis using two scenarios for each group of MS–DRGs. The first scenario assumed that 50 percent of the charges for drugs would be eliminated by using the BLINCYTO™ technology, and the second scenario assumed that 75 percent of the charges for drugs would be eliminated. The applicant further conducted sensitivity analyses for each of the top eight MS–DRGs containing cases eligible for the BLINCYTO™ technology, as well as a sensitivity analysis for all of the other MS–DRGs outside of the top eight to which eligible cases mapped. The applicant then examined the average case-weighted standardized charge per case and the average case-weighted threshold amount for all 2,649 cases identified during FY 2013 across all 246 MS–DRGs, and for 1,533 cases during FY 2013 across the top 8 MS–DRGs to demonstrate that the technology meets the cost criterion.

Under the analysis' first scenario, 50 percent of the charges for drugs incurred by using other technologies were removed in order to exclude the charges associated with the use of these technologies. The applicant determined an average case-weighted threshold amount of $60,278 for the 2,649 ALL cases in the 246 MS–DRGs identified using the thresholds in Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant also determined an average case-weighted standardized charge per case of $245,006, or $184,728 above the average case-weighted threshold amount. For the subset of 1,533 cases that mapped to the top 8 MS–DRGs, the applicant determined an average case-weighted threshold amount of $65,478 using the threshold in Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant also determined an average case-weighted standardized charge per case of $249,354, or $183,876 above the average case-weighted threshold amount. Based on the applicant's analyses, we believe that the BLINCYTO™ technology meets the cost criterion under the first scenario.

Under the second scenario, the applicant removed 75 percent of charges for drugs incurred by using other technologies in order to exclude the charges associated with the use of these technologies. The applicant determined an average case-weighted threshold amount of $60,278 for the 246 MS–DRGs identified using the thresholds from Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant determined an average case-weighted standardized charge per case of $239,321, or $179,043 above the average case-weighted threshold amount. For the subset of 1,533 cases that mapped to the top 8 MS–DRGs, the applicant determined an average case-weighted threshold amount of $65,478 using the thresholds from Table 10 in the FY 2015 IPPS/LTCH PPS final rule. The applicant determined an average case-weighted standardized charge per case of $242,423, or $176,945 above the average case-weighted threshold amount. Based on the applicant's analyses, we believe that the BLINCYTO™ meets the cost criterion under the second scenario.

In conducting the above analyses, the applicant summarized the charges from the claims it identified and standardized the charges using an unspecified data source. The applicant then inflated all charges from FY 2013 to FY 2015 using the 10.4427 percent inflation factor used by CMS to update the FY 2015 outlier threshold. In determining the costs for the technology per case, the applicant also assumed that the BLINCYTO™ technology would be administered for 28 days during each inpatient stay. The applicant also assumed a hospital markup of 2.0 percent, and applied this amount to its estimated charges per case.

We have three concerns regarding the applicant's methodology and assumptions used in its cost analyses. We are concerned that the applicant did not specify whether it used the FY 2015 IPPS final rule impact file or another data source to standardize the charges per case for this technology. We also are concerned that the applicant did not provide a basis for the hospital markup assumed when conducting its cost analyses. Unless the applicant provides this information, we are unable to determine whether the cost of the technology per case has been calculated appropriately. Moreover, we are concerned that including charges representative of a full 28-day treatment cycle is not appropriate for the purpose of calculating the charges associated with the BLINCYTO™ technology in order to determine whether the technology meets the cost criterion. According to the applicant, clinical trial data demonstrate that there are large subsets of patients who require inpatient care for the full 28-day treatment cycle because of the extreme clinical conditions relating to patients diagnosed with ALL. However, the applicant also conceded that only 25 percent of patients enrolled in the U.S. clinical trial were hospitalized for the full 28-day treatment cycle, and only 38 percent of these patients were over the age of 65. This causes us concern regarding whether the methodology used by the applicant in its cost analysis is appropriate. We are inviting public comments on if, and how, the

BLINCYTO™ technology meets the cost criterion, specifically in regard to our concerns related to the applicant's methodology.

With respect to the substantial clinical improvement criterion, the applicant asserted that the BLINCYTO™ technology represents a substantial clinical improvement for the treatment of patients diagnosed with R/R ALL because it offers a treatment option for patients who may be unresponsive to currently available options for treatment, decreases the rate of subsequent therapeutic interventions for patients who might not have otherwise achieved remission, and reduces mortality. The applicant provided data analysis results from four sources to demonstrate that the technology represents a substantial clinical improvement. These sources include a historical literature search, a model-based meta-analysis (Study 118427), a historical comparator data (Study 20120310), and a pivotal clinical trial (Study MT 103–211). We summarize the results from each of these sources below.

• The historical literature search revealed that superior regimens among currently used chemotherapeutic options result in a complete remission rate ranging from 18.0 percent to 38.6 percent, a median overall survival rate for patients experiencing early first relapse (<12 months) at 4.7 months, and a median overall survival rate for patients experiencing second or later relapse at 3 months. However, there are several limitations to using recent literature as a historical comparison for studies relating to patients diagnosed with R/R ALL, including differences in patient populations or study design characteristics across published studies, which make it difficult to formulate absolute comparisons with regard to data obtained from the BLINCYTO™ pivotal clinical trial. Therefore, the applicant conducted a model-based meta analysis (Studies 118427 and 119384), and a historical comparator study (Study 20120310) to account for these differences.

• In the model-based meta analysis (MBMA), the endpoints of complete remission (CR), duration of complete remission (DCR), and overall survival (OS) rate models were used to predict the efficacy of the BLINCYTO™ technology in cases representing patients diagnosed with relapsed/refractory ALL relative to patients treated using existing therapies. Simulations based on the MBMA for adult patients diagnosed with relapsed/refractory B-precursor ALL projected a poor outcome with existing salvage therapies, and a significant increase in the proportion of CR, DCR, and OS rates in a population with the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT103–211. For adult patients diagnosed with relapsed/refractory ALL who were treated with existing salvage therapies and having the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT 103–211, the projected proportion of CR was 0.121 (95 percent CI: 0.041 to 0.341), the median DCR rate was 4.9 months (95 percent CI: 2.5 to 9.2 months), and the median OS rate was 3.9 months (95 percent CI: 3.0 to 4.7 months). For adult patients diagnosed with R/R ALL having the same summary prognostic factors as those enrolled in the BLINCYTO™ study MT 103–211, treatment using the BLINCYTO™ technology when compared with existing salvage therapies is expected to have an odds ratio for proportion of CR of 3.50 (95 percent CI: 1.63 to 8.40), a hazard ratio for DCR of 0.53 (95 percent CI: 0.30 to 0.89), and a hazard ratio for OS of 0.60 (95 percent CI: 0.47 to 0.76). The applicant maintained that these results suggest that the BLINCYTO™ technology is associated with a reduced mortality rate and improved clinical outcomes when compared to standard chemotherapy treatment options.

• A historical comparator study was also conducted to obtain patient-level data for standard of care treatment options for patients experiencing early first relapse, refractory relapse after HSCT, and second or greater relapse in the same patient population as targeted in the BLINCYTO™ pivotal clinical trial. Study 20120310 was a retrospective pooled analysis of historical data available from 1990 to 2014 on hematological remission and survival rates among patients diagnosed with Ph- R/R B-cell precursor ALL who were treated with standard of care therapies. The primary study endpoint was CR following relapse or salvage treatment; and secondary endpoints included estimates of OS rates, RFS rates, and the proportion of patients receiving alloHSCT. The weighted median OS rate for 1,112 patients based on available data was 3.3 months (95 percent CI: 2.8 to 3.6 months) and was calculated from the start of the last salvage treatment or the first relapse (if start of the last salvage date was unavailable) until the time of death. The weighted OS rate at 6 and 12 months was 30 percent (95 percent CI: 27 percent to 34 percent) and 15 percent (95 percent CI: 13 percent to 18 percent), respectively. Among the patients who achieved CR based on available data (108 patients), the weighted median RFS rate was 5.0 months (95 percent CI: 1.2 to 6.6 months). Among the 808 patients who received alloHSCT after salvage therapy based on available data, 18 percent (95 percent CI: 15 percent to 21 percent) received alloHSCT following the last line of salvage therapy, and among patients who achieved CR, 7 percent (95 percent CI: 5 percent to 9 percent) received alloHSCT. The applicant maintained that these results highlight the poor health care outcomes for patients treated with standard chemotherapy and that BLINCYTO™ represents a significant improvement.

• BLINCYTO™ study MT 103–211 is a pivotal clinical study providing efficacy data for the BLINCYTO™ technology used for the treatment of adult patients diagnosed with Ph- R/R B-cell precursor ALL. It is a phase 2, single-arm study that included a particularly difficult patient population to treat consisting of patients diagnosed with Ph- B-cell precursor ALL who experienced either: (1) R/R after remission during 12 months or less of the first salvage treatment; (2) R/R after the first salvage treatment; or (3) R/R within 12 months after receiving alloHSCT. The primary endpoint was the rate of CR plus CRh within the first 2 cycles of treatment using the BLINCYTO™ technology. The key secondary endpoints include best overall response within 2 cycles of treatment using the BLINCYTO™ technology, RFS, time of hematological relapse, OS rates, and the proportion of patients eligible for alloHSCT who underwent the procedure after receiving treatment using the BLINCYTO™ technology. An analysis of data from the pivotal trial showed that 40 percent of patients treated with the BLINCYTO™ technology who achieved CR or CRh were able to proceed to alloHSCT. A secondary analysis from the pivotal study found that in patients who achieved CR or CRh and had a minimal residual disease assessment during the first 2 cycles, the MRD response rate (little or no evidence of disease even at the molecular level) was 82.2 percent. The applicant asserted that this finding is significant because MRD is often a harbinger of relapse and a poor prognostic factor for patients diagnosed with ALL.

We are concerned that the data provided from the clinical studies are not sufficient to demonstrate that the BLINCYTO™ technology meets the substantial clinical improvement criterion. For example, the BLINCYTO™ study MT 103–211 was

not randomized or blinded, and was comprised of a small sample group of 189 patients with a median age of 39 years. We are concerned that the sample group studied during the clinical trial is not appropriate to determine if the technology represents a substantial clinical improvement in treatment options available for the Medicare patient population. Moreover, we are concerned that meaningful conclusions cannot be drawn from the results of this study because of the lack of a control group.

With regard to the applicant's assertion that the BLINCYTO™ technology offers a treatment option for patients who may be unresponsive to currently available treatment modalities, the applicant specifically focused on how the BLINCYTO™ technology represents a treatment option for a patient population in which chemotherapy has proven to be unsuccessful, or for whom intensive chemotherapy treatment is not possible because of the risks associated with exposure to cumulative toxicities. The applicant believed that the MBMA, the historical comparator study, and the BLINCYTO™ study MT 103–211, which is a pivotal clinical trial sufficiently isolate this patient population in order to measure specific health care outcomes. We agree with this assertion. However, our concerns with the isolated patient population are that it is comprised of and represents a small sample group of patients whose age demographic is much younger than the age demographic of eligible Medicare beneficiaries.

The applicant also asserted that the BLINCYTO™ technology decreases the rate of subsequent therapeutic interventions for patients who might not have otherwise achieved remission. In other words, because treatment with the BLINCYTO™ technology appears to increase the possibility of some patients achieving remission, the applicant maintained that these patients would receive fewer therapeutic interventions and become eligible to receive alloHSCT. We believe that it is difficult to determine what services and therapeutic interventions these patients would have required if they had not achieved remission, and we are not convinced that treatment using the BLINCYTO™ technology leads to a decrease in additional therapeutic interventions. We also note that patients who successfully achieve remission proceed to alloHSCT and, therefore, receive a different set of subsequent therapeutic interventions.

With regard to the applicant's assertion that the BLINCYTO™ technology reduces mortality rates, we note that the applicant did not directly capture mortality rates as an endpoint in the BLINCYTO™ pivotal study (MT 103–211), although mortality was analyzed during the other three studies that support the new technology add-on payment application. We note that the data and the MBMA's results included with the technology's application used an OS odds ratio as a measure of mortality, and were developed from 18 studies published between January 1995 and December 2012. We are concerned that relying on the results of data using a measure of mortality that is contingent upon studies completed in the 1990s presents a limitation in regard to the methodology used in the applicant's analysis. Advances in overall oncology care over the past 2 decades may invalidate the patient population represented in these studies as a comparison group. Therefore, we find it difficult to attribute the reduced mortality rate and improved clinical outcomes revealed by these studies to the efficacy of the BLINCYTO™ technology.

We are inviting public comments on if, and how, the BLINCYTO™ technology meets the substantial clinical improvement criterion, specifically in regard our specified concerns.

c. Ceftazidime Avibactam (AVYCAZ)

Cerexa, Inc., an affiliate of Actavis, Inc., submitted an application for new technology add-on payments for FY 2016 for Ceftazidime Avibactam (AVYCAZ). AVYCAZ is used for the treatment of adult patients who have been diagnosed with complicated urinary tract Infections (cUTIs), including pyelonephritis and complicated Intra-abdominal Infections (cIAIs), for which there are limited or no available treatment options. Although AVYCAZ is indicated for the treatment of patients who have been diagnosed with cUTIs and cIAIs, the applicant asserted that the product may also be used in the treatment of patients diagnosed with cUTIs and cIAIs caused by extended-spectrum β-lactamase (ESBL)-producing Gram-negative pathogens, carbapenem-resistant Enterobacteriaceae (CRE), and multidrug-resistant (MDR) Pseudomonas aeruginosa.

AVYCAZ is an intravenous β-lactam/β-lactamase inhibitor combination antibacterial drug, consisting of an anti-pseudomonal, Cephalosporin (also referred to as Ceftazidime), and a β-lactamase inhibitor, Avibactam. Ceftazidime is currently available and widely used as an extended spectrum of Cephalosporin. However, in recent years Cephalosporin has had diminishing effects because of increasing levels of antibiotic resistance in specific bacteria. Some species of bacteria produce ß-lactamase enzymes, which cleave the ß-lactam in antibiotics such as penicillin that have a ß-lactam ring in their structure. The ß-lactamase enzymes inactivate the antibiotic and cause the bacteria to become resistant to that antibiotic. To avoid development of resistance, in current practices ß-lactamase inhibitors are administered in combination with ß-lactam antibiotics to inhibit the action of ß-lactamase enzymes and prevent the development of antibiotic resistance because ß-lactamase inhibitors block the activity of ß-lactamase enzymes. This tends to widen the spectrum of antibacterial activity. For example, a commonly used β-lactamase inhibitor, Clavulanic acid or Clavulanate, is usually combined with Amoxicillin to create Augmentin or Ticarcillin (Timentin); Sulbactam (also a commonly used ß-lactamase inhibitor) is usually combined with Ampicillin to create Cefoperazone; and Tazobactam is usually combined with Piperacillin.

Ceftazidime is not combined with any β-lactamase inhibitors. Combining Ceftazidime with Avibactam prohibits bacteria from developing resistance to the antibiotic and protects Ceftazidime from being inactivated by β-lactamase enzymes. According to the applicant, unlike other inhibitors, Avibactam does not induce Class C enzymes that diminish the activity of Cephalosporin. Administering Ceftazidime in combination with Avibactam decreases the minimum inhibitory concentration (MIC) of Class A and Class C isolates, and some Class D isolates, thereby restoring the *in vitro* activity of Ceftazidime against these resistant isolates.

AVYCAZ is administered as a treatment to patients 18 years of age, or older, who have been diagnosed with a cUTI and/or a cIAI in doses of 2.5g (2g of Ceftazidime and 0.5g of Avibactam), every 8 hours by intravenous infusion spanning over a 2-hour time period. The recommended duration of treatment with AVYCAZ for patients diagnosed with a cIAI (used in combination with Metronidazole) is 5 to 14 days as an inpatient. The recommended duration of treatment with AVYCAZ for patients diagnosed with a cUTI is 7 to 14 days as an inpatient. The FDA has authorized a randomized multi-center, active-controlled trial to evaluate the safety and tolerability of AVYCAZ in children who are at least 3 months of age, and in adults 18 years of age or older who have been diagnosed with a cUTI and/or cIAI

as part of the post-marketing surveillance studies. The FDA also authorized and recommended a clinical trial to study the use of AVYCAZ in the treatment of patients who have been diagnosed with a cIAI and to generate phase 3 data as an effort to evaluate the pharmacokinetics, safety, and clinical outcomes of adult patients diagnosed with baseline renal impairment (creatinine clearance of 50 mL/min or less) who also are eligible for, or being treated with, AVYCAZ—adjusting dosage regimens to protect renal function.

With regard to the newness criterion, AVYCAZ was approved by the FDA on February 25, 2015. As stated earlier in section II.G.1.a. of the preamble of this proposed rule, for FY 2016, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. We note that the applicant submitted a request and presented at the September 2014 Coordination and Maintenance Committee Meeting to apply for ICD–10–PCS codes that uniquely identify the administration of Ceftazidime-Avibactam Anti-infective. More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

Currently, ICD–10–PCS procedure codes 3E03329 (Introduction of other anti-infective into peripheral vein, percutaneous approach) and 3E04329 (Introduction of other anti-infective into central vein, percutaneous approach) describe the injection of an antibiotic. However, these ICD–10–PCS codes are not specific to the type of antibiotic used. We received public comments during and after the March 2015 ICD–10 Coordination and Maintenance Committee meeting that supported the creation of a unique code to identify the AVYCAZ antibiotic when it is used in the treatment of patients who have been diagnosed with cUTIs and cIAIs. As a result, the following ICD–10–PCS codes were created under the new Section X to describe the specific use of AVYCAZ and are effective October 1, 2015 (FY 2016): XW03321 (Introduction of ceftazidime-avibactam anti-infective into peripheral vein, percutaneous approach, new technology group 1); and XW04321 (Introduction of ceftazidime-avibactam anti-infective into central vein, percutaneous approach, new technology group 1). If the AVYCAZ technology is approved for new technology add-on payments, we believe that the newness period would begin on February 25, 2015, the date of FDA approval. At this time, the applicant has not submitted any information that suggests the technology was not available on the U.S. market as of the FDA approval date. The applicant maintained that AVYCAZ meets the newness criterion. We are inviting public comments on whether AVYCAZ meets the newness criterion.

According to the applicant, the most current guidelines recommend treatment for patients hospitalized because of a cUTI diagnosis using antibiotic drugs such as Cefepime, Ceftriaxone, and Piperacillin/Tazobactam.[6] For patients who have been diagnosed with a cIAI and who are advanced in age, the most current guidelines recommend treatment using antibiotic drugs such as Imipenemcilastin, Meropenem, and Piperacillin/Tazobactam.[7] We are concerned that AVYCAZ may be substantially similar to other currently available treatment options, which also are used in the treatment of these types of infections. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

As stated by the applicant, Ceftazidime is currently available and widely used in the treatment of these types of infections. In addition, the current treatment options available to Medicare beneficiaries and used to treat this patient population include antibiotics such as Polymyxins (for example, Colistin), Aminoglycosides (for example, Amikacin and Gentamicin), Carbapenems (for example, Meropenem and Imipenem/Cilastatin), or Tigecycline. The applicant maintained that the administration of Ceftazidime in combination with Avibactam broadens the spectrum of ß-lactamase inhibition when compared to administering Ceftazidime without Avibactam and other currently available therapies because Avibactam has inhibiting agents that restore the *in vitro* activity of Ceftazidime that is sometimes decreased when encountered by common Class A and Class C isolates and some Class D isolates. The applicant also asserted that the technology may be used to treat patients who have been diagnosed with cUTIs and/or cIAIs caused by extended-spectrum β-lactamase (ESBL)-producing Gram-negative pathogens, Klebsiella pneumoniae carbapenemase (KPC), carbapenem-resistant Enterobacteriaceae (CRE), and multidrug-resistant (MDR) Pseudomonas aeruginosa. However, we believe that the mechanism of action of AVYCAZ is the same as the mechanism of action of Ceftazidime because both drugs rely upon Cephalosporin to achieve a successful therapeutic outcome. Further, we are concerned that AVYCAZ involves the treatment of the same or similar type of disease and the same or similar patient population as other currently approved treatment options. Therefore, we believe that AVYCAZ bears a substantial similarity to Ceftazidime and other currently available treatment options. We are inviting public comments regarding whether AVYCAZ meets the newness criterion, specifically with regard to the substantial similarity criteria. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

With regard to the cost criterion, the applicant maintained that AVYCAZ meets the cost criterion. According to the applicant, there are 63 ICD–9–CM diagnosis codes that describe cUTIs and/or cIAIs. Cases representing patients who have been diagnosed with cUTIs and/or cIAIs may be reported on hospital claims using any 1 of 12 different ICD–9–CM diagnosis codes describing cUTIs, and any 1 of 51 ICD–9–CM diagnosis codes describing cIAIs. Therefore, cases representing patients diagnosed with either a cUTI or a cIAI may be assigned to multiple MS–DRGs. Of the 63 applicable ICD–9–CM diagnosis codes, the applicant used 35 ICD–9–CM codes to identify 2,482,157 cases from the FY 2013 MedPAR file, which mapped to 567 MS–DRGs. The top five MS–DRGs containing cases that may be eligible for AVYCAZ are: MS–DRG 689 (Kidney and Urinary Tract Infections with MCC); MS–DRG 690 (Kidney and Urinary Tract Infections

[6] Drugs for urinary tract infections. JAMA. 2014;311(8):855–6. Available at: *http://jama.jamanetwork.com/article.aspx?articleid=1832532*.

[7] Solomkin JS et al. Guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. Clin Infect Dis. 2010;50(2):133–64. Available at: *http://cid.oxfordjournals.org/content/50/2/133.full*.

without MCC); MS–DRG 871 (Septicemia or Severe Sepsis Without Mechanical Ventilation 96+ Hours With MCC); MS–DRG 872 (Septicemia or Severe Sepsis Without Mechanical Ventilation 96+ Hours Without MCC); and MS–DRG 945 (Rehabilitation with CC/MCC). The top five MS–DRGs represent approximately 30 percent of the cases identified (731,560 cases out of 2,482,157 total cases), reported using 1 of the 35 respective ICD–9–CM diagnosis codes. To demonstrate that AVYCAZ met the cost criterion, the applicant provided multiple analyses for both cUTI and cIAI cases using 100 percent or 80 percent of all of the cases, as well as analyses of subset cases treated with low-cost generic drugs and high-cost brand named drugs administered for a length of 5 and 8 days.

The applicant began its analysis by searching the FY 2013 MedPAR file and identifying 2,183,467 cases representing patients diagnosed with a cUTI across 544 MS–DRGs, and 298,690 cases representing patients diagnosed with a cIAI across 385 MS–DRGs. This resulted in the identification of 1,146,971 cases representing patients diagnosed with a cUTI across 205 MS–DRGs, and 39,080 cases representing patients diagnosed with a cIAI across 32 MS–DRGs. After searching the FY 2013 IPPS Impact File, the applicant focused its analysis on 1,067,111 cases representing patients diagnosed with a cUTI across 193 MS–DRGs and 36,181 cases representing patients diagnosed with a cIAI across 31 MS–DRGs. The applicant further modified a portion of its analysis to focus on 1,067,072 cases representing patients diagnosed with a cUTI across 192 MS–DRGs in accordance with the thresholds obtained from Table 10 of the FY 2015 IPPS/LTCH PPS final rule.

Based on these data, for this analysis, the applicant used 100 percent of all of the cases representing patients diagnosed with a cUTI (1,067,072 cases) across 192 MS–DRGs. The applicant determined an average case-weighted standardized charge per case of $42,736. The applicant then excluded the charges for the specific technology used from the average case-weighted standardized charge per case. To continue its analysis, the applicant used two different variables to exclude the charges for specific technologies used, that is, the charges for low-cost generic drugs and the charges for high-cost brand named drugs administered for a length of 5 and 8 treatment days. The applicant explained that, at a minimum, it is recommended that antibiotics be administered for at least 5 days to prevent the development of antibiotic-resistant bacteria.[8] The applicant noted that, according to the Arlington Medical Resources (AMR),[9] the average length of therapy for patients diagnosed with an UTI and/or an IAI who were successfully treated for less than 5 days only represents 0.28 percent of all cases representing these types of conditions. Therefore, a 5-day treatment regimen was selected as a basis to represent the most conservative approach. In addition, the AMR's database indicated that the average length of therapy for patients diagnosed with an UTI who were successfully treated was 8.3 days and, therefore, the applicant selected a 8-day treatment regimen as a basis to represent a more liberal approach. The applicant also used data from the AMR to determine which drugs are the most commonly purchased injectable antibiotics. The applicant estimated a total charge of $441.75 for low-cost generic drugs and charges related to the infusion of these drugs for a 5-day treatment regimen, and $706.80 for a 8-day treatment regimen. The applicant estimated a total charge of $1,535.95 for high-cost brand named drugs and charges related to the infusion of these drugs for a 5-day treatment regimen, and $2,397.58 for an 8-day treatment regimen. The applicant then standardized and inflated the charges using a factor of 7.13 percent using the Medicare Economic Index from the latest CMS Market Basket Data file.[10] The applicant then added the charges for AVYCAZ and the infusion of AVYCAZ based on a 5-day treatment regimen and an 8-day treatment regimen. Depending on the amount of charges excluded for the use of specific drugs and the charges related to the infusion of these drugs, the applicant determined a final inflated average case-weighted standardized charge per case that ranged from $42,469 to $46,842. Using the FY 2015 IPPS Table 10, the average case-weighted threshold amount for all of the MS–DRGs used is $40,303 (all calculations above were performed using unrounded numbers). Because the final inflated average case-weighted standardized charge per case under all of these scenarios exceeds the average case-weighted threshold amount, the applicant maintained that AVYCAZ meets the cost criterion under this analysis.

The applicant conducted another analysis using the 80-percent variable for 846,897 cases representing patients diagnosed with a cUTI and/or a cIAI based on 3 of the ICD–9–CM diagnosis codes identified across 15 MS–DRGs. Depending on the amount of the charges excluded for the cost of the specific drugs and the charges related to the infusion of these drugs, the applicant determined a final inflated average case-weighted standardized charge per case that ranged from $37,086 to $41,459. Using the FY 2015 IPPS Table 10, the average case-weighted threshold amount across the 15 MS–DRGs used is $36,411 (all calculations above were performed using unrounded numbers). Because the final inflated average case-weighted standardized charge per case under all of these scenarios exceeds the average case-weighted threshold amount, the applicant maintained that AVYCAZ also meets the cost criterion under this analysis.

The applicant conducted another analysis using 100 percent of all of the cases representing patients who have been diagnosed with a cIAI (36,181 cases) across 31 MS–DRGs, and determined an average case-weighted standardized charge per case of $51,436.98. The applicant then excluded the charges for the specific technology used from the average case-weighted standardized charge per case. To continue its analysis, the applicant used two different variables to exclude the charges for the specific technologies used; that is, the charges for low-cost generic drugs and the charges for high-cost brand named drugs administered for a length of 5 and 8 treatment days. The applicant explained that, at a minimum, it is recommended that antibiotics be administered for at least 5 days to prevent the development of antibiotic-resistant bacteria. The applicant also noted that, according to the AMR, the average length of therapy for patients diagnosed with an UTI and/or an IAI that was successfully treated in less than 5 days only represents 0.28 percent of all cases representing these types of conditions. Therefore, a 5-day treatment regimen was selected as a basis to represent the most conservative

[8] Antibiotics. Merck Manual. Available at: *http://www.merckmanuals.com/home/infections/antibiotics.html.*

[9] The AMR database is a U.S. hospital inpatient database that provides updated information every 6 months. AMR gathers data from approximately 300 hospitals per year, providing information from approximately 22,000 patient records. Pharmacists from these hospitals fill out an inpatient profile form by verbatim transcription of information from patient charts, such as patient demographics, surgery codes, antibiotics used, dosage, start and end dates for each antibiotic used, and specialty information. These inpatient profile forms are then submitted to AMR in paper format. Data from this sampling of hospitals is projected to the universe of US hospitals. Available at: *http://www.amr-data.com/.*

[10] Centers for Medicare and Medicaid Services. Market Basket Data. Available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData.html.*

approach. In addition, the AMR's database indicated that the length of therapy for patients diagnosed with an IAI was 11.2 days and, therefore, the applicant selected a 8-day regimen as a basis to represent a more liberal approach. The applicant then added charges for AVYCAZ and the infusion of AVYCAZ based on a 5-day or 8-day treatment regimen. Depending on the amount of the charges excluded for the specific drugs used and the charges related to the infusion of these drugs, the applicant determined a final inflated average case-weighted standardized charge per case that ranged from $58,565 to $62,937. Using the FY 2015 IPPS Table 10 thresholds, the average case-weighted threshold amount across all of the MS–DRGs used is $51,436 (all calculations above were performed using unrounded numbers). Because the final inflated average case-weighted standardized charge per case under all of these scenarios exceeds the average case-weighted threshold amount, the applicant maintained that AVYCAZ also meets the cost criterion under this analysis.

The applicant conducted another analysis using the 80-percent variable for 28,483 cases representing patients diagnosed with a cIAI based on 5 of the ICD–9–CM diagnosis codes identified across 4 MS–DRGs. Depending on the amount of the charges excluded for the specific drugs used and the charges related to the infusion of these drugs, the applicant determined a final inflated average case-weighted standardized charge per case that ranged from $50,435.54 to $54,809.30. Using the FY 2015 IPPS Table 10 thresholds, the average case-weighted threshold amount across all of the MS–DRGs used is $47,186 (all calculations above were performed using unrounded numbers). Because the final inflated average case-weighted standardized charge per case under all of these scenarios exceeds the average case-weighted threshold amount, the applicant maintained that AVYCAZ also meets the cost criterion under this analysis.

We are concerned that the applicant did not use the inflation factor of 10.4427 when calculating the average case-weighted standardized charge per case, which is the same inflation factor used by CMS to update the FY 2015 outlier threshold, and did not offer a rationale for its alternative inflation factor. We are inviting public comments on whether AVYCAZ meets the cost criterion, specifically with regard to our concerns.

The applicant maintained that AVYCAZ represents a substantial clinical improvement in the available treatment options for patients diagnosed with a cIAI and/or a cUTI, including cUTIs and cIAIs that are known or suspected to be caused by extended-spectrum β-lactamase (ESBL)-producing Gram-negative pathogens, carbapenem-resistant Enterobacteriaceae (CRE), and multidrug-resistant (MDR) Pseudomonas aeruginosa. According to the applicant, existing treatment options for these types of conditions are very limited and pose toxicity risks. The applicant stated that antibiotic-resistant infections are a serious problem for health care providers and patients. Among the bacteria resistant to all or nearly all of the antibiotics available today, CRE has developed rapidly and continues to proliferate. The applicant noted that, as of 2014, 49 States have reported confirmed CRE infections, an increase from 42 States that reported and confirmed CRE infections in 2013.[11,12] Almost half of hospital patients who get bloodstream infections from CRE bacteria die from the infection.[13] The applicant further noted that, over the last 20 years, Gram-negative bacteria have evolved in defense against recently approved broad-spectrum β-lactam agents (for example, ß-lactam ß-lactamase inhibitors [BL–BLIs] and carbapenems) by producing a multitude of ''new'' β-lactamases—including extended-spectrum β-lactamases (ESBLs) and carbapenemases that can confer resistance to these front-line agents. Because of the technology's inhibiting activity against these pathogens, the applicant maintained that AVYCAZ may provide a safer and more effective treatment option for patients diagnosed with cIAIs and cUTIs caused by these antibiotic-resistant organisms. The applicant further noted that there are serious side effects associated with the current treatment options and regimens, such as Polymyxins, Colistin, Aminoglycosides, Carbapenems, and Tigecycline,[14] including resistance to nephrotoxicity.

The applicant provided data from the REPRISE study, which compared AVYCAZ and Carbapenem, also used as a treatment option for patients diagnosed with cIAIs and cUTIs. This study was specifically designed to demonstrate the inhibiting activity of Avibactam to restore the clinical and microbiological efficacy of Ceftazidime verses Ceftazidime-resistant, β-lactamase-producing Gram-negative bacteria. According to the applicant, in the pooled cIAI and cUTI studies,[15] the by-pathogen microbiological response rate was assessed using the test of cure (TOC) as a measuring tool. TOC refers to the reculturing of a site of initial infection to determine whether the patient is cured.[16] TOC was the same or numerically higher for AVYCAZ versus the comparator for almost all pathogens isolated for the treatment of ceftazidime-nonsusceptible (CAZ–NS). We are concerned that the results of this study do not show that AVYCAZ has more favorable clinical or microbiological responses when compared to existing technologies. According to § 412.87(b)(1) of our regulations, in order to satisfy the substantial clinical improvement criterion, the applicant must demonstrate that the technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

The applicant reported that the INFORM study [17] is one of the ongoing *in vitro* studies of AVYCAZ. According to the results of this study, Avibactam extends the activity of Ceftazidime and provides a broad spectrum of activity compared to currently available therapies. In addition, AVYCAZ demonstrated activity against two of the four areas of need as stated by the CDC, and potentially demonstrated activity against a third. The two areas of need that demonstrated favorable microbiological response were carbapenem-resistant Enterobacteriaceae (CRE) and extended-spectrum β-lactamase (ESBL). We are concerned that *in vitro* studies may not necessarily correlate with clinical results.

The applicant also provided conclusions and data from one of the Phase II clinical trials conducted for patients diagnosed with cIAIs and cUTIs, respectively. The applicant reported that the patients diagnosed

[11] Tracking CRE—Carbapenempase producing CRE in the US. CDC HAI Web site. Available at: *http://www.cdc.gov/hai/organisms/cre/TrackingCRE.html*.

[12] Making health care safer—Stop infections from lethal CRE germs now. *CDC Vital Signs 2013*. Available at: *http://www.cdc.gov/vitalsigns/pdf/2013-03-vitalsigns.pdf*.

[13] Antobiotics. Merck Manual. Available at: *http://www.merckmanuals.com/home/infections/antibiotics.html*.

[14] Bader M, Hawboldt J, Brooks A. Management of complicated urinary tract infections in the era of antimicrobial resistance. *Postgraduate Medicine*.2010; 122(6):7–15.

Rishi H, Dhillon P, Clark C. ESBLs: a clear and present danger? *Critical Care Research and Practice,* 2012; Article ID 625170.

Jacoby GA, Munoz-Price LS. The New β-Lactamases.*N Engl J Med* 2005; 352:380–391.

[15] Pooled data includes subset of patients from Phase II trials and interim data from the Phase III REPRISE trial.

[16] *http://medical-dictionary.thefreedictionary.com/test+of+cure*.

[17] Data on File. Actavis 2014.

with cIAIs were randomized to either AVYCAZ with Metronidazole versus the control drug Meropenem. The clinical cure rates at TOC were 82.4 percent for the AVYCAZ + Metronidazole group, and 88.8 percent for the Meropenem group for patients diagnosed with cIAIs. For patients diagnosed with cUTIs, the applicant reported that they were randomized to either AVYCAZ versus Imipenem. The clinical cure rates at TOC were 80.4 percent versus 73.5 percent for the AVYCAZ group versus the Imipenem group for patients diagnosed with cUTIs.

The applicant also provided data from the RECLAIM–1 and RECLAIM–2 trials. The applicant reported that these trials evaluated the safety and efficacy of AVYCAZ versus the control drug used to treat patients hospitalized for cIAIs. According to the applicant, AVYCAZ technology met the objective of statistical noninferiority when compared to the control drug. However, the applicant asserted, in a subgroup of patients diagnosed with moderate renal impairment at baseline (MRIB [defined as an estimated creatinine clearance (ClCr) of >30 mL/min and ≤50 mL/min]), AVYCAZ combined with Metronidazole had lower clinical cure rates when compared to the control group. In addition to the clinical response rate findings, although the number of deaths was minimal, they were numerically higher for patients diagnosed with MRIB who were treated with AVYCAZ in combination with Metronidazole when compared to patients treated with Meropenem. The applicant acknowledged that this result was not more favorable and reviewed the individual cases of failure or indeterminate (including all deaths) for the patients diagnosed with MRIB, and identified no predominant reason for the treatment difference observed in the subgroup analysis. However, the applicant maintained that AVYCAZ represents a substantial clinical improvement because of the adverse effects of other currently available treatment options such as nephrotoxicity. We are concerned that the findings cited by the applicant lack data regarding the adverse effects of nephrotoxicity because of treatment using other currently available treatment options.

The applicant stated that, in the Phase II trials, the Medicare-eligible population represented 9.2 percent of the total population of patients diagnosed with cIAIs, and 14.8 percent of the total population of patients diagnosed with cUTIs. We are concerned that a cohort that would reflect a Medicare population was not analyzed or predefined as a subgroup in the trials to better understand and quantify the substantial clinical improvement of AVYCAZ. Furthermore, we are unsure whether a possibility of a favorable safety and tolerability profile for AVYCAZ relative to other currently available treatment options for patients diagnosed with cUTIs and cIAIs implies a substantial clinical improvement.

The applicant maintained that AVYCAZ represents a substantial clinical improvement over treatment options currently available to Medicare beneficiaries. We do not believe that the applicant has substantiated this assertion. With regard to the data indicating the safety of the technology, we are concerned that the results for the trials could be interpreted to suggest that use of the technology may lead to increased mortality. We note that the composition of the treatment and control groups may make it difficult to isolate the degree to which AVYCAZ affects safety and health care outcomes because the patients in the treatment group were also treated with another drug administered in combination with AVYCAZ. Moreover, we are concerned that the median age of the participants enrolled in the studies of AVYCAZ was between 40 and 50 years. We believe that it would be indicative to use a subgroup that actually represents the eligible Medicare population (that is, patients who are 65 years of age or older, blind, disabled, or diagnosed with end-stage renal disease). The applicant stated that AVYCAZ had greater efficacy and safety measures for patients who have limited or no other available treatment options. However, we are concerned that the patient population enrolled in the applicant's trials were not eligible Medicare beneficiaries, nor was it definitive that these participants had limited or no other available treatment options. We are inviting public comments on whether AVYCAZ meets the substantial clinical improvement criterion, specifically with regard to our stated concerns.

We did not receive any written public comments in response to the New Technology Town Hall meeting regarding the application of AVYCAZ for new technology add-on payments.

d. DIAMONDBACK 360® Coronary Orbital Atherectomy System

Cardiovascular Systems, Inc. submitted an application for new technology add-on payments for the DIAMONDBACK 360® Coronary Orbital Atherectomy System (OAS) (DIAMONDBACK® Coronary OAS) for FY 2016. The DIAMONDBACK® Coronary OAS is a percutaneous orbital atherectomy system used to facilitate stent delivery in patients who have been diagnosed with coronary artery disease and severely calcified coronary artery lesions. The system uses an electrically driven, diamond-coated crown to reduce calcified lesions in coronary blood vessels. The components of the DIAMONDBACK® Coronary OAS are: (1) The DIAMONBACK 360® Coronary Orbital Atherectomy Device (OAD); (2) the VIPERWIRE Advance Coronary Guide Wire; (3) the VIPERSLIDE Lubricant; and (4) the Orbital Atherectomy System Pump. The DIAMONBACK 360® OAD is designed to track exclusively over the VIPERWIRE, which, in turn, uses the VIPERSLIDE Lubricant to reduce the friction between the drive shaft of the DIAMONBACK 360® OAD and the VIPERWIRE. The Orbital Atherectomy System Pump provides the saline pumping mechanism and power to the DIAMONBACK 360® OAD. All DIAMONDBACK® Coronary OAS devices are single use and provide sterile application, except for the pump.

With respect to the newness criterion, the DIAMONDBACK® Coronary OAS received FDA pre-market approval as a Class III device on October 21, 2013. As stated in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. We note that the applicant submitted a request for a unique ICD–10–PCS code that was presented at the March 18, 2015 ICD–10 Coordination and Maintenance Committee meeting. If approved, the code(s) will be effective on October 1, 2015 (FY 2016). More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

According to the applicant, the DIAMONDBACK® Coronary OAS is the only atherectomy device that uses centrifugal force and orbital motion and, therefore, is not represented by the rotational, directional, or laser atherectomy device categories (as exemplified by Boston Scientific's Rotablator system, the SilverHawk/Covidient devices, and the Spectranetics ELCA Coronary Laser, respectively). In addition, the applicant asserted that the DIAMONDBACK® Coronary OAS is the first and only device approved for use in the United States as a treatment for patients who have been diagnosed with severely calcified coronary artery lesions to facilitate stent delivery and optimal deployment. Therefore, the applicant believed that the

DIAMONDBACK® Coronary OAS meets the newness criterion.

We are concerned that, in addition to patients who have been diagnosed with severely calcified coronary artery lesions, the applicant also indicated that the DIAMONDBACK® Coronary OAS may be used in the treatment of patients who *do not* have severely calcified coronary artery lesions (for example, patients for whom the degree of calcification may not be severe) and that this technology may be substantially similar to the rotational, directional, and laser atherectomy devices that are already on the U.S. market for the treatment of such patients. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, the applicant maintained that the technology uses a differential sanding mechanism of action to remove plaque while potentially minimizing damage to the medial layer of the vessel. According to the applicant, this mechanism of action is the only one among atherectomy devices to use centrifugal force and orbital motion and, therefore, is not represented by the rotational, directional, or laser atherectomy device categories. We are concerned that the applicant did not include with their application data to show the effectiveness of the orbital mechanism of the DIAMONDBACK® Coronary OAS compared to the effectiveness of the rotational, directional, and laser mechanisms of similar devices used in treating patients with calcified coronary artery lesions. Therefore, we cannot determine if the device's mechanism of action is unique among atherectomy devices as the applicant claimed.

With respect to the second criterion, the applicant determined that coronary atherectomy cases for which the DIAMONDBACK® Coronary OAS technology would be appropriate are assigned to MS–DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); MS–DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); MS–DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); MS–DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC), and MS–DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC). We are concerned that potential cases involving the DIAMONDBACK® Coronary OAS would be assigned to the same MS–DRGs as other cases that use atherectomy devices currently available on the U.S. market.

With respect to the third criterion, the applicant maintained that the DIAMONDBACK® Coronary OAS is the first and only device approved for use in the United States as a treatment for severely calcified coronary lesions. According to the applicant, advances in current stent technology have allowed most patients with coronary lesions to be treated effectively with relatively favorable long-term outcomes. However, there remain subsets of the patient population that are still challenging to treat, including patients with severe coronary calcification. According to the applicant, the DIAMONDBACK® Coronary OAS is the only atherectomy device currently available to treat this patient population because it is the first and only device approved for use in the United States for severely calcified coronary lesions. However, we are concerned that other devices currently available on the U.S. market may not necessarily be contraindicated for use in treating patients with severe coronary calcification. Specifically, we are not sure if patients with less than severe coronary calcification could be appropriately treated using the DIAMONDBACK® Coronary OAS or other atherectomy devices currently available on the U.S. market in order to determine if the DIAMONDBACK® Coronary OAS treats a different patient population as the applicant claimed.

We are inviting public comments on if, and how, the DIAMONDBACK® Coronary OAS meets the newness criterion. In our subsequent discussion of the cost and substantial clinical improvement criteria, we limit our analysis of the new technology device to a patient population who has severely calcified coronary lesions for which the other devices are contraindicated for use.

With respect to the cost criterion, the applicant determined that cases representing patients who have been treated with transluminal coronary atherectomy for which the DIAMONDBACK® Coronary OAS technology is appropriate map to MS–DRGs 246 through 251 as noted earlier in this section. The applicant searched the claims data in the FY 2013 MedPAR file for cases assigned to these six MS–DRGs (which contained claims for inpatient hospital discharges from October 1, 2012 to September 30, 2013) and identified 5,443 claims for cases reporting ICD–9–CM procedure code 17.55. The applicant indicated that it further examined the claims data for the cases that also reported ICD–9–CM diagnosis code 414.4, and identified 250 claims for cases with a diagnosis of calcified coronary lesion. The applicant stated that it applied the standard trims used by CMS when selecting cases for IPPS rate calibration. Therefore, it included cases from IPPS hospitals, including hospitals located in Maryland, and excluded cases paid by Medicare Advantage plans, statistical outlier cases, and cases from hospitals that did not submit charges in a sufficiently broad range of revenue centers.

The applicant reported that it conducted 16 sensitivity analyses based on four areas of uncertainty: Whether to include all coronary atherectomy cases in the analysis or only those cases that reported calcified coronary artery lesions; whether to consider a lower value or higher value as the acquisition cost of a typical atherectomy catheter; whether to use the full cost of the DIAMONDBACK® Coronary OAS catheter and materials or only the cost of the catheter alone; and whether to include or exclude a factor to inflate costs to FY 2015 costs. Based on the result of the sensitivity analyses with all 16 combinations of the values that the applicant performed, the applicant reported that it determined that the average case-weighted standardized charge per case for the DIAMONDBACK® Coronary OAS would exceed the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 of the FY 2015 IPPS/LTCH PPS final rule. According to the applicant, the average case-weighted standardized charge per case using the DIAMONDBACK® Coronary OAS device exceeds the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 by between approximately $6,000 to $15,000, depending on the results determined by using the combination of

values of the four areas of uncertainty. As described below, the applicant believed that using the scenario that produced the lowest difference between the average case-weighted standardized charge per case determined by the applicant's analyses and the average case-weighted threshold amounts for MS–DRGs 246 through 251 from Table 10 in the FY 2015 IPPS/LTCH PPS final rule still exceeded the Table 10 threshold amounts by $5,803.

Using the scenario that produced the lowest difference between the average case-weighted standardized charge per case determined by the applicant and the average case-weighted threshold amount in the FY 2015 IPPS/LTCH PPS final rule Table 10, the applicant included all cases reporting coronary atherectomy (specifically, the 5,443 cases reported with ICD–9–CM procedure code 17.55) in this analysis. The applicant removed the costs of the other specific technologies used during these procedures; that is, the applicant removed the higher of the two standard catheter costs, and added the full cost of the DIAMONDBACK® Coronary OAS catheter alone. To estimate the cost for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) included in the FY 2015 IPPS/LTCH PPS final rule. This resulted in an average case-weighted average standardized charge per case of $86,080. The applicant stated that it did not apply an inflation factor to convert the FY 2013 costs to FY 2015 costs for this analysis. However, in other analyses, the applicant used the 2-year inflation factor of 10.44 percent taken from the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), which was the final inflation factor used in the CMS outlier threshold calculation for the applicable fiscal year. The applicant then determined that its average case-weighted standardized charge per case exceeded the average case-weighted threshold amounts for MS–DRGs 246 through 251 in Table 10 of the FY 2015 IPPS/LTCH PPS final rule by $5,803. The applicant maintained that all of the results of the analyses using this methodology that were included in its application likewise exceeded the Table 10 threshold amounts for these MS–DRGs and, therefore, demonstrated that the DIAMONDBACK® Coronary OAS meets the cost criterion.

Using the scenario that produced the lowest difference between its average case-weighted standardized charge per case and the average case-weighted threshold amounts for MS–DRGs 246 through 251 from the FY 2015 Table 10 for the analysis of the subgroup of cases representing patients who have severely calcified coronary artery lesions, the applicant reported that it included all of the cases that report coronary atherectomy that also reported diagnosis of calcified coronary lesions (250 cases reporting ICD–9–CM procedure code 414.4). As in the previous scenario, the applicant removed costs of the other specific technologies used during these other procedures; that is, the applicant removed the higher of the two standard catheter costs, and added the full cost of the DIAMONDBACK® Coronary OAS catheter alone. To estimate the costs for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) in the FY 2015 IPPS/LTCH PPS final rule. This resulted in an average case-weighted standardized charge per case of $86,779. The applicant did not apply an inflation factor to convert the FY 2013 costs to FY 2015 costs for this analysis. The applicant then determined that the average case-weighted standardized charge per case exceeded the FY 2015 Table 10 threshold amount of $80,807 by $5,972. The applicant maintained that all of the results of the analyses using this methodology that were included in its application likewise exceeded the Table 10 threshold amounts for these MS–DRGs and, therefore, demonstrated that the DIAMONDBACK® Coronary OAS meets the cost criterion.

We question some of the assumptions underlying the four areas of uncertainty that were the basis for the applicant's sensitivity analyses. We would like to know the basis of the higher value that the applicant considered to be a possible acquisition cost of a typical atherectomy catheter. We also are concerned that the applicant did not provide a basis for determining the two values it used to remove the costs associated with the other specific technologies that may have been used during the cases included in the analysis. We are inviting public comments on if, and how, the DIAMONDBACK® Coronary OAS meets the cost criterion.

The applicant maintained that the DIAMONDBACK® Coronary OAS offers a treatment option for a patient population that has been diagnosed with severely calcified coronary arteries that are ineligible for currently available treatments and results in improved clinical outcomes for patients who have been diagnosed with complex coronary artery disease related to severely calcified coronary arteries. The applicant also stated that the DIAMONDBACK® Coronary OAS device significantly improves clinical outcomes for this patient population when compared to currently available treatment options, including reduced mortality, a reduced rate of device-related complications, a decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process), a decreased number of future hospitalizations or physician visits, more rapid beneficial resolution of the disease process treatment because of the use of the device, decreased pain, bleeding, or other quantifiable symptoms, and reduced recovery time.

The applicant included data from its ORBIT II study to demonstrate that the technology represents substantial clinical improvement over currently available treatment options, including improvement in mortality rates, major adverse cardiac event (MACE) rates, revascularization rates, and cost savings. According to the applicant, its ORBIT II study was a pivotal clinical study to evaluate the safety and effectiveness of the DIAMONDBACK® Coronary OAS in treating a subset of patients who have severely calcified coronary artery lesions. The applicant explained that the ORBIT II study was a prospective, multicenter, non-blinded clinical trial that enrolled 443 consecutive patients who have been diagnosed with severely calcified coronary lesions at 49 U.S. sites from May 25, 2010 to November 26, 2012, in which the DIAMONDBACK® Coronary OAS was used to prepare patients who had severely calcified coronary lesions for stent placement. According to the applicant, the DIAMONDBACK® Coronary OAS produced clinical outcomes that exceeded its ORBIT II study's two primary safety and efficacy endpoints within a patient population. The primary safety endpoint was 89.6 percent freedom from 30-day MACE, compared with the performance goal of 83 percent. The primary efficacy endpoint (residual stenosis <50 percent post-stent without in-hospital MACE) was 88.9 percent, compared with the performance goal of 82 percent. The applicant stated that, during the trial, stent delivery after use of the DIAMONDBACK® Coronary OAS occurred successfully in 97.7 percent of cases with <50 percent residual stenosis in 98.6 percent of the patients in the study. The applicant further stated that low rates of in-hospital Q-wave MI, cardiac death, and target vessel revascularization also were reported. The applicant believed that the results of its ORBIT II study met both the primary safety and efficacy endpoints by significant margins and not only

helped to facilitate stent delivery, but also improved both acute care and 30-day clinical outcomes compared to historical controls.

The applicant also compared the results of its ORBIT II study with historical study data that measured the performance of other coronary atherectomy devices used in the treatment of patients who have moderate to severely calcified coronary lesions. According to the applicant, the death and revascularization rates reported in the ORBIT II study were much lower than those rates reported in the literature for patients who had severely calcified coronary lesions. For example, inpatient cardiac death rates were reported on one reported study in the literature (Mosseri, et al.) as 1.6 percent and in another reported study (Abdel-Wahab, et al.) as 1.7 percent, while another study report (Clavijo, et al.) reported death at 30 days as 2.6 percent and 1.5 percent for RA + DES and DES, respectively. [18] [19] [20] The applicant maintained that, compared to these historical study data, the data results of the ORBIT II study demonstrated much lower cardiac death rates of 0.2 percent in-hospital and 0.2 percent at 30 days. The applicant further reported that the results of its ORBIT II study showed lower mortality rates at 9 months and 1 year (3 percent and 4.4 percent, respectively) compared to previously reported rates (5.0 percent and 5.85 percent at 9 months and 6.3 percent at 1 year). The study report by Mosseri, et al. also reported a 1.6 percent in-hospital target lesion revascularization rate (TLR) in a patient population with more superficial calcification,[21] whereas the study report by Clavijo, et al. reported a 1.3 percent 30-day TLR rate for the RA + DES group.[22] In contrast, the applicant reported that the results of the ORBIT II study showed a lower TLR rate of 0.7 percent (both in-hospital and 30-day), even though more patients who had severely calcified coronary lesions were included in the study, and the patients were older and had more comorbidities. The applicant stated that, at 1-year, the results of the ORBIT II study showed a higher freedom from TVR/TLR rate (94.1 percent) compared to previously reported rates (81.7 percent to 91.3 percent), even though patients who had more severely calcified coronary lesions were included in the ORBIT II study. According to the applicant, the MACE rate of 16.4 percent indicated in the results of the ORBIT II study was lower than the rate of the ROTAXUS (24.4 percent) and ACUITY/HORIZONS (19.9 percent) trials despite the use of a less stringent standard of severe calcification in the latter studies.[23] [24] Further, the applicant reported that patients in the ORBIT II study experienced a lower rate of device-related complications (such as dissection, abrupt closure, and perforation) compared to rates in the historical studies. Overall, the applicant asserted that a comparison of data from the ORBIT II study and the data from historical studies demonstrates that patients in the ORBIT II study had more severe calcium coronary lesions and potentially were more difficult to treat, although they experienced better outcomes.

We are concerned that the ORBIT II study conducted by the applicant lacked a control arm. The applicant asserted that although other FDA-approved coronary atherectomy products are available, none of them are indicated for the treatment of patients who have severely calcified coronary arteries and, therefore, could not be used as a control. The applicant believed that it accounted for this study limitation by comparing the results of the ORBIT II study to historical control subjects documented in published reports. However, we continue to be concerned that meaningful conclusions cannot be drawn from a study that did not include a comparator group. Moreover, we question the reliability of comparing data from the ORBIT II study to historical study data because different definitions of severe calcification used in each study can make absolute comparisons difficult and/or invalid. We are inviting public comments on if, and how, DIAMONDBACK® Coronary OAS meets the substantial clinical improvement criterion.

e. CRESEMBA® (Isavuconazonium)

Astellas Pharma US, Inc. (Astellas) submitted an application for new technology add-on payments for CRESEMBA® (isavuconazonium) for FY 2016. CRESEMBA® is an intravenous and oral broad-spectrum antifungal used for the treatment of adults who have severe invasive and life-threatening fungal infections, including invasive aspergillosis and mucormycosis (zygomycosis).

CRESEMBA® received FDA approval on March 6, 2015 and anticipates that the market availability on the U.S. market will start by the second week of April 2015. The FDA indication for the use of this product is for the treatment of adults who have been diagnosed with invasive aspergillosis and mucormycosis. Isavuconazonium has two formulations: An intravenous (IV) solution and an oral capsule. The IV formulation of isavuconazonium is administered at 200 mg of isavuconazole. The oral formulation of isavuconazonium is administered at 100 mg of isavuconazole. Dosing is not weight-based. According to the applicant, treatment of patients who have been diagnosed with these types of infection starts with up to 3 days of IV therapy in the inpatient hospital setting followed by daily oral therapy administered for the remainder of the inpatient stay and also the duration of treatment period, which is 13.4 days.

As stated in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. We note that the applicant submitted a request for unique ICD–10–PCS codes that was presented at the March 18, 2015 ICD–10 Coordination and Maintenance Committee meeting. If approved, the codes will be effective on October 1, 2015 (FY 2016). More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

[18] Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revascularization Med Mol Interv. 2005;6(4):147–153.*

[19] Abdel-Wahab M, Richardt G, Joachim Buttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. *JACC Cardiovasc Interv.* 2013;6(1):10–19.

[20] Clavijo LC, Steinberg DH, Torguson R, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv.* 2006;68(6):873–878.

[21] Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revascularization Med Mol Interv. 2005;6(4):*147–153.

[22] Clavijo LC, Steinberg DH, Torguson R, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv.* 2006;68(6):873–878.

[23] Genereux P, Madhavan MV, Mintz GS, et al. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes. Pooled analysis from the HORIZONS–AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) TRIALS. *J Am Coll Cardiol.* 2014;63(18):1845–1854.

[24] Abdel-Wahab M, Richardt G, Joachim Buttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. *JACC Cardiovasc Interv.* 2013;6(1):10–19.

If the technology were to be approved for a new technology add-on payment, we believe its newness period would begin on March 6, 2015, the date of FDA approval. At this time, the applicant has not submitted any specific information to establish that the technology was not available on the U.S. market as of the FDA approval date or to describe the reasons for a delay of availability until the second week of April 2015. The applicant maintained that CRESEMBA® meets the newness criterion.

CRESEMBA® is part of the category of drugs known as azole antifungal drugs that inhibit the enzyme lanosterol 14 α-demethylase. Inhibiting this enzyme disrupts the process of converting lanosterol to ergosterol and, therefore, depletes the level of ergosterol in the fungal membrane and inhibits fungal growth. Azole antifungal drugs are used to treat patients with fungal infections such as aspergillosis, and other azole antifungal drugs also used for the treatment of these patients include voriconazole, posaconazole, and itroconazole. The CDC Web site at *http://www.cdc.gov/fungal/diseases/aspergillosis/treatment.html* states that voriconazole is used for the treatment of patients with invasive aspergillosis, but Amphotericin B (Amp B) as well as other antifungal drugs can be used if patients cannot take voriconazole or the infection is not responsive to voriconazole. Amphotericin B is the first-line of therapy and the only FDA-approved treatment of patients diagnosed with mucormycosis. Amphotericin B binds with ergosterol, a component of fungal cell membranes, and forms a transmembrane channel that leads to membrane leakage, which is the primary effect leading to fungal cell death. The third class of antifungal drugs is echinocandins; examples in this group are caspofungin, micafungin, and anidulafungin. Echinocandins noncompetitively inhibit beta-1, 3-D-glucan synthase enzyme complex in susceptible fungi to disturb fungal cell glucan synthesis. Beta-glucan destruction prevents resistance against osmotic forces, which leads to cell lysis (*http://www.cdc.gov*).

According to the applicant, echinocandins are effective against aspergillosis. Voriconazole is the recommended treatment for patients diagnosed with invasive aspergillosis. However, amphotericin B and other antifungal drugs may also be used if voriconazole cannot be administered because a patient is suffering from porphyria (a rare inherited blood disorder) or has had an allergic reaction to the drug or the infection is not responding to treatment using voriconazole. In addition, according to the applicant, the efficacy of azole antifungal drugs such as posaconazole, in treating mucurmycosis is uncertain but has been described in certain situations.

The applicant stated that it is sometimes challenging to clinically distinguish the type of antifungal infection a patient may be experiencing. Therefore, the typical treatment of patients exhibiting symptoms of infection includes both amphotericin B and voriconazole. According to the applicant, for the Medicare population, both drugs are usually administered in combination because it is difficult and time-consuming to delineate the specific type of fungal infections. The applicant noted that these patients are often severely ill and immediate treatment of these symptoms is essential to the effective management of their condition.

We are concerned that CRESEMBA® may be substantially similar to other currently approved antifungal drugs. We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814) for a discussion of our established criteria for evaluating whether a new technology is substantial similar to an existing technology. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

In evaluating this technology for substantial similarity, we believe that CRESEMBA® has a similar mechanism of action as the other groups of antifungal drugs available for the treatment of patients with serious fungal infections, such as invasive aspergillosis and mucormycosis. As previously noted, voraconazole and itroconazole also are commonly used azole antifungals used to treat patients diagnosed with aspergillosis, and amphotericin B is a polyene antifungal commonly used to treat patients diagnosed with mucormycosis. The applicant maintained that the availability of the drug in an oral formulation constitutes a different mechanism of action. We disagree with the applicant's assertion because we believe a different method of administration does not necessarily equate to a different mechanism of action. Although the applicant maintained that this technology is not substantially similar because it is administered orally, the applicant did not describe why it believed a different method of administration constitutes a different mechanism of action. Because CRESEMBA® is part of the category of drugs currently available known as azole antifungal drugs that inhibit the enzyme lanosterol 14 *a*-demethylase, it appears that the mechanism of action is not different, but that merely the method of administration differs.

With respect to the second criterion for determining substantial similarity, we believe that the use of CRESEMBA® is inclusive of the current treatment options available to Medicare beneficiaries and is also currently described (although not specifically) by established procedure codes that identify similar technologies, specifically other antifungal drugs that also are used in the treatment of patients diagnosed with similar fungal infections. The use of antifungal drugs is considered a nonoperating room procedure which does not impact the MS–DRG assignment of a patient case. Therefore, the use of CRESEMBA® would not impact the MS–DRG assignment of a particular case. Furthermore, the technology is indicated for use in the treatment of the same or similar type of disease and the same or similar patient population. According to the applicant, CRESEMBA® is used in conjugation with other treatments, and this is reflected in its analysis for the new technology cost criterion. We are concerned that this technology is administered with the other currently available treatments, and therefore cannot be considered an alternative treatment option. Therefore, we believe that CRESEMBA® may be considered substantially similar to other available treatments and cannot be considered ''new'' for purposes of new technology add-on payments. We are inviting public comments on if, and how, CRESEMBA® meets the newness criterion and our concerns regarding how it is substantially similar to other treatments for serious fungal infections.

To demonstrate that the technology meets the cost criterion, the applicant performed two analyses. The applicant searched claims in the FY 2013 MedPAR file (across all MS–DRGs) for any case reporting a principal or secondary diagnosis of aspergillosis (ICD–9–CM diagnosis code 117.3), zygomycosis [phycomycosis or mucormycosis] (ICD–9–CM diagnosis code 117.7), or pneumonia in aspergillosis (ICD–9–CM diagnosis code 484.6). The applicant excluded any case that was treated at a hospital that is not paid under the IPPS, as well as any case where Medicare fee-for-service was not the primary payer. The applicant calculated the standardized charge for each eligible case and then inflated the standardized charge by 10.4427 percent

using the same inflation factor used by CMS to update the FY 2015 outlier threshold (79 FR 50379). The applicant assumed that the average length of stay for all eligible cases was 13.4 days based on its analysis. To determine the charges for the drug, the applicant assumed 13.4 days of therapy. According to the applicant, dosages of isavuconazole for a patient vary based on the day of therapy, but do not vary based on the patient's weight. For the first and second day of therapy, the patient would be administered a loading dose of 200 milligrams (mg) every 8 hours. For each subsequent day of therapy, the patient would be administered a maintenance dose of 200 mg per day.

For the first analysis, which was based on 100 percent of all MS–DRGs, the applicant identified a total of 5,984 cases with at least one of the three ICD–9–CM codes (aspergillosis (ICD–9–CM diagnosis code 117.3), zygomycosis [phycomycosis or mucormycosis] (ICD–9–CM diagnosis code 117.7), or pneumonia in aspergillosis (ICD–9–CM diagnosis code 484.6)) across a total of 333 MS–DRGs. The applicant's rationale for using all the MS–DRGs was that it believed any patient diagnosed with either invasive aspergillosis or invasive mucormycosis (zygomycosis) could be eligible for treatment using isavuconazonium, regardless of the MS-DRG assignment. The applicant identified the average case-weighted threshold amounts for these 333 MS–DRGs as $72,186 using Table 10 from the FY 2015 IPPS/LTCH PPS final rule. The applicant did not remove charges for the other specific technologies from the average case-weighted standardized charge per case. The applicant's rationale for not removing these charges was that the patients would be administrated isavuconazonium in combination with the other currently approved antifungal drugs as an effective treatment plan. The applicant computed a final inflated average case-weighted standardized charge per case of $151,450. Because this average case-weighted standardized charge per case exceeded the average case-weighted threshold amount from the FY 2015 Table 10, the applicant maintained that CRESEMBA® meets the cost criterion using this first analysis.

For its second analysis, the applicant analyzed 39 MS–DRGs that accounted for the top 75 cases of patients eligible for treatment using isavuconazonium; this was a subset of 4,510 cases. Using a methodology similar to the one used in its first analysis, the applicant computed the final inflated average case-weighted standardized charge per case of $159,622. The applicant identified an average case-weighted threshold amount for the 39 MS–DRGs of $74,366 using Table 10 from the FY2015 IPPS/LTCH PPS final rule. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in the FY 2015 Table 10, the applicant maintained that CRESEMBA® meets the cost criterion using this second analysis.

We are concerned that the applicant did not remove any charges for the other antifungal drugs used during treatments (that is, the other component of the combination) because the applicant maintained that it would most likely be necessary for patients who are treated using CRESEMBA® to also continue treatment using the other antifungal drugs or medications in order to achieve successful treatment due to the severity of their symptoms. We believe that the applicant should have removed the charges for the other antifungal drugs used for treatments. We also note that the applicant did not provide information to substantiate its assertion that the charges for these cases would not be reduced because of the severity of illness among the patients. The applicant inferred that patients treated using CRESEMBA® would be dependent upon the simultaneous and combined use of the other existing therapies to achieve successful treatment. Therefore, we are concerned about the possibility of drug toxicity, poly pharmacy, and drug-to-drug interactions, especially among the Medicare population.

We are seeking public comment on whether CRESEMBA® meets the cost criterion, specifically with regard to our concerns regarding the applicant's analyses and methodology.

With regard to substantial clinical improvement, the applicant believed that CRESEMBA® represents a substantial clinical improvement over existing therapies for patients diagnosed with invasive aspergillus and mucormycosis based on its potentially improved efficacy profile, potentially improved safety profile, more favorable pharmacokinetic profile, and improved method of administration. The applicant discussed the unmet medical need for alternative treatment options for patients diagnosed with invasive aspergillosis and mucormycosis. Current treatments have limitations related to safety, side effects, and efficacy.[25] [26] The applicant provided information regarding its SECURE study, where the primary endpoint of all-cause mortality through day 42 showed that CRESEMBA® demonstrated noninferiority to voriconazole. The primary endpoint of all-cause mortality through day 42 in the intent-to-treat population (ITT, N = 516) was 18.6 percent in the isavuconazonium treatment group and 20.2 percent in the voriconazole group. However, according to the applicant, the overall safety profile for CRESEMBA® demonstrated similar rates of mortality and nonfatal adverse events as the comparator, voriconazole. The applicant also shared information from other clinical trials. One of these clinical trials that studied the treatment of patients diagnosed with invasive aspergillosis showed treatment-emergent adverse reactions occurred in 96 percent and 99 percent of patients receiving the CRESEMBA® and voriconazole, respectively. We are concerned that the adverse reactions associated with the use of CRESEMBA® and voriconazole appear to be similar. We also are concerned that the applicant did not conduct the clinical trials evaluating head-to-head comparisons to alternative therapies such as amphotericin B. Currently, amphotericin B is the only FDA-approved drug for the treatment of mucormycosis, which also can be used to treat aspergillosis. The applicant's description of the technology was based on peer reviewed literature, which may be considered historical data.

With regard to improved efficacy, the applicant made several assertions. The applicant maintained that the use of CRESEMBA® can potentially decrease the rate of subsequent diagnostic or therapeutic interventions. According to the applicant, the technology lacks the adverse side effects of nephrotoxicity associated with amphotericin B.[27] However, we are concerned that the results of the study reported by the applicant did not reflect this.

Specifically, the applicant believed that CRESEMBA® has positive activity against a broad range of fungi, including those resistant to other agents, thereby potentially decreasing subsequent therapeutic interventions.[28] However,

[25] Lin SJ, Schranz J, Teutsch SM.: Aspergillosis case-fatality rate: systematic review of the literature. ClinInfect Dis. 2001;32:358-66.

[26] Greenberg RN, Scott LJ, Vaughn HH, Ribes JA.: Zygomycosis (mucormycosis): emerging clinical importance and new treatments. Curr Opin Infect Dis. 2004;17:517-25.

[27] Walsh TJ, Anaissie EJ, Denning DW, Herbrecht R, Kontoyiannis DP, Marr KA, et al.: Treatment of aspergillosis: clinical practice guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2008;46:327-60.

[28] González GM.: Med Mycol. 2009 Feb;47(1):71–6. doi:10.1080/13693780802562969. Epub 2008 Dec

Continued

the applicant stated that the referenced literature indicates that further in-vivo studies are required in order to confirm the efficacy for treatment of severe infections caused by these fungi in immunocompromised patients. According to the applicant, CRESEMBA® is used to treat immunocomprised patients who are severely ill. The applicant also stated that CRESEMBA® can be used to treat patients diagnosed with invasive fungal infections before the pathogen has been identified, thereby potentially decreasing subsequent diagnostic and therapeutic interventions.[29] The applicant maintained that the use of CRESEMBA® decreases the number of future hospitalizations or physician visits. We are concerned that the applicant did not provide data to support this determination. One of the applicant's studies, SECURE, which was a global, Phase 3, multicenter, randomized, double-blind, parallel group, noninferiority trial that evaluated isavuconazole versus voriconazole for the primary treatment of patients with invasive fungal disease (IFDs) caused by aspergillus spp. and other filamentous fungi was discussed by the applicant in its application. The results of the study were presented in a paper stating that the length of stay for patients hospitalized with renal impairment was statistically significantly shorter in the treatment of patients in the isavuconazole arm (9 days) compared with patients treated with voriconazole in the control arm. According to the applicant, patients treated with isavuconazonale showed shorter hospital length of stay compared to those treated with voriconazole in the overall study population. Subgroup analyses of patients who were aged 65 years and older and patients with a BMI equal to or greater than 30 kg/m2 also had shorter, but not statistically significant, differences in length of stay when treated with isavuconazonale compared to voriconazole. The paper on the study revealed concerns about the small sample size in the subgroup (n = 516) and that the differences were not statistically significant.[30]

With regard to improved safety and a more favorable pharmacokinetic profile, the applicant made several assertions. The applicant asserted that CRESEMBA® has the potential for simpler and more predictable dosing based on improved pharmacokinetics compared with other azole antifungal drugs, but the applicant did not provide data to substantiate this assertion. In addition, the applicant asserted that CRESEMBA® has a lower drug-drug interaction potential than voriconazole or itraconazole, but did not provide data to substantiate this assertion. Furthermore, the applicant maintained that CRESEMBA® can be safely used in treating patients with renal impairment, whereas currently available treatments can harm the kidneys.[31] In the paper accompanying the application, the applicant discussed aspergillosis and the various treatment options available and the advantages of voriconazole over deoxycholate amphotericin B (D–AMB) as primary treatment for patients with invasive aspergillosis. We are concerned that these results were not communicated in the resulting data provided by the applicant that were obtained from the trials. We also are concerned that the applicant did not provide a rationale for its assertion that the use of CRESEMBA® represents a substantial clinical improvement for Medicare beneficiaries because of ''simpler and more predictable dosing'' nor did the applicant provide additional information and data regarding drug-to-drug interactions and nephrotoxicity.

In addition, the applicant maintained that the technology has an improved method of administration compared to current treatment alternatives. Specifically, the applicant asserted that the availability of this technology as an oral formulation is an improvement compared to other existing treatments, which are solely administered intravenously. We are concerned about the applicant's assertion because other currently approved and available antifungal drugs, such as voriconazole (tablets, oral suspension, or intravenous administration), itraconazole (capsules, oral solution, or parenteral solution), and posaconazole (oral suspension or parenteral solution), also can be administered orally as well as parenteral for patients diagnosed with these types of fungal infections. In addition, we are aware that intravenous administration of antifungal drugs may be necessary because patients diagnosed with invasive aspergillosis and mucuromycosis and treated as inpatients are often severely ill and may not be able to tolerate any food or medications orally. We are seeking public comments on whether or not CRESEMBA® meets the substantial clinical improvement criterion, specifically taking into consideration our concerns described above.

We did not receive any written public comments in response to the New Technology Town Hall Meeting regarding the application for CRESEMBA® for new technology add-on payments.

f. Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for Idarucizumab, a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. Dabigatran is an oral direct thrombin inhibitor currently indicated to: (1) Reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) treat deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; and (3) reduce the risk of recurrence of DVT and PE in patients who have been previously diagnosed with NVAF. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode.

Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations. If FDA approval is granted, Idarucizumab would be the only FDA-approved therapy available to neutralize the anticoagulant effect of Dabigatran. The current approach for the management of the anticoagulant effect of Dabigatran prior to an invasive procedure is to withhold administration of Dabigatran, when possible, for a certain duration of time prior to the procedure to allow sufficient time for the patient's kidneys to flush out the medication. The duration of time needed to flush out the medication prior to the surgical procedure is based on the patient's kidney function. According to the applicant, if surgery cannot be

18. PMID: 19101837 [PubMed—indexed for MEDLINE]

[29] Kontoyiannis DP, Lewis RE.: How I treat mucormycosis. Blood. 2011;118:1216-24.

[30] Khandelwal N, Franks B, Shi F, Spalding J, Azie N. Health Economic Outcome Analysis of Patients Randomized in the SECURE Phase 3 Trial Comparing Isavuconazole to Voriconazole for Primary Treatment of Invasive fungal Disease Caused by Aspsergillus Species or Other Filamentous Fungi.

[31] Walsh TJ, Anaissie EJ, Denning DW, Herbrecht R, Kontoyiannis DP, Marr KA, et al. Treatment of aspergillosis: Clinical practice guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2008;46:327-60.

delayed to allow the kidneys the necessary time to flush out the traces of Dabigatran, there is an increased risk of bleeding.

Based on the proposed FDA indication for Idarucuzimab, the product can be used in the treatment of patients who have been diagnosed with NVAF and administered Dabigatran to reverse life-threatening bleeding events, or who require emergency surgery or medical procedures and rapid reversal of the anticoagulant effects of Dabigatran is necessary and desired. As of this date, Idarucuzimab has not received approval from the FDA. However, in June 2014, the FDA granted Idarucizumab Breakthrough Therapy Designation. In addition, the applicant plans to seek Fast Track Designation from the FDA. Currently, there are no specific ICD–9–CM or ICD–10–PCS procedure codes that describe the use of Idarucizumab. As stated above, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. The applicant submitted a request for unique ICD–10–PCS codes that was presented at the March 18, 2015 ICD–10 Coordination and Maintenance Committee meeting. If approved, the codes will be effective on October 1, 2015 (FY 2016). More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.* We are inviting public comments on whether Idarucizumab meets the newness criterion.

With regard to the cost criterion, the applicant conducted four analyses. The applicant began by researching the FY 2013 MedPAR file for cases that may be eligible for Idarucizumab using a combination of ICD–9–CM diagnosis and procedure codes. Specifically, the applicant searched the database for cases reporting anticoagulant therapy diagnosis codes E934.2 (Agents primarily affecting blood constituents, anticoagulants) or V58.61 (Long-term (current) use of anticoagulants) in combination with either current standard of care procedure codes 99.03 (Other transfusion of whole blood), 99.04 (Transfusion of packed cells), 99.05 (Transfusion of platelets), 99.06 (Transfusion of coagulation factors), 99.07 (Transfusion of other serum), or 39.95 (Hemodialysis), and Dabigatran indication diagnosis codes 427.31 (Atrial fibrillation), 453.40 (Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.41 (Acute venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.42 (Acute venous embolism and thrombosis of deep vessels of distal lower extremity), 453.50 (Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.51 (Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.52 (Chronic venous embolism and thrombosis of deep vessels of distal lower extremity), 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), 415.19 (Other pulmonary embolism and infarction), 416.2 (Chronic pulmonary embolism), V12.51 (Personal history of venous thrombosis and embolism), or V12.55 (Personal history of pulmonary embolism).

To further target potential cases that may be eligible for Idarucizumab, the applicant also excluded specific cases based on Dabigatran contraindications, including all cases representing patients who have been diagnosed with chronic kidney disease (CKD) stage V (diagnosis code 585.5), end-stage renal disease (diagnosis code 585.6), prosthetic heart valves (diagnosis code V43.3), and cases representing patients who have been diagnosed with both CKD stage IV (diagnosis code 585.4) and either DVT or PE (using the same ICD–9–CM diagnosis codes listed above). As a result, the applicant identified 103,752 cases that mapped to 694 MS–DRGs. The applicant standardized the charges and computed an average case-weighted standardized charge per case of $57,611.

The applicant then identified hospital charges potentially associated with the current treatments to reverse anticoagulation, specifically charges associated with pharmacy services, dialysis services, and laboratory services for blood work. Due to limitations associated with the claims data, the applicant was unable to determine the specific drugs used to reverse anticoagulation and if these cases represented patients who required laboratory services for blood work or dialysis services unrelated to the reversal of anticoagulation. Therefore, the applicant subtracted 40 percent of the charges related to these three categories from the standardized charge per case, based on the estimation that the full amount of charges associated with these services would not be incurred by hospitals if Idarucizumab is approved and available for use in the treatment of patients who have been diagnosed with NVAF and administered Dabigatran during treatment. The applicant then inflated the standardized charge per case by 10.4227 percent, the same inflation factor used by CMS to update the FY 2015 outlier threshold (79 FR 50379). This resulted in an inflated average case-weighted standardized charge per case of $59,582. Using the FY 2015 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 694 MS–DRGs is $54,850 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion under this analysis.

The applicant also performed a similar analysis by using the same data from the FY 2013 MedPAR file and subtracting 60 percent of the charges associated with pharmacy services, dialysis services, and laboratory services for blood work. This resulted in an inflated average case-weighted standardized charge per case of $57,560. Using the FY 2015 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 694 MS–DRGs is $54,850 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case for the applicable MS–DRGs exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under this analysis.

Further, the applicant conducted two additional analyses using the same data from the FY 2013 MedPAR file and variables used in the previous analyses. However, instead of using potentially eligible cases that mapped to 100 percent of the 694 MS–DRGs identified, the applicant used potentially eligible cases that mapped to the top 75 percent of the 694 MS–DRGs identified. By applying this limitation, the applicant identified 77,667 cases that mapped to 92 MS–DRGs. Under the analysis' variable that subtracted 40 percent of the charges associated with the current treatments to reverse anticoagulation, the applicant computed an inflated average case-weighted standardized charge per case of $56,627. Under the analysis' variable that subtracted 60 percent of the charges associated with the current treatments to reverse anticoagulation, the applicant computed an inflated average case-weighted standardized charge per case of $54,677. Using the FY 2015 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 92 MS–DRGs using both scenarios is $53,008 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted

standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under these variant analyses.

The applicant noted that the inflated average case-weighted standardized charge per case computed using all four scenarios did not include any charges for Idarucizumab. Therefore, the applicant maintained that the technology would also meet the cost criterion if charges for Idarucizumab were included because the inflated average case-weighted standardized charge per case would increase and further exceed the average case-weighted threshold amount using the variables of all four analyses. We are inviting public comments regarding the applicant's analyses with respect to the cost criterion.

With regard to substantial clinical improvement, according to the applicant, there are currently no specific FDA-approved antidotes to reverse the anticoagulant effects of Dabigatran. Management of the treatment of patients who have been diagnosed with NVAF and administered Dabigatran and experience bleeding may often include supportive care such as Hemodialysis and the use of fresh frozen plasma, blood factor products such as prothrombin complex concentrates (PCC), activated prothrombin complex concentrates, and recombinant factor VIIa or delayed intervention. Protamine sulfate and Vitamin K are typically used to reverse the effects of Heparin and Warfarin, respectively. However, due to the mechanism of action in Dabigatran, the applicant maintained that the use of protamine sulfate and Vitamin K may not be effective to reverse the anticoagulant effect of Dabigatran.

The applicant provided information regarding the management of major bleeding events experienced by patients who were administered Dabigatran and Warfarin during the RE-LY trial.[32] During this study, most major bleeding events were only managed by supportive care. Patients who were administered 150 mg of Dabigatran were transfused with pack red blood cells more often when compared to patients who were administered Warfarin (61.4 percent versus 49.9 percent, respectively). However, patients who were administered Warfarin were transfused with plasma more often when compared to patients who were administered 150 mg of Dabigatran (30.2 percent versus 21.6 percent, respectively). In addition, the use of Vitamin K in the treatment of patients who were administered Warfarin was more frequent when compared to the frequency of use in the treatment of patients who were administered 150 mg of Dabigatran (27.3 percent versus 10.3 percent, respectively). The use of PCCs, recombinant factor VIIa and other coagulation factor replacements in the treatment of patients who were administered both Warfarin and 150 mg of Dabigatran was minimal, and did not significantly differ in frequency when compared among patients assigned to either group. Hemodialysis was used in a single case.

The applicant reported that, currently, it is recommended that the administration of Dabigatran be discontinued 1 to 2 days (CrCl ≥50 ml/min) or 3 to 5 days (CrCl <50 ml/min), if possible, before invasive or surgical procedures because of the increased risk of bleeding.[33] A longer period of discontinuation time should be considered for patients undergoing major surgery, spinal puncture, or placement of a spinal or epidural catheter or port, if complete hemostasis is required. The applicant stated that delaying emergency medical or surgical procedures can cause urgent conditions to become more severe if intervention is not initiated. The applicant further maintained that delaying emergency medical or surgical procedures for an extended period of time can ultimately lead to negative healthcare outcomes and increased healthcare costs. The applicant asserted that rapidly reversing the anticoagulant effect of Dabigatran administered to patients that require an urgent medical procedure or surgery allows the medical procedure or surgery to be performed in a timely manner, which in turn may decrease complications and minimize the need for more costly therapies.

The applicant noted that Idarucizumab was shown to neutralize the anticoagulant effect of Dabigatran in both animal models and healthy human volunteers.[34] In a swine blunt liver trauma injury model, the applicant stated that Idarucizumab effectively reversed life-threatening bleeding episodes resulting from trauma in pigs. The applicant also provided data from a randomized, double-blind, placebo-controlled phase I study of healthy male volunteers to investigate the safety, tolerability, and pharmacokinetics of administering single rising doses of Idarucizumab (Part 1) and explore the variant of dosages of Idarucizumab administered to patients that effectively reversed the anticoagulant effect of Dabigatran (Part 2). Safety data is limited in humans to 110 healthy male patients enrolled in the study that were administered dosages of Idarucizumab that ranged from 20 mg to 8 grams. In this study, 135 patients received placebo. The applicant reported that adverse events were generally mild in intensity and non-specific. Healthy human volunteers enrolled in the phase I study (1321.1) were administered Idarucizumab in dosages of 2 and 4 grams, which resulted in immediate and complete reversal of the anticoagulant effect of Dabigatran that was sustained for several hours. The applicant noted that in preclinical studies, the reversal of the anticoagulant effects of Dabigatran was associated with the reversal of bleeding. These effects were consistent in animal models of renal dysfunction, hypovolemia and shock, and trauma related bleeding. The applicant concluded that the data from these studies demonstrates that Idarucizumab effectively, safely, and potently reverses the anticoagulant effect of Dabigatran in both animal models and healthy human volunteers.

With regard to the substantial clinical improvement criterion, we believe that Idarucizumab, if approved by the FDA, may represent a treatment option that is not currently available to Medicare beneficiaries and, therefore, represents a substantial clinical improvement. However, we are concerned that the clinical data are not sufficient. Specifically, the applicant provided data from an animal model. In addition, the primary clinical data in relation to human volunteers are based primarily on a trial to measure safety. While the applicant did provide clinical data on the effectiveness of Idarucizumab, we are concerned that the evidence presented does not support the substantial clinical improvement criterion. Specifically, the applicant provided data from a small sample used to demonstrate effectiveness. Usually during clinical studies, phase III of a clinical trial is typically used to gather data from a larger patient population to demonstrate effectiveness. We are inviting public comments on whether or not Idarucizumab meets the substantial

[32] Healy, et al.: Periprocedural bleeding and thromboembolic events with dabigatran compared with warfarin: results from the randomized evaluation of long-term anticoagulation therapy (RE-LY) randomized trial, Circulation, 2012; 126:343–348.

[33] Pradaxa® (Dabigatran Etexilate Mesylate) prescribing information. Ridgefield, CT: Boehringer Ingelheim; 2014.

[34] Honickel, et al.: Reversal of dabigatran anticoagulation *ex vivo:* Porcine study comparing prothrombin complex concentrates and idarucizumab, Thrombosis and Hemostasis, International Journal for Vascular Biology and Medicine, Vol. 113, April 2015.

clinical improvement criterion, specifically in regard to these concerns.

g. LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY 2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.[35] Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).[36]

The applicants for LUTONIX® and IN.PACT™ Admiral™ stated that, in patients diagnosed with PAD, the femoropopliteal artery is characterized by difficult to treat lesions that can be long and diffuse, in a vessel that is considered the most mechanically stressed artery with a number of dynamic forces that impact the artery including shortening/elongation, torsion, compression and flexion. According to the applicants, the unique challenges of treating the femoropopliteal artery in patients diagnosed with PAD relate to insufficient outcomes from current endovascular therapies, in particular PTA and stent implantations. Coating of femoral and coronary stents with an antiproliferative drug, such as paclitaxel, sirolimus, everolimus, or zotarolimus, that is slowly released when it comes in contact with the arterial wall, is intended to reduce development of restenosis in the stented segment of the artery.[37] [38]

The applicants noted that drug-coated balloon catheters are designed to deliver an antiproliferative drug directly to the arterial segment being dilated. Rather than using a stent to deliver the drug slowly to the dilated area, the drug coating of a balloon is designed to transfer the drug to the arterial wall by direct contact over a few minutes. The applicant maintained that if the drug is absorbed into the arterial wall, rather than being washed away by blood flow once the balloon is deflated, the drug can exert its antiproliferative effects on the vessel with the goal of preventing restenosis.

The applicants stated that the drug-coated balloon catheter is a device-drug combination product comprised of a device component (an over-the-wire balloon catheter) and a drug component (a paclitaxel-urea coating in the case of IN.PACT™ and a paclitaxel- sorbitol for LUTONIX™ Admiral™) on the balloon, intended for the treatment of patients with PAD, specifically superficial femoral artery (SFA) and popliteal artery disease. The device is engineered for two modes of action: the primary mode of action is attributable to the balloon's mechanical dilatation of de novo or restenotic lesions in the vessel; and the secondary mode of action consists of drug delivery and application of paclitaxel to the vessel wall to inhibit the restenosis that is normally associated with the proliferative response to the PTA procedure. Following predilatation with a nondrug-coated PTA balloon, the interventionalist selects a drug-coated balloon with diameter of 100 percent of reference vessel diameter (RVD) and length sufficient to treat 5mm proximal and distal to the target lesion and predilated segment (including overlap of multiple balloons). The interventionalist inflates the drug-coated balloon for a minimum inflation time of 30 seconds for delivery of paclitaxel, and keeps the balloon inflated for as long as necessary to achieve a satisfactory procedural result, which is the standard of care for all balloon angioplasties.

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. Because cases eligible for the two devices would group to the same MS–DRGs and we believe that these devices are substantially similar to each other (that is, they are intended to treat the same or similar disease in the same or similar patient population and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action), we believe that it is appropriate to evaluate both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discuss each set of data separately. However, we intend to make one determination regarding new technology add-on payments that will apply to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and that we believe that continuing our current practice of extending a new technology add-on payment without a further application from the manufacturer of the competing product or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products from having to submit separate new technology applications.
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval. (70 FR 47351)

If these substantially similar technologies had been submitted for review in different (and subsequent)

[35] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwälder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[36] Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK.: Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013; 61:1555–70. Available at: *http://dx.doi.org/10.1016/j.jacc.2013.01.004*.

[37] Owens, CD.: Drug eluting balloon overview: technology and therapy. Presented at LINC 2011, Leipzig, Germany.

[38] Scheller B.: Opportunities and limitations of drug-coated balloon in interventional therapies. Herz 2011;36:232–40.

years, rather than the same year, we would evaluate and make a determination on the first application and apply that same determination to the second application. However, because the technologies have been submitted for review in the same year, we believe it is appropriate to consider both sets of cost data and clinical data in making a determination because we do not believe that it is possible to choose one set of data over another set of data in an objective manner.

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015. As stated in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. We note that the applicant submitted a request and presented at the September 2014 ICD–10 Coordination and Maintenance Committee Meeting to create ICD–10–PCS codes to uniquely identify drug-coated PTA balloons used for treating PAD. More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

We received public comments during and after the ICD–10 Coordination and Maintenance Committee meeting that supported the creation of unique codes to identify the use of a drug-coated balloon in procedures performed for treating PAD. As a result, the following ICD–10–PCS codes listed in the table below were created and are effective October 1, 2015 (FY 2016):

ICD–10–PCS code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

As we discuss above, the approval of new technology add-on payments would extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology (66 FR 46915). Moreover, as we discuss above, we believe that applications for substantially similar technologies should be evaluated in a manner that avoids, among other things, having to compare the merits of competing technologies on the basis of substantial clinical improvement. If we receive applications for substantially similar technologies in different years, we would apply the first determination to any subsequent applications for substantially similar technologies. However, because, in this case, two substantially similar technologies have applied for a new technology add-on payment for the same Federal fiscal year, we believe it is consistent with our policy to make one determination using all of the information submitted for the

technologies rather than choosing one set of information to consider and not considering the other set of information. We believe that, in accordance with our policy, it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, based on our policy, if approved for new technology add-on payments, we believe that the beginning of the newness period would be October 10, 2014. We are inviting public comments on whether these two technologies meet the newness criterion.

As we stated above, each applicant submitted separate analyses regarding the cost criterion for each of their devices and both applicants maintained that their device meets the cost criterion. We summarize each analysis below.

With regard to LUTONIX®, to demonstrate that the technology meets the cost criterion, the applicant performed three different analyses. The applicant first searched the FY 2013 MedPAR data file that was used for the recalibration of the FY 2015 MS–DRG relative payment weights in the FY 2015 IPPS/LTCH PPS final rule. The applicant applied the standard trims that CMS used when selecting cases for IPPS rate recalibration as described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49911). In other words, the applicant included cases from IPPS hospitals and Maryland hospitals and excluded cases paid by Medicare Advantage plans, cases from hospitals that did not submit charges in a sufficiently broad range of revenue centers, and statistical outlier cases as described in the FY 2015 IPPS/LTCH PPS final rule. The applicant then searched for all claims reporting ICD–9–CM procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) and also reporting at least one of the following seven ICD–9–CM diagnosis codes (440.20 (Atherosclerosis of native arteries of the extremities, unspecified), 440.21 (Atherosclerosis of native arteries of the extremities with intermittent claudication), 440.22 (Atherosclerosis of native arteries of the extremities with rest pain), 440.23 (Atherosclerosis of native arteries of the extremities with ulceration), 440.24 (Atherosclerosis of native arteries of the extremities with gangrene), 440.29 (Other atherosclerosis of native arteries of the extremities), and 443.9 (Peripheral vascular disease, unspecified indicating peripheral artery disease). The applicant excluded all claims that reported any ICD–9–CM procedure codes involving a stent. A total of 23,157 cases reporting peripheral angioplasty were identified. Of these 23,157 cases, MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC and without CC/MCC, respectively) accounted for 65 percent of cases; MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively), MS–DRGs 239 and 240 (Amputation for Circulatory System Disorders Except Upper Limb and Toe with MCC and with CC, respectively), and MS–DRG 853 (Infectious and Parasitic Diseases with Operating Room Procedure with MCC) accounted for 17 percent of cases (among these, peripheral angioplasty was secondary to some other circulation-related procedure: a major cardiovascular procedure (MS–DRGs 237 and 238), amputation due to poor circulation (MS–DRGs 239 and 240), or (typically) amputation with sepsis (MS–DRG 853)). The remaining 18 percent of cases were spread across a large number of other MS–DRGs. Next, the applicant obtained the average case-weighted charge per case based on the distribution of cases by MS–DRG and then identified the average case-weighted threshold for the three MS–DRG groupings from the threshold amounts in Table 10 of the FY 2015 IPPS/LTCH PPS final rule. The applicant then calculated the unadjusted (unstandardized) average case-weighted charge per case for all MS–DRGs. According to the applicant, charges were not removed for any prior technology. To estimate the charge for the new technology, the applicant divided the projected cost per patient by the national average CCR for supplies (0.292) in the FY 2015 IPPS/LTCH PPS final rule, to arrive at the average case-weighted standardized charges per case. The average case-weighted standardized charges per case for the three primary MS–DRGs 252–254 group (65 percent), the five additional MS–DRGs 237–240 and MS–DRG 853 group (17 percent), and the other MS–DRGs (18 percent) were $69,243, $81,156, and $95,138, respectively. The applicant then inflated the average standardized case-weighted charges per case from FY 2013 to FY 2015 using the 2-year inflation factor of 10.44 percent specified in the FY 2015 IPPS/LTCH PPS final rule and added charges related to the new technology to the average case-weighted standardized charges per case, although the applicant indicated that it was not clear on the need to include an inflation factor. The final inflated average case-weighted standardized charges per case for the three primary MS–DRG groups (65 percent), the five additional MS–DRG groups (17 percent), and across other MS–DRGs (18 percent) were $85,386, $98,543, and $104,052, respectively. Because the final inflated average case-weighted standardized charge amounts exceed the corresponding average case-weighted threshold amounts of $69,594, $74,449, and $75,215, respectively, using the FY 2015 IPPS Table 10, the applicant maintained that the LUTONIX® meets the cost criterion for new technology add-on payments.

With regard to IN.PACT™ Admiral™, to demonstrate that the technology meets the cost criterion, the applicant performed two different analyses. The applicant believed that a case involving an angioplasty procedure that used the IN.PACT™ Admiral™ drug-coated balloon catheter would map to the same MS–DRGs as a case involving a plain balloon angioplasty procedure, MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively). The applicant first searched the FY 2013 MedPAR claims data that were used for the recalibration of the FY 2015 MS–DRG relative payment weights in the FY 2015 IPPS/LTCH PPS final rule. The data in this file included discharges occurring on October 1, 2012 through September 30, 2013. The applicant excluded claims for all discharges for Medicare beneficiaries enrolled in a Medicare Advantage plan. The applicant also limited claims to those hospitals that were included in the FY 2013 IPPS Final Rule Impact File. In addition, the applicant removed claims in accordance with the trims specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53326) that were used to recalibrate the MS–DRG relative payment weights. The applicant then searched for all claims reporting ICD–9–CM procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) in combination with claims reporting at least one of the following seven ICD–9–CM diagnosis codes (440.20 through 440.24, 440.29, and 443.9) indicating peripheral artery disease. The applicant excluded all claims that reported any ICD–9–CM procedure codes for stent implantation. The applicant believed that excluding all cases reporting stenting procedures would potentially underestimate the average charges for cases reporting peripheral angioplasty. A total of 23,157 cases involving peripheral angioplasty procedures were identified. Of these 23,157 cases, a majority (65 percent; 15,040 cases) mapped to one of the 3 primary MS–DRGs, MS–DRGs 252, 253, or 254. The remaining 35 percent of the cases

(8,117) were assigned to a number of MS–DRGs other than the 3 primary MS–DRGs. Next, the applicant determined the distribution of cases by MS–DRG and the case-weighted threshold amounts from Table 10 in the FY 2015 IPPS/LTCH PPS final rule, for both the primary MS–DRG group and the total MS–DRG group. The applicant began by calculating the unadjusted (unstandardized) case-weighted average charge per case for all MS–DRGs. Following this computation, the applicant standardized the charges on each of the identified claims using the FY 2013 factors from the FY 2015 IPPS/LTCH PPS Final Rule Impact File, to match the year of the claims data used in this analysis (FY 2013 MedPAR file). According to the applicant, charges were not removed for any other specific technologies that may have been used because the applicant expected that a plain balloon will be utilized to predilate the vessel in a majority of drug-coated balloon angioplasty cases prior to the use of the drug-coated balloon (that is, the applicant did not believe it was necessary to remove charges associated with the other specific prior technology (a plain PTA balloon catheter in this case). The applicant then inflated the average case-weighted standardized charges per case from FY 2013 to FY 2015 using the 2-year inflation factor of 10.44 percent specified in the FY 2015 IPPS/LTCH PPS final rule and added charges related to the new technology to the average charges per case. The final inflated average case-weighted standardized charge per case both for the primary MS–DRGs group and the total MS–DRG group were $82,944 and $101,611, respectively. Because the final inflated average case-weighted standardized charge per case for the applicable MS–DRG exceeds the average case-weighted threshold amounts of $69,594 and $75,215, respectively, using the FY 2015 IPPS Table 10, the applicant maintained that the IN.PACT™ Admiral™ technology meets the cost criterion for new technology add-on payments.

We are concerned that both applicants excluded cases of patients that received stent implantations from their analysis because the applicants believed that their technology can be used instead of stenting. We are seeking public comments on whether LUTONIX® and IN.PACT™ Admiral™ meet the cost criterion.

With regard to substantial clinical improvement, the applicant believed that LUTONIX® represents a substantial clinical improvement because it meets an unmet clinical need by providing access to ''no stent zones'' and because it can achieve greater patency; preserve the flexibility of future interventions; and address stent fractures and re-stenosis.[39] [40]

The applicant shared the findings from its LEVANT 1 and LEVANT 2 trials.

LEVANT 1: In the LEVANT 1 trial, 101 patients were randomized to a LUTONIX® drug-coated balloon treatment group or a control group that received percutaneous transluminal angioplasty (PTA) only. The primary endpoint of mean angiographic Late Lumen Loss at 6 months favored the LUTONIX® drug-coated balloon treatment group (0.46±1.13) compared to the control PTA group (1.09±1.07), with a p-value of 0.016.

We are concerned that the results were not statistically significant with regard to the p-value documented. Adverse events were similar for both groups and through 24 months; the percentage of patients with any death, amputation, or target vessel thrombosis was 8 percent in the treatment group compared to 12 percent in the control group.

LEVANT 2: The LEVANT 2 study is the applicant's pivotal study that was conducted as a prospective, multicenter, single blind, 2:1 (test: control) randomized trial comparing the LUTONIX® drug-coated balloon angioplasty to standard balloon angioplasty used during the treatment of patients with femoropopliteal arteries. The applicant documented that the patient characteristics and lesions in both groups were well-matched; 43 percent of patients were diabetic; 35 percent were current smokers; 37 percent were female; and 8 percent had critical limb ischemia.

The study was conducted to show that drug-coated balloon angioplasty improves clinical outcomes for a patient population as compared to currently available treatments. All endpoints were adjudicated by a blinded Clinical Events Committee (CEC) and duplex ultrasound and angiographic core laboratories.

The applicant specified two primary endpoints that must both be met in order for the study to be successful. The first endpoint was primary patency at 12 months, defined as freedom from target lesion restenosis and target lesion revascularization (TLR). The results were the following: primary patency for LUTONIX® was 65.2 percent compared to primary patency of 52.6 percent for PTA. Kaplan-Meier analysis was 73.5 percent for LUTONIX® compared to 56.8 percent for PTA ($p < 0.001$). The second primary efficacy endpoints were composite safety endpoints at 12 months, which included freedom from index-limb amputation; reintervention and related death. The results were 83.9 percent for LUTONIX® compared to 79.0 percent for PTA.

The secondary efficacy endpoints at 12 months for this trial were freedom from Target lesion revascularization (TLR), and the results were 89.7 percent for the LUTONIX® treatment group compared to 84.8 percent for the PTA control group, with $p = 0.17$. Another end point was freedom from Target vessel revascularization (TVR), where the result for the LUTONIX® treatment group was 76.2 percent compared to 66.6 percent in the control group with a p-value of 0.041. Clinical indicators, such as Ankle brachial index (ABI), Rutherford scores (categorization of symptomology), quality of life (QOL), walking distance, and walking impairment WIQ, were significantly improved with a p-value of <0.001. The applicant assessed the primary safety endpoint using Kaplan-Meier survival analysis and stated that there was no evidence of statistical difference.

We are concerned that the patient population studied may not reflect the Medicare population. In particular, we note that only 37 percent of the studied patients were female. For instance, it could be beneficial to see additional subgroup analyses to test for statistical interaction between treatment and subgroups to ascertain that there is no imbalance in response to different subpopulations, such as males versus females.

With regard to substantial clinical improvement for the IN.PACT™ Admiral™, the applicant stated that evidence demonstrates that the technology significantly improves key clinical outcomes compared to previous technologies for patients with intermittent claudication. Examples of such key clinical outcomes included a decrease in recurrence of restenosis (disease process); a decrease in rates of repeat interventions (subsequent therapeutic interventions); a decrease in future hospitalizations; improved patient symptoms (decreased pain), and improvement in quality of life and function. To further demonstrate substantial clinical improvement, the applicant asserted that historical proof-of-concept research has demonstrated the utility of various drug-coated balloon technologies in reducing restenosis and reintervention compared

[39] Scheinert, D., et al.: Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol, 2005. 45(2): p. 312–5.

[40] Klein, A.J., et al.: Quantitative assessment of the conformational change in the femoropopliteal artery with leg movement. Catheter Cardiovasc Interv, 2009. 74(5): p. 787–98.

with PTA.[41] [42] With this assertion, the applicant stated that there was no evidence of the promising primary patency and target lesion revascularization rates from large randomized controlled trials. This led the applicant to design the IN.PACT™ SFA Trial. The IN.PACT™ SFA Trial is a prospective, randomized-controlled, global, multicenter, single-blinded study conducted with independent, blinded adjudication of all key endpoints. The primary safety end point was freedom from device-related and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven TVR through 12 months. The primary effectiveness endpoint was primary patency, a composite endpoint comprising an anatomic measure (binary restenosis as measured by duplex ultrasound or angiography) and a clinical measure (Clinically Driven Target Lesion Revascularization (CD–TLR)). The IN.PACT™ SFA Trial was designed as a two-phase, global, multicenter trial in which 331 patients with symptoms of claudication or rest pain and with a positive diagnostic finding of de novo stenosis and/or non-stented restenotic lesions in the SFA and/or popliteal artery (PPA) were randomized in a 2:1 fashion to treatment with IN.PACT™ Admiral ™ drug-coated balloon or uncoated balloon angioplasty. The trial was prospectively designed to be conducted in two phases: IN.PACT™ SFA Phase I (conducted in Europe) and IN.PACT™ SFA Phase II (conducted in the United States), jointly referred to as IN.PACT™ SFA Trial. According to the applicant, the patient demographics were well-matched and of which 34 percent were women. We are concerned that the applicant did not match the gender variable. The applicant noted that, during the SFA Trial, both the study subjects and trial sponsor were blinded to the treatment assignments through completion of the 12-month primary endpoint evaluations. The applicant also stated that the independent Clinical Events Committee and the Core Laboratories were blinded to the treatment assignment and the duration of the follow-up of study participants. In addition, operators (implanting physicians and catheterization laboratory staff, including research coordinators) were not blinded to the treatment delivered due to macroscopic visual differences between IN.PACT™ Admiral™ drug-coated balloon and control technology.

The applicant reported the following: The primary endpoints were: Improved primary patency rates in the IN.PACT™ Admiral™ drug-coated balloon arm compared to the control arm; and primary patency within 12 months is defined as freedom from clinically driven target lesion revascularization and freedom from restenosis as determined by duplex ultrasonography peak systolic velocity ratio ≤2.4 or ≤50 percent stenosis as assessed by angiography. Results showed that the 12-month primary patency rate was 82.2 percent in the IN.PACT™ Admiral™ drug-coated balloon arm versus 52.4 percent in the PTA arm (P <0.001). In addition, the 12-month freedom from binary restenosis (assessed by DUS/angiography) was 83.5 percent in the IN.PACT™ Admiral™ drug-coated balloon group compared to 66.3 percent in the PTA group (P = 0.001). The second endpoint measured was Ankle-Brachial Index (ABI) showing 0.951 in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 0.866 in the control arm, P = 0.002. The ABI is an objective hemodynamic measure used to predict the severity of PAD in the lower extremity. The test is done by comparing the systolic blood pressure at the ankle and the systolic blood pressure in the arm while a person is at rest. In general, higher values are better than lower values; a normal resting ankle-brachial index is from 1.0 to 1.4, an abnormal resting ankle-brachial index is 0.9 or lower and an ABI of 0.91 to 0.99 is considered borderline abnormal.[43] Secondary endpoints were primary sustained clinical improvement, defined as freedom from target limb amputation, target vessel revascularization, and increase in Rutherford class; comparing IN.PACT™ Admiral™ with the control arm was 85.2 percent versus 68.9 percent; P <0.001. The rate of repeat target lesion revascularization (TLR), defined by the applicant as repeat revascularization of the target lesion by percutaneous endovascular treatment or bypass surgery, was 2.4 percent in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 20.6 percent in the control arm. In addition, the target vessel revascularization (TVR) procedures (that is, any revascularization done to any segment of the entire target vessel that may reflect restenosis of a target lesion or disease progression causing a new lesion in the target artery)[44] was 4.3 percent in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 23.4 percent in the control arm with a p-value of <0.001).

Other secondary endpoints were conducted and the patients were followed at 1, 6, and 12 months to assess the following claudication symptoms: EQ–5D; Walking Impairment Questionnaire (WIQ); 6-minute walk test in a subset. Claudication symptoms were 7.3 percent in the IN.PACT™ Admiral™ drug-coated balloon arm compared to 20.7 percent in the control arm. For WIQ (defined as the ability of PAD patients to walk defined distances and speeds, plus climb stairs, thus evaluating claudication severity levels[45]), the gains in improvement were similar in both groups. The 6-minute walk test, which is a measure of functional exercise capacity, was equivocal in both arms. Quality of life (QOL) was measured using five domains of the EQ–5D (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and was found to be equivocal.

The applicant also conducted extensive subgroup analyses of the primary safety end point, efficacy endpoint, and TLR rates to assess the response to IN.PACT™ Admiral™ in various subpopulations, including: Rutherford category (2, 3, and 4); diabetes; age (≥75); lesion length (<5 cm, ≥5 cm to <10 cm, ≥10 cm to <18 cm); total occlusion, and gender. According to the applicant, although the trial was not designed to power the subgroup analyses, in 9 of these 11 subgroups, patients in the IN.PACT™ Admiral™ treatment group were shown to have statistically significant better outcomes than patients in the PTA control group

[41] Werk M, Albrecht T, Meyer DR, Ahmed MN, Behne A, Dietz U, Eschenbach G, Hartmann H, Lange C, Schnorr B, Stiepani H, Zoccai GB, Hänninen EL.: Paclitaxel-coated balloons reduce restenosis after femoropopliteal angioplasty: evidence from the randomized PACIFIER trial. Circ Cardiovasc Interv 2012 5: 831–40.

[42] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwälder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[43] Hirsch AT, Haskal ZJ, Hertzner NR, et al.: ACC/AHA guidelines for the management of subjects with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aorta): executive summary. J Am Coll Cardiol 2006;47:1239–312.

[44] Werk M, Langner S, Reinkensmeier B, Boettcher HF, Tepe G, Dietz U, Hosten N, Hamm B, Speck U, Ricke J.: Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. Circulation 2008;118: 1358–65.

[45] Jones WS, Schmit KM, Vemulapalli S, Subherwal S, Patel MR, Hasselblad V, Heidenfelder BL, Chobot MM, Posey R, Wing L, Sanders GD, Dolor RJ.: Treatment Strategies for Patients With Peripheral Artery Disease. Comparative Effectiveness Review No. 118. (Prepared by the Duke Evidence-based Practice Center under Contract No. 290–2007–10066–I.) AHRQ Publication No. 13–EHC090–EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2013. Available at: *http://www.effectivehealthcare.ahrq.gov/reports/final.*

in the primary effectiveness and safety endpoints as well as clinically-driven TLR. This includes subgroups: Rutherford categories 2 & 3; diabetes; age (≥75); lesion length ≥5 cm to <10 cm; lesion length ≥10 cm to <18 cm; total occlusion; and gender (both male and female). In the two subgroups that did not meet statistical significance (Rutherford category 4 and lesion length <5 cm), data for the primary effectiveness and safety endpoints as well as the clinically driven TLR trended in favor of IN.PACT™ Admiral™.

We are concerned about the clinical meaningfulness of some of the endpoints measured by the trials conducted by the applicant. For example, there were no changes in functional measures such as walking distances. The applicant indicated that this may be because patients in the control group had additional procedures to the point their symptoms were controlled to the same extent as those of the drug-coated balloon group. We believe that this assertion could be better supported with data. Another related example is the higher ankle-brachial index in the drug-coated balloon catheter group. While this is also consistent with an enduring physiologic effect of the drug-coated balloon device, we are concerned that these ABI measurements appear to have been made by unblinded study personnel.

We are concerned that the IN.PACT™ Admiral™ technology may not be the optimal treatment for all patients diagnosed with peripheral arterial disease. The drug-coated balloon catheter has been compared only with a standard balloon, and no other alternatives, such as stents, surgery, or intensive exercise therapy. Therefore, it is unknown whether a drug-coated balloon strategy would yield the same, better, or worse outcomes than these alternatives. We also note that while there appears to be broader anatomical applicability, not all of the studies provided definitively indicate that it is a clinical improvement over PTA.

We are seeking public comment on whether LUTONIX® and IN.PACT™ Admiral™ meet the substantial clinical improvement criterion, specifically with regard to our concerns discussed.

Below we summarize the written public comments on the LUTONIX® and IN.PACT™ Admiral™ technologies that we received in response to the town hall meeting.

Comment: One commenter, a major society on vascular medicine, stated that without new technology add-on payments for drug-coated balloon catheters, facilities will not be adequately compensated for procedures involving these devices and patient access to these new beneficial technologies will be hampered. The commenter believed that the technology being developed by both manufacturers meets the newness criterion. The commenter stated that the drug-coated balloon catheters represent advancement in medical technology that substantially improves, relative to technologies previously available, the treatment of Medicare beneficiaries. Specifically, the commenter stated that the results of the clinical trials for these devices have established that these devices achieve more durable patency by reducing restenosis, which in turn reduces the rate of repeat interventions. The commenter further stated that these devices do not require a permanent implant, which preserves future treatment options. The commenter also noted documented improvements treatment results for patients diagnosed with PAD according to an article in the *JAMA*.[46] The commenter expressed support for approval of new technology add-on payments for both the LUTONIX® and the IN.PACT™ Admiral™ technologies, with hopes of minimizing any financial barriers that might prevent patients from having access to this technology.

Another commenter supported the approval of new technology add-on payments for the LUTONIX® and IN.PACT™ Admiral™ technologies and for other drug-coated balloon catheters in the treatment of patients diagnosed with SFA in the United States. Specifically, the commenter stated that the clinical study results have shown that using drug-coated balloon catheters both keep a vessel open for a longer period of time and reduce the total number of repeat procedures that may need to be performed. The commenter further stated that treatment using existing therapies in his own practice have resulted in patients returning for repeat procedures 1 to 2 times per year. The commenter noted that the additional benefit of reducing revascularization, which allows patients to remain mobile for longer periods of time, further reduces potential complications and hospitalizations.

The commenter also noted that colleagues outside the United States have had access to this technology for over 5 years and the technology's use has shown positive results in different patient and lesion subgroups, which provides strong evidence that supports the wide use of drug-coated balloon catheters. The commenter stated that there are a number of publications that advocate that the reduced need for revascularization also results in significant cost savings for health care systems, and recommended that these additional savings and value to be shared with hospitals in the United States. The commenter stated that, although there is clear clinical evidence that supports the use of drug-coated balloon catheters, there are concerns that hospital administrators may limit the use of these catheters because of the added cost burden that would be completely imposed on hospitals in the current health care system.

Response: We appreciate the commenters' input. We will consider these comments in our analysis and final determination of the applications for new technology add-on payments for FY 2016.

h. VERASENSE™ Knee Balancer System (VKS)

OrthoSensor submitted an application for new technology add-on payments for the VERASENSE™ Knee Balancer System (VKS) for FY 2016. The VKS is a sterile, single patient use device to intraoperatively provide a means to dynamically balance the patient's knee during total knee arthroplasty (TKA) surgery. The applicant maintained that quantitative metrics, viewed on a monitor through real time wireless information, enable the surgeon to improve soft tissue stability and kinetics during TKA surgery. The VKS device includes a tibial trial insert composed of an array of responsive sensors that delivers quantified kinetic balance data during TKA surgery. The quantitative data provides a basis for the surgeon to make data-based decisions regarding tissue dissection during TKA surgeries, resulting in a more stable outcome.

According to the applicant, the VKS device combines dual sensor elements, coupled with micro-processing technology, to accurately depict intra-articular kinetics and contact point locations within the knee. The tibial trial insert is placed in the knee capsule. Proper placement of the insert does not require any force or infiltration of the bone or soft tissue in the knee. The applicant stated that the VKS device uses wireless communication protocols that overcome line-of-sight or other interference issues, therefore eliminating the need for line-of-sight or direct antenna-based tracking during the TKA surgery.

[46] Goodney, Tarulli, Faerber, et al. Fifteen-Year Trends in Lower Limb Amputation, Revascularization, and Preventive Measures Among Medicare Patients. *JAMA Surg.* 2015;150(1):84–86.

The first version of the VKS received FDA approval in 2009 for the OrthoRex Intra-Operative Load Sensor. The device was indicated for use as a tool to adjust the femoral knee implant to reduce instability from flexion gap asymmetry using a single patient use sterile force sensor. The applicant noted that the first version of the VKS was not available on the U.S. market at the time of FDA approval in 2009. The applicant stated that the 510K approval from the FDA allowed permission to continue to test the device and improve upon the specificity of the sensors. The applicant stated that the first version of the VKS did not enter on the U.S. market until late 2011. Further advancements were made to the VKS to more accurately refine the sensor specificity, which provides more accurate balance data unique to the contours of specific knee implant components. The applicant further explained that the tibial trial sensor was redesigned to respond quantitatively and specifically to the variations of the contours of specifically manufactured knee implants. The advanced sensor specificity, developed in conjunction with data gained from clinical trials, provides information regarding force and balance metrics that aid the surgeon's understanding and measurement of knee balance. The applicant noted that without the advancements to the sensor specificity, which were perfected based on knowledge gained from the clinical trials, the sensor would not be as clinically useful as it is currently. These advancements resulted in additional FDA clearances on June 13, 2013, and October 14, 2013. The product's description was updated on January 28, 2014.

The applicant maintained that the VKS meets the newness criterion. The applicant analyzed the relative weights from 2010 to 2014 for the MS–DRGs that may contain cases that would be eligible for the advanced VKS technology (MS–DRGs 461 through 470). The applicant noted that there was no increase in the calculation of the FY 2014 or FY 2015 relative weights for these MS–DRGs to represent the additional cost of the advanced VKS technology.

We are concerned that the advancements made to the VKS that resulted in the additional FDA approval clearances in 2013 may not be significant enough to distinguish the advanced technology from the first version of the VKS, which received FDA approval in 2009. We believe that the advanced VKS may be substantially similar to the first version of the VKS (that was first available on the U.S. market in late 2011) and, therefore, would not meet the newness criterion. In addition, the costs associated with the VKS should be reflected in the FY 2013 and subsequent relative payment weights for these MS–DRGs because the product has been available and used for the Medicare population since 2011.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of the criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

In evaluating the application under the substantial similarity criteria, we believe that the first version of the VKS and the advance version of the VKS use the same mechanism of action to achieve the desired outcome by using a sterile device that is equipped with sensors used to adjust the femoral knee implant to reduce instability from flexion gap asymmetry. In addition, we believe that cases involving the first version of the VKS would be assigned to the same MS–DRG as the cases involving the advanced VKS. Moreover, we believe that both the first version of the VKS and the advanced version of the VKS treat the same or similar disease and the same or similar patient population. Specifically, both of the VKS technologies are used in the treatment of patients undergoing TKA surgery. Because we believe that the technology meets all three of the substantial similarity criteria, we believe that the beginning of the newness period for this technology would commence when it became available on the U.S. market in late 2011. Therefore, the VKS may not be considered ''new'' for purposes of new technology add-on payments.

As discussed in the FY 2005 IPPS final rule (69 FR 49003), once data become available to reflect the cost of the technology in the relative weights, the technology can no longer be considered ''new'' and eligible to receive new technology add-on payments. Section 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Further, after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section. Therefore, we believe that the costs of this technology are included in the charge data and the MS–DRGs have been recalibrated using that data. Therefore, the technology can no longer be considered ''new'' for the purposes of this provision, regardless of whether or not there was an increase in the MS–DRG relative weights during FYs 2014 and 2015, specifically because of the inclusion of the cost of the technology.

As previously stated, we believe that the beginning of the newness period for the VKS commenced when the product was first made available on the U.S. market in late 2011. The 3-year anniversary date of the product's availability on the U.S. market occurred in late 2014, which is prior to the beginning of FY 2016. Therefore, we do not believe that the VKS technology can be considered ''new'' for purposes of new technology add-on payments. We are inviting public comments regarding whether or not the VKS technology is substantially similar to existing technologies, and whether or not the VKS technology meets the newness criterion.

Currently, there are no ICD–9–CM or ICD–10–PCS procedure codes that uniquely identify the use of this technology. As stated above, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. The applicant submitted a request for a unique ICD–10–PCS code that was presented at the March 18, 2015 ICD–10 Coordination and Maintenance Committee meeting. If approved, the code(s) will be effective on October 1, 2015 (FY 2016). More information on this request can be found on the CMS Web site located at the following link: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.*

With regard to the cost criterion, the applicant supplied three analyses to demonstrate that it meets the cost criterion. The applicant believed that cases that are eligible for the VKS technology map to MS–DRGs 461 and 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC and without MCC, respectively), MS–DRGs 466 through 468 (Revision of

Hip or Knee replacement with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively). The first analysis used data from the 2012 National Inpatient Sample (NIS) from the Agency for Research and Quality (AHRQ). We note that the NIS includes Medicare, Medicaid, and commercial and uninsured claims data. However, the applicant limited its search to Medicare cases only.

The applicant searched for all Medicare cases assigned to MS–DRGs 461 and 462 and found 812 and 14,200 cases respectively (for a total of 15,012 cases). The applicant noted that the 15,012 cases assigned to MS–DRGs 461 and 462 also include cases representing hip revision procedures. Therefore, to determine the number of eligible cases reporting bilateral knee revisions assigned to MS–DRGs 461 and 462, based on clinical information,[47] the applicant approximated that 4 percent of the cases assigned to MS–DRGs 461 and 462 represent Medicare beneficiaries who may be eligible for the VKS for a bilateral knee revision procedure. As a result, the applicant focused its analysis on 32 cases assigned to MS–DRG 461 (812 cases * .04), and 568 cases assigned to MS–DRG 462 (14,200 cases * .04). We are concerned that the statistical data obtained from clinical information that the applicant used to determine the percentage of cases representing bilateral knee revisions still includes cases representing hip revision procedures. Specifically, the applicant did not uniquely identify cases representing bilateral knee revisions and only produced a percentage of all cases that still includes cases for hip revision procedures.

According to the applicant, eligible cases for the VKS technology include cases representing knee revision procedures that also map to MS–DRGs 466 through 468 (which represent degrees of severity calculated for each MS–DRG). To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant first searched the NIS database for the total number of Medicare cases assigned to these MS–DRGs. This resulted in a total of 54,105 cases. The applicant noted that MS–DRGs 466 through 468 also include cases for hip and knee revision procedures. Therefore, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of Medicare cases for each MS–DRG (5,195 for MS–DRG 466, 28,650 for MS–DRG 467, and 20,260 for MS–DRG 468) by the total number of Medicare cases assigned to MS–DRGs 466, 467, and 468 (54,105). The applicant then multiplied the percentage for each MS–DRG (9.6 percent for MS–DRG 466, 52.9 percent for MS–DRG 467, and 37.4 percent for MS–DRG 468) by the total amount of cases assigned to each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures assigned to each of these three MS–DRGs: 3,054 cases in MS–DRG 466; 16,842 in MS–DRG 467; and 11,910 in MS–DRG 468. We are concerned that the methodology the applicant used to determine the percentage of cases representing knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. Rather, the applicant used the percentage of Medicare cases assigned to each MS–DRG of the overall total cases for the three MS–DRGs, which includes knee and hip revisions, and multiplied by this percentage to further reduce the total number of cases. We do not believe that this further reduction to the total number of Medicare cases has sufficiently isolated cases representing knee revision procedures.

According to the applicant, eligible cases for the VKS technology also include TKA procedures that map to MS–DRGs 469 and 470. To determine the number of eligible cases reporting TKA procedures assigned to MS–DRGs 469 and 470, the applicant first searched the NIS database for the total number of Medicare cases assigned to these MS–DRGs. This resulted in 35,740 cases in MS–DRG 469 and 547,955 cases in MS–DRG 470. The applicant noted that MS–DRGs 469 and 470 also include cases representing hip replacement and other joint replacement procedures. Therefore, in order to determine the number of TKA procedures within these MS–DRGs, the applicant searched the NIS database for cases reporting ICD–9–CM procedure codes that typically map to these MS–DRGs. The applicant first searched for cases representing TKA across all MS–DRGs that reported ICD–9–CM procedure code 81.54 (Total knee replacement) and found 336,050 cases. The applicant then searched the NIS database for cases representing hip and other joint replacement procedures across all MS–DRGs that reported ICD–9–CM procedure codes 81.51 (Total hip replacement), 81.52 (Partial hip replacement), 81.56 (Total ankle replacement), 81.57 (Replacement of joint of foot and toe), and 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified) and found 238,050 cases. This resulted in a total of 574,100 cases representing knee, hip, and other joint replacement procedures.

The applicant then divided the number of cases representing TKA procedures by the total number of cases (336,050/574,100) and determined that 58.5 percent of all cases assigned to MS–DRGs 469 and 470 are related to TKA procedures. The applicant then multiplied the percent of cases representing TKA procedures (58.5 percent) by the number of cases assigned to MS–DRGs 469 and 470, which resulted in 20,920 cases in MS–DRG 469 (35,740 * .585) and 320,746 cases in MS–DRG 470 (547,955 * .585). We are concerned that the methodology the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint replacement procedures.

Based on the analysis above, the applicant maintained that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 through 470 was 374,071. The applicant determined an average case-weighted charge per case of $57,341. The applicant then determined that it was necessary to remove charges related to the other computer-assisted devices/technologies used during these procedures and charges for operating room time because procedures involving the VKS do not require operating room time, and the charges for the VKS technology would inevitably be different. Therefore, the applicant removed approximately $146 from the average case-weighted charge per care for cases assigned to MS–DRGs 461 and 462, and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466 through 470. The applicant noted that the $146 in charges removed from the average case-weighted charges per case for cases assigned to MS–DRGs 461 and 462 was slightly higher than the charges removed from cases assigned to MS–

[47] Memtsoudis SG, Valle AGD, Besculides MC, Gaber, Sculco TP.: In-hospital complications and mortality of unilateral, bilateral, and revision TKA. 2008, Clin Orthop Relat Res, 466:2617–2627.

DRGs 466 through 470 because these charges were for bilateral procedures which require additional operating room time.

Data from the NIS database is only available on a national level and not on a hospital-specific level. Therefore, in order to standardize the charges per case, the applicant used the FY 2012 IPPS Impact File and the mean value of all relevant standardization factors to standardize the charges per case. We are concerned that the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, we believe that the standardization performed by the applicant does not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $68,121. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that average case-weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $57,341. Because the final inflated average case-weighted standardized charge per case for the applicable MS–DRGs exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The applicant's second analysis used data from the 2013 American Hospital Discharge Data (AHD) based on 57 randomly selected hospitals. The applicant searched the data and did not find any cases assigned to MS–DRG 461. The applicant noted that it used a value of 10 cases for its analysis of cases assigned to MS–DRG 461 because data reflecting a zero value indicates that the hospital performed less than 10 procedures. The applicant found 533 cases assigned to MS–DRG 462. To determine the number of cases representing bilateral knee revision procedures in MS–DRG 462, similar to the first analysis, the applicant multiplied the total number of cases assigned to MS–DRG 462 by 4 percent, which resulted in 21 cases. Similar to our statement about the first analysis, we are concerned that the applicant did not uniquely identify cases representing bilateral knee revision procedures and only produced a percentage of all cases, which still includes cases representing hip revision procedures.

To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant first searched the AHD database for the total number of cases assigned to these MS–DRGs. This resulted in a total of 2,969 cases. Because these MS–DRGs include cases representing hip and knee revision procedures, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of cases for each MS–DRG (122 for MS–DRG 466; 1,746 for MS–DRG 467; and 1,101 for MS–DRG 468) by the total number of cases in MS–DRGs 466 through 468 (2,969). The applicant then multiplied the percentage for each MS–DRG (4.1 percent for MS–DRG 466; 58.8 percent for MS–DRG 467; and 37.1 percent for MS–DRG 468) by the total number of cases in each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures in each of these three MS–DRGs: 1,307 cases in MS–DRG 466; 18,704 in MS–DRG 467; and 11,794 in MS–DRG 468. Similar to our concerns about the first analysis, we are concerned that the methodology the applicant used to determine the percentage of cases of knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. The applicant simply used the percentage of Medicare cases for each MS–DRG of the overall total cases for the three MS–DRGs, which include knee and hip revision procedures, and multiplied by this percentage to further reduce the number of cases. We do not believe that this further reduction to the total number of Medicare cases has isolated cases representing knee revision procedures.

The applicant used the same methodology from the first analysis to determine the number of eligible cases representing TKA procedures assigned to MS–DRGs 469 and 470. The applicant searched the AHD database and found 1,217 cases assigned to MS–DRG 469 and 24,620 cases assigned to MS–DRG 470. To determine the number of cases representing TKA procedures within these MS–DRGs, the applicant multiplied the total number of cases within these MS–DRGs by the percentage of 58.5 percent from the NIS database, which represents the percentage of knee replacement procedure cases among the total number of cases representing knee, hip and joint replacement procedures. This resulted in 712 cases in MS–DRG 469 (1,217 * .585) and 14,411 cases in MS–DRG 470 (24,620 * .585). Similar to our concerns expressed earlier, we are concerned that the methodology the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip replacement and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint replacement procedures.

Based on this analysis, the applicant maintained that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 and 470 was 46,960. The applicant determined an average case-weighted charge per case of $80,702. For the rest of the analysis, the applicant followed the same methodology as the first analysis. The applicant removed $146 from the average case-weighed charge per case for cases assigned to MS–DRGs 461 and 462 and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466 through 470 for charges related to other computer-assisted devices/technologies used during these procedures and additional charges for the use of the operating room.

Similar to the first analysis, the applicant used the FY 2012 IPPS impact file and the mean value of all relevant standardization factors from all hospitals to standardize the charges per case. Similar to above, we are concerned that the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, the standardization performed by the applicant does not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $90,515. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that the average case-

weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $80,699. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for the applicable MS–DRGs, the applicant maintained that the VKS technology meets the cost criterion.

The applicant's third analysis used data from the FY 2015 CMS Before Outliers Removed (BOR) file. The BOR file contained 469 cases in MS–DRG 461 and 9,396 cases in MS–DRG 462. To determine the number of cases representing bilateral knee revision procedures assigned to MS–DRGs 461 and 462, similar to the first analysis, the applicant used an assumption of 4 percent, which resulted in 19 cases in MS–DRG 461 and 376 cases in MS–DRG 462. Similar to our concerns stated earlier, we are concerned that the applicant did not uniquely identify cases representing bilateral knee revision procedures and only produced a percentage of all cases, which still includes cases representing hip revision procedures.

To determine the number of eligible cases reporting knee revision procedures assigned to MS–DRGs 466 through 468, the applicant again analyzed the BOR file which contained a total of 44,420 cases. Similar to first two analyses, because these MS–DRGs include cases representing hip and knee revision procedures, to determine the number of cases representing knee revision procedures in each of these three MS–DRGs, the applicant first divided the number of cases for each MS–DRG (4,202 for MS–DRG 466; 23,390 for MS–DRG 467; and 16,828 for MS–DRG 468) by the total number of cases in MS–DRGs 466 through 468 (44,420). The applicant then multiplied the percentage for each MS–DRG (9.5 percent for MS–DRG 466; 52.7 percent for MS–DRG 467; and 37.9 percent for MS–DRG 468) by the total number of cases in each MS–DRG. Based on this calculation, the applicant approximated the following number of cases representing knee revision procedures in each of these three MS–DRGs: 3,009 cases in MS–DRG 466; 16,747 in MS–DRG 467; and 12,049 in MS–DRG 468. Similar to our concerns stated earlier, we are concerned that the methodology the applicant used to determine the percentage of cases representing knee revision procedures still includes cases representing hip revision procedures. Specifically, in its methodology, the applicant did not use any source of statistical relevance to isolate cases representing knee revision procedures. Rather, the applicant used the percentage of Medicare cases for each MS–DRG of the overall total number of cases for the three MS–DRGs, which includes cases representing knee and hip revision procedures, and multiplied by this percentage to further reduce the number of cases. We do not believe that this further reduction to the total number of Medicare cases has isolated cases representing knee revision procedures.

The applicant used the same methodology from the first analysis to determine the number of eligible cases reporting TKA procedures assigned to MS–DRGs 469 and 470. The BOR file contained 27,737 cases in MS–DRG 469 and 437,649 cases in MS–DRG 470. To determine the number of cases representing TKA procedures within these MS–DRGs, the applicant multiplied the total number of cases within these MS–DRGs by the percentage of 58.5 percent obtained from the NIS database, which represents the percentage of knee replacement cases among the total number of cases representing knee, hip, and joint replacement procedures. This resulted in 16,236 cases in MS–DRG 469 (27,737 * .585) and 256,178 cases in MS–DRG 470 (437,649 * .585). Similar to our concerns stated earlier, we are concerned that the methodology the applicant used to determine the percentage of cases representing TKA procedures still includes cases representing hip and other joint replacement procedures. Specifically, the applicant did not uniquely identify cases representing TKA procedures and only produced a percentage of all cases, which still includes cases representing hip and other joint revision procedures.

Based on this analysis, the applicant maintained that the total number of cases across MS–DRGs 461 and 462 and MS–DRGs 466 through 470 was 304,614. The applicant determined an average case-weighted charge per case of $56,282. For the rest of the analysis, the applicant followed the same methodology as the first analysis. The applicant then removed $146 from the average case-weighted charge per case for cases assigned to MS–DRGs 461 and 462 and $73 from the average case-weighted charge per case for cases assigned to MS–DRGs 466–470 for charges related to other computer-assisted devices/technologies used during these procedures and additional charges for the use of the operating room.

Similar to the first analysis, the applicant used the FY 2012 IPPS Impact File and the mean value of all relevant standardization factors from all hospitals to standardize the charges per case. Similar to our concerns stated earlier, we are concerned that the analysis provided by the applicant did not use hospital-specific data and, therefore, the standardization process may be inaccurate because of the use of mean factors rather than hospital-specific factors. By using mean factors rather than hospital-specific factors, we believe that the standardization performed by the applicant does not sufficiently take into account hospital variations.

The applicant then inflated the charges using an inflation factor of 10.4227 percent based on the inflation factor in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379), and added the charges related to the VKS technology to the adjusted average case-weighted standardized charge per case. This resulted in a final inflated average case-weighted standardized charge per case of $66,382. Using the FY 2015 IPPS Table 10 thresholds, the applicant determined that the average case-weighted threshold amount for MS–DRGs 461 and 462 and MS–DRGs 466 through 470 is $64,280. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount for the applicable MS–DRGs, the applicant maintained that the VKS technology meets the cost criterion.

Based on the information provided by the applicant, combined with the weight of our concerns, we are unable to determine if and how the VKS technology meets the cost criterion. We are inviting public comments on whether or not the VKS technology meets the cost criterion, specifically with regard to the concerns raised.

With regard to substantial clinical improvement, the applicant maintained that the VKS technology represents a substantial clinical improvement. The applicant stated that the device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant explained that the use of the VKS technology has improved patient outcomes, including rapid recovery of patients diagnosed with comorbidities, the early return to normal activities, and increased levels of activity and functionality. The applicant noted that patients treated using the VKS technology during TKA procedures did not experience readmission within 30 days, nor was it necessary for the treating physician (the surgeon) to complete a problem focused medical evaluation during the patient's recovery. The applicant further noted that patients having a more favorable immediate outcome with a stable TKA

were shown to return to normal function more rapidly than patients with unbalanced knees. Therefore, the applicant stated that patients with complex medical conditions would be able to respond to the early return of normal daily living.

The applicant also believed that the device offers the ability to diagnose a medical condition for a patient population experiencing medical conditions that are currently undetectable, or offers the ability to diagnose a medical condition earlier than that which is capable using currently available technologies. The applicant explained that the VKS technology provides an improved evaluation/diagnosis compared to an unbalanced TKA implant. Specifically, the applicant stated that the device enables the surgeon to obtain intraoperative measures enabling the surgeon to improve upon the placement of the TKA tibial and femoral components. Additionally, intraoperatively the device leads to an immediate diagnosis of an implant that can now be accurately positioned due to informed fine tissue dissection. The applicant stated that the intraoperative technique has been demonstrated to result in increased implant stability and functional congruence. The applicant cited the following examples of outcomes that have been frequently documented and evaluated within clinical studies of medical devices:

- Intended to address the leading causes of early implant failure in TKA: Instability, malrotation and malalignment;[48]
- Dynamic intercompartmental load data and Kinetic Tracking enables evidence based soft tissue releases to improve stability through full ROM;[49]
- Provides intraoperative feedback on tibial–femoral component rotation, position of femoral Contact Points and femoral roll-back to facilitate optimal component position
- Enables reproducible, teachable surgical technique through quantifying surgeon ''feel''; and
- Captures intraoperative data for inclusion in patient EMR, registries or comparative effectiveness studies.

The applicant stated that use of the device significantly improves clinical outcomes for a patient population experiencing these types of medical procedures when compared to currently available treatments. The applicant explained that extensive research and development has resulted in the VKS technology demonstrating improved patient outcomes in multi-center studies. The applicant further explained that the VKS technology has intraoperatively provided a unique opportunity to observe the short-term clinical outcomes of patients with a quantifiably balanced knee versus those who have quantifiably unbalanced knees. According to the applicant, in a multi-center study, the use of the VKS technology has been shown to reduce post-operative pain and improve activity and patient satisfaction scores with statistical significance. Additionally, the applicant stated that 97 percent of patients whose knees were balanced using the VKS technology reported that they were ''satisfied'' to ''very satisfied'' at 1-year post-operative compared to 81 percent patient satisfaction after a TKA procedure without the use of the VKS technology. The applicant stated that the VKS technology provided a 16-percent improvement in patient satisfaction for balanced knees; the first significantly notable increase of patient-reported satisfaction in over 30 years.[50]

According to the applicant, the use of the VKS technology avoided early implant failure. The applicant explained that considering the objective to ameliorate the present risks of revision in TKA procedures, the VKS technology has been advanced to address the need for improved knee balance through fine tissue dissection using information from the VKS technology intelligent tibial trial. While not disturbing the surgical flow of TKA procedures, the applicant stated that the VKS technology provides the surgeon with data on the dynamic intercompartmental load, and kinetic tracking enables evidence-based soft tissue releases to improve stability through full ROM.[51] The applicant noted that the results of multi-center studies, using the VKS technology intraoperatively, have provided an opportunity to observe the short-term clinical outcomes of patients with a quantifiably balanced knee versus those who have quantifiably unbalanced knees.

The applicant further stated that the VKS technology provides intraoperative information on tibial–femoral component rotation, position of femoral contact points and femoral roll-back to facilitate optimal component position. One clinical study[52] reported 170 primary TKA procedures where the VKS technology corrected what would have resulted in unbalanced and malrotated implants in 53 percent of the patients. The applicant noted that when referencing the tibial tubercle to maximize tibiofemoral congruency, 53 percent of patients exhibited asymmetrical tibiofemoral congruency in extension. The applicant further stated that of those patients, 68 percent were shown to have excessive internal rotation of the tibial tray relative to the femur, while 32 percent exhibited excessive external rotation. Additionally, the average tibiofemoral incongruency deviated from a neutral position by 6°, ranging from 0.5° to 19.2. The applicant stated that when comparing the VKS with the convention of using the tibial tubercle to maximize tibiofemoral congruency to confirm the final rotation of the tibial tray, the VKS technology provided superior information. The applicant added that data from using the tibial tubercle to maximize tibiofemoral congruency to confirm the final rotation of the tibial tray are highly variable and inconsistent for confirming the final rotation of the tibial tray.

The applicant stated that the VKS technology has demonstrated and resulted in a ''balanced knee'' after TKA procedures with 6 month and 1 year outcome scores showing a significant improvement over conventional or computer-assisted TKA procedures. According to the applicant, by not disrupting the surgical flow the VKS technology has been viewed by surgeons to provide information enabling them to improve upon the balance of the knee, reduce the degree of rotation and only dissect the fine tissue as needed sparing the release of the ligaments. The applicant further stated that the VKS technology has been shown to enable reproducible, teachable surgical technique through quantifying surgeon ''feel.''

The applicant provided patient outcomes at 6 months and believed that this demonstrated a significant improvement for the ''balanced knee'' TKA procedures using the VKS technology. According to the applicant, multivariate binary logistic regression analyses were performed for both Knee Society Scores (KSS) and Western Ontario and McMaster Universities

[48] Rodriguez-Merchan EC.: Instability Following Total Knee Arthroplasty. *HSSJ* 2011; 7:273–278.

[49] Roche MW, Elson LC, Anderson CR.: A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation. Orthopedics. 2014 (In Press).

[50] Gustke KA, et al.: Increased satisfaction after total knee replacement using sensor-guided technology. *Bone Joint J* 2014;96–B:1333–8.

[51] Gustke, Golladay, et al.: *A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA. The Journal of Arthroplasty* 25 November 2013 (Article in Press DOI: 10.1016/j.arth.2013.10.020)

[52] Roche MW, Elson LC, Anderson CR: A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation. Orthopedics. 2015 (In Press)

Arthritis Index (WOMAC) scores at 6 months. Variables run in these analyses included: age at surgery, BMI, gender, preoperative ROM, preoperative alignment, change in activity level (preoperative to 6 months), and joint state (balanced versus unbalanced). For KSS and WOMAC, both step-wise and backward multivariate logistic regression analyses were calculated to be best fit models with similar significance (P = 0.001). Ultimately, the step-wise model was used. The applicant stated that the binary model revealed that the variable exhibiting the most significant effect of improvement on KSS and WOMAC scores was balanced joint state (P = 0.001; P = 0.004). The applicant noted that joint state was the most highly significant variable; this demonstrated similar levels of significance throughout all possible combinations of variables included in the model (P = 0.001). The applicant added that joint state was also observed to be the sole significant factor in patient-reported outcome score improvement (P b 0.001).

The applicant added that analysis of the data revealed there was also a concurrent significance observed with activity level (P = 0.005). However, the applicant noted that activity level was not significant on its own. The applicant concluded that a balanced joint state results in a higher activity level,[53] which would make activity level more of a dependent variable, rather than a predictor. Therefore, to demonstrate activity level, the applicant used a regression analysis and evaluated KSS and WOMAC scores at 6 months, with odds ratios. According to the applicant, odds ratios were calculated based on meaningful clinical improvement in KSS scores, WOMAC scores, and activity levels at 6 months. Additionally, based on literature review, ''meaningful improvement'' for KSS scores were anything greater than 50 points; WOMAC scores greater than 30 points; and gains in activity level greater than or equal two 2 lifestyle levels (from lowest score to highest: sedentary, semisedentary, light labor, moderate labor, heavy labor). Also, scores from the unbalanced group were used as the reference point. The applicant stated that odds ratio for balanced joint state and improved KSS score was 2.5, with a positive coefficient (95 percent CI). The applicant believed that this suggested a high probability of obtaining a meaningful improvement in KSS with a balanced knee joint, over those who do not have a balanced knee. According to the applicant, the odds ratio for balanced joint state and improved WOMAC score was 1.3, with a positive coefficient (95 percent CI). The applicant believed that this suggested a favorable probability that patients with a balanced joint state will achieve a meaningful improvement in WOMAC score, over those that do not have a balanced knee. According to the applicant, the odds ratio for balanced joint state and improved activity level was 1.8, with a positive coefficient (95 percent CI). The applicant believed that this also suggested a favorable probability of meaningful gains in activity level in those with a balanced knee, versus those with an unbalanced knee.

The applicant further stated that 1 year clinical trial evidence supports the VKS technology protocol for TKA procedures. According to the applicant, of the 135 patients undergoing sensor-guided surgery, 13 percent remained unbalanced (by surgeon discretion). The applicant stated that ''surgeon discretion,'' in this analysis, indicates that the surgeon recognized and accepted the ''unbalanced'' intercompartmental load difference as presented by the VKS technology, but felt that the knee was in a clinically acceptable state. Pre-operatively, there was no statistical difference in any outcomes measures between the two cohorts, the averages of which were: total KSS = 105 ± 24.6; total WOMAC = 47 ± 14.8.

Additionally, according to the applicant, at 1 year, the average total KSS score of balanced patients exceeded that of unbalanced patients by 23.3 points (P <0.001); 179 ± 17.2 and 156 ± 23.4 for the balanced and unbalanced cohort, respectively. The balanced cohort average score for KSS pain and function, separately, were 96.4 and 82.4 respectively; the unbalanced cohort scored 87.8 and 68.3 points for pain and function. The applicant stated that the disparities between the balanced and unbalanced patients' pain and function scores were also highly statistically significant (P <0.001, P=0.022).

For WOMAC, the applicant noted that that the balanced cohort improved their score by 8 points; 10 ± 11.8 and 18 ± 17 for balanced and unbalanced patients, respectively (WOMAC is scored with an inverse scale; lower scores indicate more improvement). The applicant further stated that while this difference did not prove to be statistically significant by the standards set forth for this analysis (P = 0.085), the authors believed that this is due, in part, to the large standard deviations associated with both cohorts.

According to the applicant, the balanced cohort's average activity level score was 48.6, which corresponds with the light to moderate labor categories (tennis, light jogging, heavy yard work) and the unbalanced patient's average activity level score was 26.7, which corresponds to the upper limits of the semi-sedentary range (light housework, walking for limited distances). The applicant believed that the difference between the average scores was statistically significant (P = 0.015). The applicant noted that the most notable aspect of every outcome measure collected is that the unbalanced patient scores at 1 year still failed to achieve the level of improvement of the balanced patient scores at 6 months.

We have a number of concerns regarding the applicant's assertions regarding substantial clinical improvement. First, we are concerned that during the trials, after using the device surgeons continued to make manual adjustments to the spacers to set the knee replacement. The applicant maintained that the VKS technology presents better accuracy for the surgeon when making adjustments to the spacers when implanting a knee replacement. However, we are concerned that the evidence does not delineate the degree of any improved outcomes or patient satisfaction associated with use of the VKS technology versus additional manual adjustments made by the surgeon. We also are concerned that most of the clinical evidence is based on patient satisfaction surveys. While the survey data appeared to demonstrate that patient satisfaction improved, we do not believe that the data presented is sufficient to determine if the VKS technology represents a substantial clinical improvement over manual adjustment. Furthermore, the use of historical literature controls might be useful during early clinical development, but there are possible biases and limitations of this research design. Specifically, there could be multiple differences in the pre-procedure clinical characteristics of patients with ''unbalanced'' knees and those with ''balanced'' knees that could affect outcomes, such as more severe initial disease, more pre-operative misalignment, more obesity, or more comorbidity. These and other potential confounders were not documented or adjusted for in the analyses of outcomes in the literature provided by the applicant. Additionally, as discussed above, the applicant released a first version of the VKS technology in 2011

[53] Gustke, Golladay, et al.: A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA. The Journal of Arthroplasty 25 November 2013 (Article in Press DOI: 10.1016/j.arth.2013.10.020).

and advancements were made to the VKS technology that resulted in additional FDA clearances in 2013. The applicant stated in its application that the first version is considered the first technology of its kind and, therefore, we believe that the VKS technology may no longer be considered new. The applicant submitted an application for the advanced version of the VKS technology from 2013. However, the applicant did not present clinical data to distinguish the improvements made to the advanced version from the first version. Therefore, we are unable to determine if the advanced version represents a substantial clinical improvement over existing technologies (that is, the first version of the VKS technology). We are inviting public comments on whether the VKS technology meets the substantial clinical improvement criterion, specifically with regard to our concerns.

i. WATCHMAN® Left Atrial Appendage (LAA) Closure Technology

Boston Scientific Corporation submitted an application for new technology add-on payments for FY 2016 for the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology (WATCHMAN® System). (We note that, as discussed in detail later in this section, the applicant submitted an application for new technology add-on payments for FY 2015 for the WATCHMAN® System, but withdrew its application after we issued the FY 2015 IPPS/LTCH PPS proposed rule.) According to the applicant, when a patient has been diagnosed with atrial fibrillation (AF), the left atrium does not expand and contract normally. As a result, the left atrium is not capable of completely emptying itself of blood. Blood may pool, particularly in the part of the left atrium called the left atrial appendage. This pooled blood is prone to clotting, causing formation of a thrombus. If a thrombus breaks off, it is called an embolism (or thromboembolism). An embolism can cause a stroke or other peripheral arterial blockage.

The applicant asserted that the WATCHMAN® System device is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy for patients diagnosed with nonvalvular AF who are eligible for Warfarin therapy but for whom the risks of long-term oral anticoagulation outweigh the benefits.

With regard to newness criterion, the applicant anticipated FDA premarket approval of the WATCHMAN® System in the first half of 2015. According to the applicant, the WATCHMAN® System is the first LAA closure device that would be approved by the FDA. Therefore, the applicant believed that the technology meets the newness criterion. Effective October 1, 2004 (FY 2005), ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device) was created to identify and describe procedures using the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology. As stated in section II.G.1.a. of the preamble of this proposed rule, effective October 1, 2015 (FY 2016), the ICD–10 coding system will be implemented. Under the ICD–10–PCS, procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) is the comparable translation for ICD–9–CM procedure code 37.90.

We are inviting public comments on if, and how, the WATCHMAN® System meets the newness criterion.

With regard to the cost criterion, the applicant used the FY 2013 MedPAR file (which contained inpatient hospital claims data for discharges from October 1, 2012 to September 30, 2013) to search for cases reporting ICD–9–CM procedure code 37.90. The applicant provided two analyses. The first analysis includes all claims that reported ICD–9–CM procedure code 37.90, regardless of whether the code indicated a principal procedure that determined the MS–DRG assignment of the case. This analysis identified 507 cases across 29 MS–DRGs. The applicant noted that the MedPAR file contained claims that were returned to the provider that reported charges for actual cases from clinical trials that used the WATCHMAN® System that were well below post-FDA approval pricing. Therefore, the applicant removed the premarket device related charges. The applicant then standardized the charges, applied an inflation factor of 1.10443 based on the 2-year charge inflation factor listed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and then added post-FDA approval charges for the WATCHMAN® System. Using the anticipated cost of the device after FDA approval and the National Average Implantable Device cost center CCR, the applicant estimated device charges post-FDA approval, combined those with the inflated average case-weighted standardized charges per case, and determined a final inflated average case-weighted standardized charge per case of $150,213. The average case-weighted threshold amount in the FY 2015 IPPS Table 10 for these MS–DRGs was $97,505. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount of $97,505, the applicant maintained that the WATCHMAN® System meets the cost criterion using this analysis. We are inviting public comments on the whether the WATCHMAN® System meets the cost criterion based on this analysis.

In the applicant's second analysis, cases eligible for the WATCHMAN® System were identified by claims reporting ICD–9–CM procedure code 37.90 assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively). The applicant believed that these are the MS–DRGs to which cases are typically assigned if the WATCHMAN® System is used in the principal procedure performed during the inpatient stay. The applicant applied the trims in the FY 2015 IPPS/LTCH PPS final rule (79 FR49910 through 49911), which resulted in 369 cases.

As with its first analysis, the applicant determined standardized nondevice charges for the applicable cases using claims data from the FY 2013 MedPAR file and applied an inflation factor. The applicant calculated average nondevice charges by subtracting what the applicant believed was the average total implantable device charges (calculated as the sum of the five individual device charge fields in the MedPAR file that constitute the Implantable Device cost center). Similar to its first analysis, the applicant then standardized the charges, applied an inflation factor of 1.10443, subtracted the device charges reported on the MedPAR claims (reflecting costs during the IDE study) and replaced them with the anticipated charges following FDA approval (converting the costs of the device to charges with a CCR of 0.349 based on the national average implantable device CCR from the FY 2015 IPPS/LTCH PPS final rule (79 FR 49914)), combined those with the inflated average case-weighted standardized charges per case, and determined a final inflated average case-weighted standardized charge per case of $117,663. The average case-weighted threshold amount for these MS–DRGs in the FY 2015 IPPS Table 10 was $72,804. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted MS–DRG threshold amount of $72,804, the applicant maintained that the WATCHMAN® System meets the cost

criterion using this analysis. We note that the applicant searched for cases reporting ICD–9–CM procedure code 37.90. In section II.G.3.b. of the preamble of this proposed rule, we present a proposal regarding cardiac ablation and other specified cardiovascular procedures. Specifically, we are proposing to assign the procedures performed within the heart chambers using intracardiac techniques, including those identified by ICD–9–CM procedure code 37.90, to two new proposed MS–DRGs: Proposed MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and proposed MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC). We believe that this could have implications for determining whether the applicant meets the cost criterion. There have been instances in the past where the coding associated with a new technology application is included in a proposal to change one or more MS–DRGs. For example, in the FY 2013 IPPS/LTCH PPS final rule, we describe the cost analysis for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft which was identified by ICD–9–CM procedure code 39.78. In that same rule, we finalized a change to the assignment of that procedure code, reassigning it from MS–DRGs 252, 253, and 254 to MS–DRGs 237 and 238. Because of that change, we determined that, for FY 2013, in order for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft to meet the cost criteria, it must demonstrate that the average case-weighted standardized charge per case exceeds the thresholds for MS–DRGs 237 and 238 (77 FR 55360). We note that in that example, MS–DRGs 237 and 238 existed previously; therefore, thresholds that were 75 percent of one standard deviation beyond the geometric mean standardized charge for these DRGs were available to the public in Table 10 at the time the application was submitted. In this case, if MS–DRGs 273 and 274 were to be finalized for FY 2016, we recognize that thresholds that are 75 percent of one standard deviation beyond the geometric mean standardized charge would not have been available at the time the application was submitted. However, we believe that it could be appropriate for the applicant to demonstrate that the average case-weighted standardized charge per case exceeds these thresholds for MS–DRGs 273 and 274. Accordingly, we intend to calculate supplemental threshold values using the data used to generate the FY 2015 IPPS/LTCH PPS Table 10 and reassign the procedure codes in accordance with the proposals outlined in section II.G.3.b. of the preamble of this proposed rule. We intend to make these supplemental threshold values available for public consideration on our Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. We are inviting public comments on whether considering these supplemental threshold values as part of the cost criterion evaluation for this application is appropriate and also on how to address similar future situations in a broader policy context should they occur. We also are inviting public comments on the whether the WATCHMAN® System meets the cost criterion based on the applicant's analysis.

Regarding the substantial clinical improvement criterion, we note that the applicant applied for new technology add-on payments for FY 2015 (as discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28043 through 28045)). However, prior to the publication of the FY 2015 IPPS/LTCH PPS final rule, the applicant withdrew its application. Before the withdrawal of the application, CMS stated its concerns with the application in the FY 2015 IPPS/LTCH PPS proposed rule. The applicant included responses to CMS' previous concerns with the FY 2015 application in its FY 2016 application. Therefore, we are addressing the applicant's responses to the previous concerns specified in the FY 2015 IPPS/LTCH PPS proposed rule as well as our observations on the current FY 2016 application in this FY 2016 IPPS/LTCH PPS proposed rule.

The applicant asserted that the WATCHMAN® System, a system that reduces the risk of thromboembolic stroke in patients diagnosed with high-risk nonvalvular AF who are eligible for Warfarin therapy, but in whom the potential risks of Warfarin therapy outweigh the potential benefits, meets the substantial clinical improvement criterion because the WATCHMAN® System is superior to currently available treatments. The applicant claimed that the WATCHMAN® System is ideal for patients diagnosed with a prior hemorrhagic stroke while on Warfarin therapy, patients not adherent to Warfarin therapy, patients with difficulty achieving a therapeutic international normalized ratio (INR), and patients with an increased risk or history of falls. The applicant acknowledged that anticoagulation using Warfarin therapy or one of the novel oral anticoagulation agents (NOACs), such as dabigatran, rivaroxaban, or apixaban, is effective for preventing thromboembolism in patients who can tolerate such medication over the long term. However, these medications are associated with certain risks. The applicant stated that the most used and studied agent, Warfarin, requires dietary restrictions, has a high-risk of drug interactions, genetic variability in dose-response, and the need for frequent monitoring. According to the applicant, the average patient diagnosed with AF and treated with Warfarin therapy achieves a therapeutic INR for approximately one-half of the treatment time. The applicant further stated that these NOACs also have nonadherence risks, high discontinuation rates (up to 20 percent within 2 years), are difficult to monitor effectiveness, and in some cases have no readily available reversal strategy.

In support of its assertion that the WATCHMAN® System is a substantial improvement, the applicant submitted data from two pivotal studies (PROTECT AF and the WATCHMAN® Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL)). The data included results of a meta-analysis of the PROTECT AF and PREVAIL studies, an imputed placebo analysis, and a post hoc analysis of the bleeding risks associated with the WATCHMAN® System. According to the applicant, the clinical evidence from these trials and analyses establish the following: implantation of the WATCHMAN® System is safe; the WATCHMAN® System is superior to Warfarin when evaluated against a composite endpoint of all stroke, systemic embolism, and cardiovascular unexplained death in long-term follow-up; the WATCHMAN® System provides a greater reduction in major bleeding events after the conclusion of post procedure anti-thrombotic medication; and the WATCHMAN® System reduces the incidence of ischemic stroke when compared to patients diagnosed with AF who are not treated with Warfarin or other anticoagulation medication.

We note that, unlike in the FY 2015 application, the applicant did not include data from the ASAP study. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28043 through 28045), we expressed concerns that data from the ASAP study suggested that the device did not prevent strokes and was insufficient to demonstrate efficacy in the secondary patient population (patients diagnosed with AF who were ineligible for oral anticoagulation). We specifically stated that the ASAP

Registry (5) enrolled 150 patients, at one of four centers, that had a contraindication to even short-term anticoagulation, mostly a history of prior bleeding, and there was no control group. Device implantation led to a serious adverse event in 13 patients (8.7 percent), including one case of device thrombus leading to ischemic stroke. Five other patients had a device-related thrombus that did not lead to stroke (4 of these patients were treated with low molecular weight heparin), resulting in an overall 4.0 percent incidence (6 out of 150) of device-associated thrombus. In the PROTECT AF trial study, 20 of the 473 patients (4.2 percent) had device-associated thrombus, 3 of which led to an ischemic stroke. The rates of device-related thrombus are similar in the two studies (4.0 percent versus 4.2 percent), but the number of patients studied is smaller in the ASAP Registry (5) study compared to the PROTECT AF clinical trial study. In the 14-month follow-up data for the ASAP Registry (5) study, the rate of stroke or systemic embolism was 2.3 percent per year, which was said to be ''lower than expected'' based on prior data for patients diagnosed with AF who were not treated with warfarin (there was no concurrent control group). The data provided suggested efficacy in this patient population. However, we stated that we were concerned that there was not strong evidence that the device prevents stroke.

In the FY 2016 application, the applicant responded that, because the current intended use and indications for the WATCHMAN® System in the United States do not include patients who are ineligible for treatment using Warfarin therapy, the data from the ASAP study are irrelevant to the FY 2016 application. The applicant provided data from an imputed placebo analysis, a post-hoc analysis that compared the observed rate of ischemic strokes in patients treated with the WATCHMAN® System compared to no therapy, in order to address our concern that there was not strong evidence that the device prevented stroke.

According to the applicant, in the PROTECT AF trial, 463 patients were randomized to the WATCHMAN® System device and 244 patients to Warfarin therapy. Most patients randomized to the WATCHMAN® System device had it implanted (408 = 88 percent). Over the average 3.8 years of follow-up, more patients in the Warfarin therapy group withdrew (45 versus 15) or were lost to follow-up (11 versus 13) than in the WATCHMAN® System device group, leading to shorter mean follow-up (3.7 versus 3.9 years) in the Warfarin therapy group.

The applicant presented data shown in the following table and maintained that the results of the PROTECT study demonstrate primary efficacy and support that the WATCHMAN® System is noninferior and superior at 4 years.

TABLE 3—PROTECT PRIMARY EFFICACY SUPPORTS WATCHMAN® NON-INFERIORITY AND SUPERIORITY AT 4 YEARS

Patient years	Years of mean follow-up	WATCHMAN® System observed rate per 100 patient years	Warfarin observed rate per 100 patient years	Percentage reduction vs. warfarin (percent)	Posterior probability *		
					Non-inferiority (NI) (percent)	Superiority (S) (percent)	
1065	1.5	3	4.9	38	>99.9	90.00	NI.
1588	2.3	3	4.3	29	>99.9	84.60	NI.
2621	3.8	2.3	3.8	40	>99	96	NI and S.
2717	4	2.2	3.7	39	>99.9	95.40	NI and S.

* For Bayesian analysis, a posterior probability of 97.5 percent represents non-inferiority; ≥95 percent represents superiority.

In the FY 2015 IPPS/LTCH PPS proposed rule, we expressed concern that the evidence presented by the applicant demonstrating superiority compared to Warfarin therapy was insufficient. We expressed concern that the PROTECT AF trial was not designed to demonstrate superiority, and instead was designed to demonstrate noninferiority. We also expressed concern that the PREVAIL trial endpoint was not significantly improved in the conventional hypothesis testing statistical analysis at any time point. We stated that the longer term data showed improved efficacy and safety, but still remain sparse. In the FY 2016 application, the applicant stated that, under a Bayesian analysis, the distributions of the posterior probabilities are not symmetrical. According to the applicant, posterior probabilities represent the appropriate way to determine statistical significance in Bayesian methodology. As predefined in the PROTECT AF trial, a posterior probability for noninferiority of equal to or more than 97.5 percent, and a prespecified level of at least 95 percent to support superiority were the criteria for statistical testing. According to the applicant, in both cases (noninferiority and superiority), the criteria were met for long-term follow-up as demonstrated in the results of the PROTECT AF trial. We agree that the Bayesian methodology is a valid method of analysis. However, we were referencing the overall efficacy noninferiority in the PREVAIL trial.

We continue to be concerned that the data results from the PROTECT AF study are insufficient to show superiority of the WATCHMAN® System over Warfarin therapy. We note that the study was unblinded with a noninferiority design. We believe that the reduction in cardiovascular mortality shown in the results from the PROTECT AF study was unexpected and not well explained. Among the 57 patients in the WATCHMAN® System group who died, only 53 patient cases were assigned a cause of death and only 5 of the 9 ''unexplained/other deaths'' were included in the primary endpoint, although the protocol established that unexplained deaths were to be considered as cardiovascular mortalities. The total number of ''cardiovascular or unexplained deaths'' would have been 21, not 17. In the Warfarin therapy group, there was 1 ''unexplained/other'' death that should have been included in the primary endpoint, resulting in a total of 23, not 22. We acknowledge that it may be difficult to calculate the impact of these additional events as the intention-to-treat analysis of the primary endpoint. However, we are concerned that the inclusion of the additional deaths could have made the posterior probabilities for the device less favorable. Based on the data at face value, it appears that the WATCHMAN® System does not demonstrate statistically significant superiority over treatment with Warfarin therapy until 3.8 years has elapsed and the patient has been administered 6 months of oral anticoagulation and been exposed to the risk of the device-related complications. We are concerned that the applicant has

not demonstrated substantially improved clinical outcomes.

In the prospective randomized evaluation of the PREVAIL study, the goal was to assess the safety and efficacy of LAA occlusion for stroke prevention in patients diagnosed with NVAF compared to long-term Warfarin therapy. The PREVAIL study was a confirmatory randomized trial designed to further assess the efficacy and safety of the WATCHMAN® System device. Patient selection and study design were similar to the PROTECT AF study. Two efficacy and 1 safety coprimary endpoints were assessed at 18 months. The rate of the first coprimary efficacy endpoint overall efficacy (composite of stroke, systemic embolism [SE], and cardiovascular/unexplained death) was 0.064 in the WATCHMAN® System device group versus 0.063 in the control group (rate ratio 1.07 [95 percent credible interval (CrI) 0.57 to 1.89]) and did not achieve the prespecified criteria of noninferiority (upper boundary of 95 percent CrI 1.75). The rate for the second coprimary efficacy endpoint (stroke or SE >7 days' postrandomization) was 0.0253 versus 0.0200 (risk difference 0.0053 [95 percent CrI –0.0190 to 0.0273]), which achieved noninferiority. Early safety events were significantly lower than the results of the PROTECT AF study, which satisfies the prespecified safety performance goal. The PREVAIL study was designed to demonstrate noninferiority with wide efficacy margins. However, as previously stated, we are concerned that the results of the study did not show the overall efficacy of the technology to be noninferior.

The applicant submitted data from a patient-level meta-analysis that combined the data from the PROTECT AF study with the data from the PREVAIL study. According to the applicant, this analysis supports the efficacy of the WATCHMAN® System and shows that the device was performing as expected compared to the Warfarin therapy control arm. The datasets were combined and weighted. According to the applicant, multiple outcomes of interest were examined, starting with the primary efficacy endpoint and then looking at individual outcomes: All stroke (ischemic and hemorrhagic) and associated disability; systemic embolism; cardiovascular/unexplained death; and major bleeding. The overall incidence of all strokes (ischemic and hemorrhagic) was not statistically different in the WATCHMAN® System arm and the Warfarin therapy arm. However, the applicant stated that there were statistical differences identified when it analyzed the stroke subtypes. The applicant indicated that, initially, there were more ischemic strokes in the WATCHMAN® System arm. However, after accounting for early procedural complications, including strokes (within 7 days post procedure) in the PROTECT AF study, the difference for ischemic stroke between the two arms fell below statistical significance (p = 0.21). According to the applicant, there were significantly more hemorrhagic strokes and cardiovascular deaths in the Warfarin therapy arm compared to the WATCHMAN® System arm, showing a 78 percent and 52 percent reduction in those events respectively (p = 0.004 and p = 0.006). To better assess the clinical impact of the different subtypes of strokes on patients, the applicant also performed statistical tests on disabilities resulting from stroke. The applicant indicated that, using a validated stroke severity assessment tool (Modified Rankin score), analyses show that there were significantly less disabling strokes with the WATCHMAN® System than Warfarin therapy. The applicant believed that this represents a substantial clinical improvement for the WATCHMAN® System device.

The applicant conducted an imputed placebo analysis to assess the benefit that untreated patients may expect with the WATCHMAN® System device. The applicant contended that many patients who are eligible for Warfarin therapy are not receiving any treatment and, therefore, are left unprotected from stroke. With annual ischemic stroke rates ranging from 5.6 percent to 7.1 percent, the applicant maintained that the WATCHMAN® System device provides a substantive clinical benefit. In order to assess the benefit that untreated patients may be able to expect with the WATCHMAN® System, the sponsor performed the following exploratory analysis. The observed device ischemic strokes rates were compared against the estimated stroke risk of untreated nonvalvular AF patients. A placebo arm was then constructed using ''well-established, validated literature'' models based on both the CHADS2 and CHA2DS2–VASc scores. The applicant reported that this analysis showed the WATCHMAN® System device reduced stroke in the untreated patient population by 61 to 81 percent.

We previously expressed concern that there was a lack of strong evidence demonstrating that the WATCHMAN® System prevents stroke at all. The applicant responded that the imputed placebo analysis cited above addresses this concern. The applicant provided the table below as part of its FY 2016 application to show the relative risk reduction in Ischemic stroke rates using the WATCHMAN® System versus no therapy.

TABLE 5—WATCHMAN® SHOWS SIGNIFICANT REDUCTION IN ISCHEMIC STROKES COMPARED TO NO THERAPY

Study	Average CHADS (2 footnote on acronym) score WATCHMAN® patients	Observed WATCHMAN® annual ischemic stroke rate (95 percent CI)	Imputed untreated annual event rate	Relative risk reduction
PROTECT AF	2.2	1.3 (0.9, 2.0)	5.6–5.7	77% (64%, 84%)
PREVAIL-only	2.6	2.3 (1.3, 4.0)	6.6–6.7	65% (39%, 80%)
CAP	2.5	1.2 (0.8, 1.8)	6.4	81% (72%, 88%)

While the results of this analysis appear to suggest a large reduction in ischemic stroke rates in patients who did not receive any treatment, we continue to have some concerns regarding whether the WATCHMAN® System device prevents strokes. The indication for the treatment of the WATCHMAN® System device is for patients who are eligible for Warfarin therapy as opposed to patients who are ineligible for Warfarin therapy. We are concerned that the results of the imputed placebo analysis are not sufficient to determine whether the WATCHMAN® System reduces the risk of stroke in patients who are eligible for Warfarin therapy. The applicant suggested that patients who are subtherapeutic or noncompliant with Warfarin therapy would have the same risk of stroke as patients who do not receive any therapy. However, the applicant but did not offer any evidence

that these two groups have the same risk of stroke. The WATCHMAN® System device is intended only for use in patients who are eligible for the anticoagulation, not for patients who have contraindications to oral anticoagulation. Because the device will not be labeled for use in those patients, we believe that an analysis comparing stroke risk of untreated patients to those patients treated with the WATCHMAN® System is of limited value in assessing the technology's benefit over existing therapy.

The applicant asserted that one of the primary goals of mechanical LAA closure is to provide an alternative treatment for patients other than long-term Warfarin therapy and exposure to the associated risk for bleeding. Although the primary efficacy endpoint of the PROTECT AF and PREVAIL studies considered hemorrhagic stroke, it did not encompass other types of major bleeding that may be associated with the use of Warfarin. The applicant indicated that it performed a supplemental analysis to determine the relative risks of all types of bleeding. The applicant divided the follow-up interval into four subsections (7 days, 45 days, 6 months, and 54 months). The applicant compared bleeding events in the WATCHMAN® System group with the Warfarin therapy group and concluded that, after 6 months (and discontinued use of Clopidogrel in the WATCHMAN® System group), the continued use of Warfarin was associated with a 3.4 fold increase in the risk of major bleeding. According to the applicant, the significant reduction in bleeding after the procedural and concomitant medication therapy (6 months) with the cessation of long-term anticoagulants illustrates the substantial clinical benefit of the WATCHMAN® System. However, given the high burden endured (most notably, the higher risk of bleeding occurring in the first 7 days of an inpatient hospital stay) to achieve a reduction in bleeding in the long term, we do not believe that the WATCHMAN® System meets the criteria for substantially improved clinical outcomes. We are inviting public comments on whether this technology meets the substantial clinical improvement criterion, particularly in light of the applicant's response to our previous concerns and our current concern that there remains insufficient evidence that the WATCHMAN® System substantially improves clinical outcomes in patients diagnosed with nonvalvular AF and who are eligible for Warfarin therapy.

We did not receive any public comments in response to the New Technology Town Hall meeting held on February 13, 2015 in regard to the WATCHMAN® System technology.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2016 hospital wage index based on the statistical areas appears under sections III.A.2. and G. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2016 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.J. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2016 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply, beginning October 1, 2015 (to the FY 2016 wage index), appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed Rule

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico, and provided guidance on the use of the delineations of these statistical areas based on new standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and the 2010 Census of Population and Housing data (we refer to these revised OMB delineations as the ''new OMB delineations'' in this proposed rule). A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the new OMB labor market area delineations for the FY 2015 wage index. For FY 2016, we are continuing to use the new OMB delineations that we adopted beginning with FY 2015 to calculate the area wage indexes and the transition periods, which we discuss below.

B. Worksheet S–3 Wage Data for the Proposed FY 2016 Wage Index

The proposed FY 2016 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2012 (the FY 2015 wage indexes were based on data from cost reporting periods beginning during FY 2011).

1. Included Categories of Costs

The proposed FY 2016 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

• Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);

• Home office costs and hours;

• Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47318)); and

• Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2015, the proposed wage index for FY 2016 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2016 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the proposed wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2016 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2011, and before October 1, 2012. For wage index purposes, we refer to cost reports during this period as the ''FY 2012 cost report,'' the ''FY 2012 wage data,'' or the ''FY 2012 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4 for Form CMS–2552–10. The data file used to construct the proposed FY 2016 wage index includes FY 2012 data submitted to us as of February 25, 2015. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2016 wage index, we identified and excluded 93 providers with aberrant data that should not be included in the proposed wage index. If data elements for some of these providers with aberrant data are corrected, we intend to include data from those providers in the final FY 2016 wage index. We also adjusted certain aberrant data elements within a provider's data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for contract housekeeping and dietary services, we imputed estimates, in accordance with established policies as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than February 25, 2015. We intend to resolve all unresolved data elements by the date the FY 2016 IPPS/LTCH PPS final rule is issued. The revised data will be reflected in the FY 2016 IPPS/LTCH PPS final rule.

In constructing the proposed FY 2016 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2012, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For this FY 2016 IPPS/LTCH PPS proposed rule, we removed 12 hospitals that converted to CAH status on or after February 13, 2014, the cut-off date for CAH exclusion from the FY 2015 wage index, and through and including February 5, 2015, the cut-off date for CAH exclusion from the FY 2016 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, we calculated the proposed FY 2016 wage index based on 3,335 hospitals.

For the proposed FY 2016 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2015 wage index (79 FR 49964). Table 2, which contains the proposed FY 2016 wage index associated with this proposed rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 7 multicampus hospitals.

D. Method for Computing the Proposed FY 2016 Unadjusted Wage Index

The method used to compute the proposed FY 2016 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, and FY 2015 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, and 79 FR 49967, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2011, through April 15, 2013, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage for

FY 2016. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2011	11/15/2011	1.02167
11/14/2011	12/15/2011	1.02029
12/14/2011	01/15/2012	1.01893
01/14/2012	02/15/2012	1.01756
02/14/2012	03/15/2012	1.01620
03/14/2012	04/15/2012	1.01484
04/14/2012	05/15/2012	1.01348
05/14/2012	06/15/2012	1.01213
06/14/2012	07/15/2012	1.01080
07/14/2012	08/15/2012	1.00951
08/14/2012	09/15/2012	1.00825
09/14/2012	10/15/2012	1.00699
10/14/2012	11/15/2012	1.00568
11/14/2012	12/15/2012	1.00433
12/14/2012	01/15/2013	1.00292
01/14/2013	02/15/2013	1.00148
02/14/2013	03/15/2013	1.00000
03/14/2013	04/15/2013	0.98259

For example, the midpoint of a cost reporting period beginning January 1, 2012, and ending December 31, 2012, is June 30, 2012. An adjustment factor of 1.01080 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above, the proposed FY 2016 national average hourly wage (unadjusted for occupational mix) is $40.1203. The proposed FY 2016 Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $16.718.

E. Proposed Occupational Mix Adjustment to the FY 2016 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the Proposed FY 2016 Occupational Mix Adjustment Based on the 2013 Medicare Wage Index Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49967 through 49968), the occupational mix adjustment to the FY 2015 wage index was based on data collected on the 2010 Occupational Mix Survey Hospital Reporting Form (CMS–10079 (2010)). For the proposed FY 2016 wage index, we are proposing to use the occupational mix data collected on the new 2013 survey to compute the occupational mix adjustment for FY 2016, as discussed in section II.B.2. of the preamble of this proposed rule.

2. New 2013 Occupational Mix Survey for the Proposed FY 2016 Wage Index

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2010 to compute the occupational mix adjustment for the FY 2013, FY 2014, and FY 2015 wage index. Therefore, we were required to collect data in 2013 and are using these data to compute the occupational mix adjustment for the FY 2016 wage index.

On December 7, 2012, we published in the **Federal Register** a notice soliciting comments on the proposed 2013 Medicare Wage Index Occupational Mix Survey (77 FR 73032 through 73033). The new 2013 survey, which is being applied to the proposed FY 2016 wage index, includes the same data elements and definitions as the 2010 survey and provides for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). The comment period for the notice ended on February 5, 2013. After considering the public comments that we received on the December 2012 notice, we made a few minor editorial changes and published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/WAGE-INDEX-OCCUPATIONAL-MIX-SURVEY2013.pdf*.

The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html?DLPage=1&DLSort=1&DLSortDir=descending*. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site afterward, on July 11, 2014.

As with the Worksheet S–3 cost report wage data, we asked our MACs to revise or verify data elements in hospitals' occupational mix surveys that resulted in certain edit failures. Certain surveys with aberrant data elements are excluded from the proposed FY 2016 wage index, but any data elements resolved and revised in time to be included in the final wage index will be reflected in the FY 2016 IPPS/LTCH PPS final rule.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2016

For FY 2016, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, and FY 2015 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, 78 FR 50588 through 50589, and 79 FR 49968, respectively). As a result of applying this methodology, the proposed FY 2016 occupational mix adjusted national average hourly wage is $40.0853. The proposed FY 2016 occupational mix adjusted Puerto Rico-specific average hourly wage is $16.6329.

Because the occupational mix adjustment is required by statute, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2016 wage index. For the proposed FY 2016 wage index, because we are using the Worksheet S–3, Parts II and III wage data of 3,335 hospitals, and we are using the occupational mix surveys of 3,039 hospitals for which we also have Worksheet S–3 wage data, that represents a ''response'' rate of 91.1

percent (3,039/3,335). In the proposed FY 2016 wage index in this proposed rule, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

In the FY 2011 IPPS/LTCH PPS proposed rule and final rule (75 FR 23943 and 75 FR 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement was effective for the 2013 occupational mix survey as well as the 2010 occupational mix survey. We instructed MACs to continue gathering this information as part of the FY 2016 wage index desk review process. We stated that we would review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2016 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2016, we apply the occupational mix adjustment to 100 percent of the proposed FY 2016 wage index. We calculated the proposed occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the proposed FY 2016 wage index results in a proposed national average hourly wage of $40.0853 and a proposed Puerto-Rico specific average hourly wage of $16.6329. After excluding data of hospitals that either submitted aberrant data that failed critical edits or that did not have FY 2012 Worksheet S–3, Parts II and III, cost report data for use in calculating the proposed FY 2016 wage index, we calculated the proposed FY 2016 wage index using the occupational mix survey data from 3,039 hospitals. For the proposed FY 2016 wage index, because we are using the Worksheet S–3, Parts II and III wage data of 3,335 hospitals, and we are using the occupational mix survey data of 3,039 hospitals for which we also have Worksheet S–3 wage data, those data represent a ''response'' rate of 91.1 percent (3,039/3,335). The proposed FY 2016 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Proposed average hourly wage
National RN	38.70789914
National LPN and Surgical Technician	22.793680926
National Nurse Aide, Orderly, and Attendant	15.944111418
National Medical Assistant	18.009577806
National Nurse Category	32.783151666

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.783151666. Hospitals with a nurse category average hourly wage (as calculated in Step 4 of the occupational mix calculation) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6 of the occupational mix calculation) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4 of the occupational mix calculation) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6 of the occupational mix calculation) of greater than 1.0.

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42.54 percent, and the national percentage of hospital employees in the all other occupations category is 57.46 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 26.72 percent in one CBSA to a high of 80.55 percent in another CBSA.

The proposed FY 2016 Puerto Rico-specific average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Proposed Puerto Rico average hourly wage
Puerto Rico RN	16.762672135
Puerto Rico LPN and Surgical Technician	10.053073049
Puerto Rico Nurse Aide, Orderly, and Attendant	9.695410146
Puerto Rico Medical Assistant	21.962356196
Puerto Rico Nurse Category	14.563182257

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the Puerto Rico percentage of hospital employees in the nurse category is 49.93 percent, and the Puerto Rico percentage of hospital employees in the all other occupations category is 50.07 percent.

We also compared the proposed FY 2016 wage data adjusted for occupational mix from the 2013 survey to the proposed FY 2016 wage data adjusted for occupational mix from the 2010 survey. This analysis illustrates the effect on area wage indexes of using the 2013 survey data compared to the 2010 survey data; that is, it shows whether hospitals' wage indexes would increase or decrease under the 2013 survey data as compared to the prior 2010 survey data. Of the 407 urban CBSAs and 47 rural CBSAs, our analysis shows that the proposed FY 2016 wage index values for 183 (45.0 percent) urban areas and 20 (42.6 percent) rural areas would increase. Fifty-three (13.0 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and 5 (1.2 percent) urban areas would increase by 5 percent or more. Four (8.5 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas would increase by 5 percent or more. However, the proposed wage index values for 220 (54.1 percent) urban areas and 27 (57.4 percent) rural areas would decrease using the 2013 survey data. Seventy-two (17.7 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and one (0.2 percent) urban area would decrease by 5 percent or more. Seven (14.9 percent) rural areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no rural areas would decrease by 5 percent or more. The largest positive impacts using the 2013 survey data compared to the 2010 survey data are 15.0 percent for an urban area and 3.8 percent for a rural area. The largest negative impacts are 5.0 percent for an urban area and 1.9 percent for two rural areas. Four urban areas and no rural areas would be unaffected. These results indicate that the proposed wage indexes of more CBSAs overall (54.4 percent) would decrease due to application of the 2013 occupational mix survey data as compared to the 2010 occupational mix survey data to the wage index.

Further, a larger percentage of urban areas (45.0 percent) would benefit from the use of the 2013 occupational mix survey data as compared to the 2010 occupational mix survey data than would rural areas (42.6 percent).

We compared the proposed FY 2016 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 222 (54.5 percent) urban areas and 24 (51.1 percent) rural areas would increase. One hundred one (24.8 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and 6 (1.5 percent) urban areas would increase by 5 percent or more. Nine (19.1 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas would increase by 5 percent or more. However, the proposed wage index values for 185 (45.5 percent) urban areas and 23 (48.9 percent) rural areas would decrease. Ninety-three (22.9 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no urban areas would decrease by 5 percent or more. Eight (17.0 percent) rural areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no rural areas would decrease by 5 percent or more. The largest positive impacts would be 17.4 percent for an urban area and 2.7 percent for two rural areas. The largest negative impacts would be 4.7 percent for an urban area and 2.1 percent for a rural area. No urban or rural areas would remain unchanged by application of the proposed occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.5 percent) would benefit from application of the proposed occupational mix adjustment than would rural areas (51.1 percent).

G. Transitional Wage Indexes

1. Background

In the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28060 and 49957, respectively), we stated that, overall, we believed implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of the implementation of these new OMB labor market area delineations. We also realized that some hospitals would have higher wage index values due to the implementation of the new OMB labor market area delineations.

The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) explained the methodology utilized in implementing prior transition periods when adopting changes that have significant payment implications, particularly large negative impacts. Specifically, for FY 2005, in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we provided transitional wage indexes when the OMB definitions were implemented after the 2000 Census. The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962) established similar transition methodologies to mitigate any negative payment impacts experienced by hospitals due to our adoption of the new OMB labor market area delineations for FY 2015.

As finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49960) and as discussed below, for FY 2016, we are in the second year of two 3-year transition periods for wage index: one for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act); and one for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations. In addition, the 1-year transition that we applied in FY 2015 for hospitals that experienced a decrease in wage index under the new OMB delineations expires at the end of FY 2015 and does not apply in FY 2016.

2. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49959), for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we adopted a policy to assign them the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2016 will represent the second year of this transition policy, and we are not proposing any changes to this policy in this proposed rule. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957), we stated our belief that it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. We continue to believe that assigning the wage index of the hospitals' FY 2014 area for a 3-year transition is the simplest and most effective method for mitigating negative payment impacts due to the adoption of the new OMB delineations.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR49959), we noted that there were situations where a hospital could not be assigned the wage index value of the CBSA in which it geographically was located in FY 2014 because that CBSA split and no longer exists and some or all of the constituent counties were added to another urban labor market area under the new OMB delineations. If the hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, we established that hospitals located in such counties that became rural under the new OMB delineations were assigned the wage index of the urban labor market area that contains the urban county in their FY 2014 CBSA to which they are closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). Any such assignment made in FY 2015 will continue for FYs 2016 and 2017, except as discussed below. We continue to believe this approach minimizes the negative effects of the change in the OMB delineations.

Under the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, if a hospital for FY 2014 was located in an urban county that became rural for FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or such hospital seeks and is granted any reclassification or redesignation for FY 2016 or FY 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it. We established the transition policy to assist hospitals if they experience a negative payment

impact specifically due to the adoption of the new OMB delineations in FY 2015. If a hospital chooses to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the transition adjustment policy is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

As we did for FY 2015 (79 FR 49959), with respect to the wage index computation for FY 2016, we will follow our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, as we began with FY 2015, for FY 2016, the wage data of all hospitals receiving this type of 3-year transition adjustment will be included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations. After the 3-year transition period, beginning in FY 2018, these formerly urban hospitals discussed above will receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959) that the hospitals receiving this 3-year transition because they are in counties that were urban under the FY 2014 CBSA definitions, but are rural under the new OMB delineations, will not be considered urban hospitals. Rather, they will maintain their status as rural hospitals for other payment considerations. This is because our application of a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our adoption of the new OMB delineations. We did not establish transitions for other IPPS payment policies that may be impacted by our adoption of the new OMB delineations.

3. Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural Under the New OMB Delineations

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959 through 49960), there were some hospitals that, for FY 2014, were geographically located in rural areas but were deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals redesignated under section 1886(d)(8)(B) of the Act were no longer eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the FY 2015 policy we established for other hospitals in counties that were urban and became rural under the new OMB delineations, we finalized a policy to apply a 3-year transition to these hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural.

For FY 2016, we are not proposing any changes to this policy and will continue to the second year of the implementation of our policy to provide a 3-year transition adjustment to hospitals that are deemed urban under section 1886(d)(8)(B) of the Act under the FY 2014 labor market area delineations, but are considered rural under the new OMB delineations, assuming no other form of wage index reclassification or redesignation is granted. We assign these hospitals the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA was split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, such hospitals are assigned the wage index of the hospitals reclassified to the urban labor market area that contains the urban county in their FY 2014 redesignated CBSA to which they are closest. We assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area. This wage index assignment will be forfeited if the hospital obtains any form of wage index reclassification or redesignation.

4. Expiring Transition for Hospitals That Experience a Decrease in Wage Index Under the New OMB Delineations

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49960 through 49962), we stated that, while we believe that instituting the latest OMB labor market area delineations would create a more accurate wage index system, we also recognized that implementing the latest OMB delineations may cause some short-term instability in hospital payments. Therefore, in addition to the 3-year transition adjustments for hospitals being transitioned from urban to rural status as discussed earlier, in the FY 2015 IPPS/LTCH PPS final rule, we established a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index. This 1-year blended wage index expires at the end of FY 2015. We are not proposing any additional transition adjustment for hospitals that experienced a decrease in wage index values due to the adoption of the new OMB delineations for FY 2015 but, as discussed previously, will continue the 3-year transition adjustments for hospitals that changed from urban to rural status that we finalized in the FY 2015 IPPS/LTCH PPS final rule. We established a longer 3-year transition adjustment for hospitals losing urban status because there are significantly fewer affected urban-to-rural hospitals, and we believe the negative impacts to a hospital shifting from urban to rural status are typically greater than other types of transitions. We stated our belief that a transition period longer than 1 year to address other impacts of the adoption of the new OMB delineations would reduce the accuracy of the overall labor market area wage index system because far more hospitals would be affected. The 1-year transition for all negatively affected hospitals in FY 2015 provided an opportunity for hospitals to evaluate potential reclassification options, and mitigated initial negative impacts due to labor market assignment changes. We continue to believe that the adoption of the latest labor market delineations improves the accuracy and integrity of the hospital wage index system. Therefore, we believe it is necessary to allow this transition adjustment to expire.

5. Budget Neutrality

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), for FY 2015, we applied the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner. For FY 2016, we are proposing to apply the 3-year transition adjustments in a budget neutral manner. We are proposing to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on the proposed budget neutrality adjustment for FY 2016, we refer readers to section II.A.4.b. of the Addendum to this proposed rule.

H. Proposed Application of the Proposed Rural, Imputed, and Frontier Floors

1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the proposed FY 2016 wage index associated with this proposed rule, we estimated that 459 hospitals would receive an increase in their FY 2016 proposed wage index due to the application of the rural floor.

2. Proposed Imputed Floor for FY 2016

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy five times, the last of which was adopted in the FY 2015 IPPS/LTCH PPS final rule and is set to expire on September 30, 2015. (We refer readers to further discussions of the imputed floor in the FY 2014 and FY 2015 IPPS/LTCH PPS final rules (78 FR 50589 through 50590 and 79 FR 49969 through 49970, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States, Delaware, New Jersey, and Rhode Island, with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.J. of the preamble of this proposed rule).

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States, New Jersey and Rhode Island, and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI-MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 2 (formerly Table 4D) associated with the FY 2013 IPPS/LTCH PPS final rule, which is available via the Internet on the CMS Web site, included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor.

As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

For FY 2016, we are proposing to extend the imputed floor policy (both the original methodology and the

alternative methodology) for 1 additional year, through September 30, 2016, while we continue to explore potential wage index reforms. We are proposing to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this proposed additional 1-year extension. We are inviting public comments on the proposed additional 1-year extension of the imputed floor through September 30, 2016.

The wage index and impact tables associated with this FY 2016 IPPS/LTCH PPS proposed rule (which are available via the Internet on the CMS Web site) reflect the proposed continued application of the imputed floor policy at § 412.64(h)(4) and a proposed national budget neutrality adjustment for the imputed floor for FY 2016. There are 16 providers in New Jersey, and no providers in Delaware that would receive an increase in their proposed FY 2016 wage index due to the proposed continued application of the imputed floor policy under the original methodology and 4 hospitals in Rhode Island that would benefit under the alternative methodology.

3. Proposed State Frontier Floor

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161)). Forty-seven hospitals would receive the frontier floor value of 1.0000 for their FY 2016 wage index in this proposed rule. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. Although Nevada also is defined as a frontier State, its proposed FY 2016 rural floor value of 1.0300 is greater than 1.0000, and therefore, no Nevada hospitals would receive a frontier floor value for their FY 2016 wage index. We are not proposing any changes to the frontier floor policy for FY 2016.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2016 wage index are identified in Table 2 (formerly Table 4D) associated with this proposed rule, which is available via the Internet on the CMS Web site.

I. Proposed FY 2016 Wage Index Tables

We are proposing to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. The wage index tables have consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that are made available via the Internet on the CMS Web site. However, with the exception of Table 4E, we are proposing to streamline and consolidate these 11 tables into 2 tables. We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the proposed revisions to the wage index tables.

J. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS/LTCH PPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations that we are proposing for FY 2016, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

2. FY 2016 MGCRB Reclassifications

a. FY 2016 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2016 reclassification requests. Based on such reviews, there are 285 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2016. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2016, hospitals reclassified beginning in FY 2014 or FY 2015 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 275 hospitals approved for wage index reclassifications in FY 2014 that continue for FY 2016, and 312 hospitals approved for wage index reclassifications in FY 2015 that continue for FY 2016. Of all the hospitals approved for reclassification for FY 2014, FY 2015, and FY 2016, based upon the review at the time of this proposed rule, 872 hospitals are in a reclassification status for FY 2016.

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2016 will be incorporated into the wage index values published in the FY 2016 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2017

Applications for FY 2017 reclassifications are due to the MGCRB by September 1, 2015 (the first working day of September 2015). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2015, via the Internet on the CMS Web site at: *http://cms.gov/Regulations-andGuidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute if certain adjacency and commuting criteria are met. The criteria utilize standards for designating Metropolitan Statistical Areas published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2015, we used the new OMB delineations based on the 2010 Decennial Census data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties are referred to as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. The chart for this FY 2016 proposed rule with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

4. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, 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 DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.D. of the preamble of this proposed rule.)

In addition, we adopted a minor procedural change in that rule that allows a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. Therefore, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

K. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

1. Background

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

2. New Data Source for the Proposed FY 2016 Out-Migration Adjustment

When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau which was derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at the time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016. We have reviewed and analyzed the alternative dataset from the Census Bureau and are proposing new out-migration adjustments in this FY 2016 proposed rule, as discussed below (as we indicated we would in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49984 through 49985).

To determine the new out-migration adjustments and applicable counties that we are proposing for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. The tabulation was specific to hospital military and civilian employees (hospital sector Census code 8190/NAICS code 622) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico. For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.54 million resident addresses per year. The results of the ACS are used to formulate

descriptive population estimates, and, as such, the sample on which the dataset is based represents the actual figures that would be obtained from a complete count.

3. Proposed FY 2016 Out-Migration Adjustment

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. For FY 2016 and subsequent years, until such time that CMS finalizes out-migration adjustments based on the next Census, we are proposing that the out-migration adjustment be based on the data derived from the custom tabulation of the ACS described in section III.K.2. of the preamble of this proposed rule. As discussed above, we believe that these data are the most appropriate to establish qualifying counties because they are the most accurate and up-to-date data that are available to us. We are proposing that the FY 2016 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012 and we believe they continue to be appropriate for FY 2016. (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) Table 2 (formerly Table 4J) associated with this proposed rule (which is available via the Internet on the CMS Web site) lists the proposed out-migration adjustments for the FY 2016 wage index.

4. Use of Out-Migration Adjustment Data Applied for FY 2014 or FY 2015 for 3 Years

Section 1886(d)(13)(F) of the Act states that a wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49984 through 49985), we stated that even if we proposed to adopt new out-migration adjustment data for FY 2016, hospitals that are already receiving an out-migration adjustment beginning with a fiscal year prior to FY 2016 would still receive their out-migration adjustment based on the data used prior to FY 2016 for the years that remain of their 3-year qualification period in FY 2016 and after. Therefore, for FY 2016, hospitals that qualified in FY 2014 or FY 2015 to receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014 will continue to receive the same out-migration adjustment for the remainder of their 3-year qualification period. For example, if a hospital qualified for the out-migration adjustment in FY 2014, but also would qualify in FY 2016 under the proposed new commuting patterns and the new OMB labor market area delineations for FY 2016, this hospital will still receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014, regardless of whether the FY 2016 adjustment would be higher or lower than the adjustment based on FY 2014 data. If the hospital qualifies in FY 2017 (after the expiration of the 3-year qualifying period for the out-migration adjustment, which began in FY 2014) to receive the out-migration adjustment based on the new commuting data and OMB delineations in effect in FY 2017, it could receive the out-migration adjustment based on the new data for FYs 2017, 2018, and 2019. Conversely, for example, if a hospital qualified for the out-migration adjustment in FY 2014, but would *not* qualify in FY 2016 under the proposed new commuting patterns and the new OMB delineations for FY 2016, this hospital will still receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014.

Based on the new out-migration adjustment data used for this proposed rule, 325 hospitals would receive the out-migration adjustment for FY 2016. Of hospitals that were eligible for the out-migration adjustment for FY 2015 but whose 3-year qualifying period for the out-migration adjustment expired, 5 hospitals are no longer eligible for the out-migration adjustment under the new data (3 hospitals in Alabama, 1 hospital in Missouri, and 1 hospital in Ohio). Of the 325 hospitals, the out-migration adjustment of 243 hospitals would be unaffected, as these hospitals would receive the same out-migration adjustment because they are still within an existing 3-year eligibility period under the previous out-migration adjustment data. Of the 243 hospitals, 8 hospitals would have received a higher out-migration adjustment using the new data (1 hospital in Alabama, 2 hospitals in Massachusetts, 1 hospital in Michigan, and 4 hospitals in Pennsylvania) and 4 hospitals would have received a lower out-migration using the new data (1 hospital in Idaho, 2 hospitals in Oregon, and 1 hospital in South Carolina). Eighty-two hospitals would be newly eligible for the out-migration adjustment in FY 2016 using the new data. The following table shows the States and Territory in which the 82 affected hospitals are located:

State	Number of hospitals that would be newly eligible under the new out-migration data for FY 2016
Alabama	2
Arizona	2
California	6
Florida	3
Georgia	8
Idaho	1
Illinois	1
Indiana	3
Kansas	1
Louisiana	5
Maine	1
Massachusetts	0
Michigan	2
Minnesota	1
Mississippi	3
Missouri	1
North Carolina	4
Ohio	4
Oklahoma	2
Oregon	0
Pennsylvania	3
Puerto Rico	5
South Carolina	1
Tennessee	4
Texas	6
Vermont	1
Washington	5
West Virginia	4
Wisconsin	3
Totals	82

L. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2016 wage index were made available on May 23, 2014, and the preliminary CY 2013 occupational mix data files on July 11, 2014, through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital

community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated April 7, 2014, we instructed all MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the May 23, 2014 wage data files and July 11, 2014 occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by October 6, 2014. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the Internet, through the April 7, 2014 memorandum referenced above.

The MACs notified the hospitals by mid-February 2015 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-October revision requests. The MACs also submitted the revised data to CMS by December 16, 2014. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 13, 2015. Hospitals had until March 2, 2015, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or the MAC's mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by April 8, 2015. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the MAC's policy interpretations was April 15, 2015. We note that, as we did for the FY 2015 wage index, for the FY 2016 wage index, in accordance with the FY 2016 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2016-WI-Time-Table-Final.pdf*, the April appeals had to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*. Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2012 data used to construct the proposed FY 2016 wage index. We noted that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by February 27, 2015.

We will release the final wage index data public use files on May 1, 2015 on the Internet at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html*. The May 2015 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the MACs by April 8, 2015).

After the release of the May 2015 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before April 8, 2015.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 13, 2015 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the May 2015 final public use files, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital should notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than June 1, 2015. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2016 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2016-WI-Time-Table-Final.pdf*, the June appeals are required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by June 1, 2015) will be incorporated into the final wage index in the FY 2016 IPPS/LTCH PPS final rule, which will be effective October 1, 2015.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2016 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals have access to the final wage index data by May 1, 2015, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2016 wage index by August 2015, and the implementation of the FY 2016 wage index on October 1, 2015. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are

identified by hospitals and brought to our attention after June 1, 2015, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the June deadline for making corrections to the wage data for the following fiscal year's wage index (for example, June 1, 2015, for the FY 2016 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 1, 2015 deadline for the FY 2016 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 1, 2015 deadline for the FY 2016 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

M. Labor-Related Share for the Proposed FY 2016 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: ''The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. . . .'' We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this ''would result in lower payments to a hospital than would otherwise be made.'' However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate ''from time to time'' the proportion of hospitals' costs that are ''attributable to wages and wage-related costs.'' Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014 and for FY 2015 of 69.6 percent. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this proposed rule, for FY 2016, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2016, we are proposing to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2015.

Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site, reflect this proposed labor-related share. For FY 2016, for all IPPS hospitals whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indexes are greater than 1.0000, for FY 2016, we are proposing to apply the wage index to a proposed labor-related share of 69.6 percent of the national standardized amount. We note that, for Puerto Rico

hospitals, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0000.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50601 through 50603), we also rebased and revised the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as a base year. We finalized a labor-related share for the Puerto Rico-specific standardized amounts for FY 2014 of 63.2 percent. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49990), for FY 2015, we did not make any further changes to the Puerto Rico specific average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. For FY 2015, we continued to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2014.

For FY 2016, we are proposing to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2015. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. For FY 2016, we are proposing that the labor-related share of a hospital's Puerto Rico-specific rate would be either the Puerto Rico-specific labor-related share of 63.2 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a proposed Puerto Rico-specific wage index greater than 1.000 for FY 2016, we are proposing to set the hospital's rates using a labor-related share of 63.2 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount would result in higher payments. Conversely, a hospital with a proposed Puerto Rico-specific wage index of less than or equal to 1.000 for FY 2016 would be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share would result in higher payments. The proposed Puerto Rico labor-related share of 63.2 percent for FY 2016 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site.

N. Proposed Changes to 3-Year Average Pension Policy and Proposed Changes to the Wage Index Timetable Regarding Pension Costs for FY 2017 and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590), we revised our policy for reporting costs of qualified defined benefit pension plans for the Medicare wage index. Under that revised policy, the pension costs that are to be included in the wage index equal a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period or, if less than a 3-year period, the number of years that the hospital has sponsored a defined benefit plan. The 3-year average is centered on the base cost reporting period for the wage index. For example, the FY 2016 wage index will be based on Medicare cost reporting periods beginning during Federal FY 2012, and will reflect the average pension contributions made in a hospital's cost reporting period that began during Federal FYs 2011, 2012, and 2013. As stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51587), we centered the 3-year average on the base cost reporting period for the wage index in order to ensure that the average annual pension cost reflected in the wage index is consistent with the cost reporting period applicable to all other costs included in the index. We also stated that we did not anticipate that the use of contributions made in the period immediately following the base cost reporting period (for example, using Federal FY 2013 as one of the 3-year periods for FY 2016) would create an administrative burden because by the time the MAC would be reviewing a hospital's base cost reporting period wage data for inclusion in the subsequent year's wage index, trust account statements and general ledger reports to support the contributions should be readily available. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for a complete discussion of this policy.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49987 through 49990), we finalized changes to the FY 2017 wage index timeline. We stated that we believed the timeline changes would not only improve the accuracy of the February public use file (PUF), but also would reduce the number of hospital appeals based on the February PUF. Among these changes to the wage index timeline for FY 2017 is a requirement that hospitals must request revisions to the preliminary PUF by the first week of September 2015. In response to our FY 2015 proposal to change the wage index timeline for FY 2017, a public commenter stated that the proposed FY 2017 deadline of early August 2015 did not provide enough time for hospitals to incorporate their pension data into the desk review process because the Internal Revenue Service (IRS) Form 5500 (used as the basis for reporting pension contributions for defined benefit plans) is due 7 months after the end of the plan year (July 31), with possible extensions through mid-September. In response to that comment, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989), we provided for a general deadline of early September to submit revisions to the wage index data posted in the May 2015 preliminary PUF, but provided a limited exception for submission of pension data for certain hospitals. Specifically, starting with the FY 2017 wage index, we will allow an extension for a hospital with a fiscal year begin date on or after August 15 of a year to submit its initial pension data by mid-October 2015, which would revise the preliminary PUF. We stated that we believed the majority of hospitals, which do have fiscal year begin dates prior to August 15 of a year, would be able to submit their pension data, along with the remainder of their wage index documentation, to their MACs by the beginning of September of each year, in time for the beginning of the annual wage index desk review process. We also stated that, in future rulemaking, we may consider revisions to the 3-year average pension policy that would allow all hospitals to submit their pension data at the same time. We refer readers to the FY 2015 IPPS/LTCH PPS final rule for a complete discussion of the changes to the FY 2017 wage index timeline (79 FR 49987 through 49990).

We have now reconsidered the changes made to the FY 2017 wage index timeline in light of our experience to date with the administrative aspects of the 3-year average pension policy as explained above and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590). Based on our findings, we believe that a revision of the 3-year average pension policy is warranted, beginning with the FY 2017 wage index.

Specifically, in this FY 2016 proposed rule, instead of the 3-year average being centered on the base cost reporting period for the wage index, we are proposing that, for the FY 2017 wage index and all subsequent fiscal year wage indexes, the 3-year average would be based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years. For example, the FY 2017 wage index will be based on Medicare cost reporting

periods beginning during Federal FY 2013. Therefore, the FY 2017 wage index would reflect the average pension contributions made in hospitals' cost reporting periods beginning during Federal FYs 2011, 2012, and 2013 (rather than Federal FYs 2012, 2013, and 2014 under the current FY 2015 policy). Our proposed change in the 3-year averaging period would produce a 1-year lag in reporting pension costs relative to reporting all other costs included in the wage index and, for most hospitals, would result in the same 3-year average pension costs for both the FY 2016 and FY 2017 wage index. That is, for FY 2016, the 3-year average consists of Federal FYs 2011, 2012, and 2013, and under our proposal, the 3-year average for FY 2017 also would consist of Federal FYs 2011, 2012, and 2013. Under our proposal, the 3-year average for FY 2018 would consist of Federal FYs 2012, 2013, and 2014.

For FY 2017 only, we are proposing that all hospitals submit requests to revise their previously submitted pension data by early October to mid-October (instead of the first week of September, as stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989). We had anticipated proposing an early September deadline for all hospitals to submit revisions on all data in the preliminary PUF, including pension data. However, we realized that such a deadline would involve requiring hospitals to submit all of the revisions to pension data prior to the effective date of this rule. Therefore, we are proposing this deadline change of early October to mid-October so that all hospitals would submit revisions to their pension data by the same deadline, which should simplify the deadline for submitting those data as well as provide more time to most hospitals to submit these data. Because the pension data for FY 2017 would be the same pension data already used in FY 2016 (as mentioned above), we would expect minimal revisions to the pension data for FY 2017. Because we are proposing an extension until early to mid-October for all hospitals to revise their pension data for FY 2017, we are proposing to eliminate the limited exception and extension for hospitals with a fiscal year begin date of on or after August 15, as set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989). The exception is no longer necessary, given the proposed use of data from older cost reports for the 3-year averaging of pension costs and the proposed extension of time for submission of revisions of pension data for all hospitals for FY 2017. For FY 2018 and subsequent fiscal years, we are proposing to require that all hospitals request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September. The September deadline for FY 2018 and subsequent fiscal years is consistent with the deadline established in the FY 2015 IPPS/LTCH PPS final rule (7 FR 49989) for the FY 2017 wage index data. Specifically, in that final rule, in response to commenters, we established the early September deadline as a feasible deadline for hospitals to request revisions to their preliminary wage and occupational mix data. In addition, we also stated that a deadline in early September would be manageable for hospitals, while also providing the MACs with the most amount of time possible to complete their desk reviews.

This proposal also allows for a single deadline for all hospitals to submit revisions to their wage data, including their pension costs (as stated above). A single deadline is preferable because it would result in less confusion and would be easier to administer for all hospitals. In addition, the limited exception for hospitals with a fiscal year begin date of on or after August 15 would have provided administrative relief only to a minority of hospitals. Furthermore, in many cases, hospitals that participate in a systemwide pension plan or State-run retirement system have been unable to obtain timely documentation to support their allocated share of total plan contributions. We believe that a shift in the 3-year average to the base cost reporting period plus the prior 2 cost reporting years would provide all hospitals sufficient time to collect and submit their pension data by the proposed September deadline, and allow MACs to complete their desk reviews on schedule, thereby improving the accuracy of the February PUF.

For the reasons outlined above, we are proposing to revise the current policy used to compute the 3-year average for pension costs for the wage index, such that, beginning with the FY 2017 wage index, the 3-year average would be based on pension contributions made during the base cost reporting period plus the prior 2 cost reporting years.

The chart below includes the FY 2017 wage index timetable published in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989), except for the mid-October deadline for submitting pension data to the MACs for hospitals with fiscal year begin dates on or after August 15, which we are proposing to eliminate in this proposed rule. It also includes our proposal for FY 2017 for all hospitals to request revisions to their pension data by mid-October 2015 (rather than early October as published in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49989)).

FY 2017 WAGE INDEX TIMETABLE WITH PROPOSED DEADLINE FOR PENSION REVISIONS

Actions	Deadlines
Posting of Preliminary PUF on CMS Web site	Mid-May 2015.
Deadline for Hospitals to Request Revisions to Preliminary PUF	First week of September 2015.
Deadline for Hospitals to Request Revisions to Pension Data	Early October 2015 to Mid-October 2015.
Deadline for MACs to Complete Desk Reviews	Mid-November 2015.
Posting of January PUF on CMS Web site (formerly "February" PUF)	Late January 2016.
Deadline Following Posting of January PUF for Hospitals to Request Revisions	Mid-February 2016.
Completion of Appeals by MACs and Transmission of Final Wage Data to CMS	Mid to Late March 2016.
Deadline for Hospitals to Appeal in April	Early April 2016.
Posting of Final Rule PUF	Late April 2016.
Deadline for Hospitals to Appeal in May	Late May 2016.
Expected Issuance of IPPS Final Rule	August 1, 2016.

For FY 2018 and subsequent fiscal years, we are proposing the same timetable as in FY 2017, except there would no longer be a separate deadline in October for submitting and/or revising pension data. Rather, all requests to submit and/or revise pension data (as well as any other requests for revisions to the preliminary PUF) for FY

2018 and subsequent fiscal years would be required to be submitted by hospitals to MACs in the first week of September each year.

O. Clarification of Allocation of Pension Costs for the Wage Index

As discussed in section III.N. of the preamble of this proposed rule, the pension cost to be included in the Medicare wage index equals a hospital's average cash contributions deposited to its defined benefit pension plan over a 3-year period. Since implementing this policy, we have become aware of some confusion with respect to how hospitals are to compute the 3-year average when allocating their pension costs on the Medicare cost report if a hospital participates in a pension plan or retirement system that also covers other entities. In this FY 2016 IPPS/LTCH PPS proposed rule, we are clarifying that if a hospital participates in a pension plan or retirement system that also covers other entities the hospital must report its respective 3-year average pension cost (or prefunding balance) reflecting only the hospital's allocated share of total plan contributions, and *not* including any share of pension costs of other entities. For each hospital, this is accomplished by first determining the hospital's allocated portion of pension contributions for each year of the 3-year average, and then computing the 3-year average for that hospital based only on that hospital's respective allocated pension contributions. This is consistent with the regulations at 42 CFR 413.24(a), which state, in pertinent part, that providers must provide adequate cost data based on their financial and statistical records. Therefore, a provider may not claim as an allowable cost the costs of services associated with another entity. It is not appropriate to compute the 3-year average (or prefunding balance) based on the total contributions made to the plan by all participating entities and then determine a hospital's allocated portion of the 3-year average cost (or prefunding balance) because there are instances in which the 3-year average could be skewed because a hospital may be including pension costs from another entity in its 3-year average. Specifically, if the allocated percentage of total plan contributions for one or more of the participating entities changes during the 3-year average, the average will be skewed. The allocated percentage to each entity can change due to mergers, changes in plan coverage, or other factors. We also note that the allocation of contributions between the various entities participating in a pension plan or pension system should agree with the methodology used for plan reporting purposes and/or financial statement purposes, and the methodology used should be applied consistently over time. Furthermore, if wage index reporting is required for two or more hospitals covered under the same pension plan or retirement system, those hospitals should ensure that the allocation of plan contributions for each reporting period is determined on a consistent basis to avoid duplicate reporting of costs.

IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

A. Proposed Changes in the Inpatient Hospital Update for FY 2016 (§ 412.64(d))

1. Proposed FY 2016 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient operating costs by a factor called the ''applicable percentage increase.'' For FY 2016, we are setting the applicable percentage increase by applying the adjustments listed below in the same sequence as we did for FY 2015. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence: The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to (1) a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act; (2) a 66⅔ percent reduction to three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act; (3) an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and (4) an additional reduction of 0.2 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2016 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule, we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49993 through 49996), we continued to use the FY 2010-based IPPS operating and capital market baskets for FY 2015 and the labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket. For FY 2016, we are proposing to continue using the FY 2010-based IPPS operating and capital market baskets and the labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket.

Based on the most recent data available for this FY 2016 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2016 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2014, which is estimated to be 2.7 percent. We are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 market basket update and the MFP adjustment in the final rule.

For FY 2016, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount (as displayed in the table below).

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. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the

Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As described in the FY 2012 IPPS/LTCH PPS final rule, in order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the FY 2012 IPPS/LTCH PPS final rule, we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For FY 2016, we are proposing an MFP adjustment of 0.6 percentage point. Similar to the market basket update, for this proposed rule, we are using the most recent data available to compute the MFP adjustment. As noted above, we are proposing that if more recent data become subsequently available, we would use such data, if appropriate, to determine the FY 2016 market basket update and MFP adjustment in the FY 2016 IPPS/LTCH PPS final rule.

Based on the most recent data available for this proposed rule as described above, we have determined four proposed applicable percentage increases to the standardized amount for FY 2016, as specified in the table below:

PROPOSED FY 2016 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2016	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.35	0.0	−1.35
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.9	0.55	1.225	−0.125

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2016 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to modify paragraph (vi) of § 412.64(d)(1) to include the applicable percentage increase to the FY 2016 operating standardized amount.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, in this FY 2016 IPPS/LTCH PPS proposed rule, for FY 2016, we are proposing the following updates to the hospital-specific rates applicable to SCHs: A proposed update of 1.9 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 1.225 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of 0.55 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of −0.125 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As mentioned above, for this FY 2016 proposed rule, we used IGI's first quarter 2015 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2014. Similarly, we used IGI's first quarter 2015 forecast of the MFP adjustment. We are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the update for SCHs in the final rule.

We note that the MDH program expired for discharges beginning on April 1, 2015 under current law.

2. Proposed FY 2016 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific

standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.9 percent for FY 2016. For this proposed rule, we used the first quarter 2015 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2014. We are proposing that if more recent data become subsequently available, we would use such data, if appropriate, to determine the final FY 2016 applicable percentage increase for the final rule. We note that the provisions of section 1886(b)(3)(B)(viii) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, and the provisions of section 1886(b)(3)(B)(ix) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that are not meaningful EHR users, are not applicable to hospitals located in Puerto Rico.

Similarly, for this FY 2016 proposed rule, we used IGI's first quarter 2015 forecast of the MFP adjustment. We are proposing that if more recent data become subsequently available, we would use such data, if appropriate, to determine the MFP adjustment for the final rule.

B. Rural Referral Centers (RRCs): Proposed Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR Part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2016 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2016 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2014 (October 1, 2013 through September 30, 2014), and include bills posted to CMS' records through December 2014.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2015, they must have a CMI value for FY 2014 that is at least—

- 1.6075; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located. The proposed median CMI values by region are set forth in the following table.

Region	Proposed case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3737
2. Middle Atlantic (PA, NJ, NY)	1.4532
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5042
4. East North Central (IL, IN, MI, OH, WI)	1.5109
5. East South Central (AL, KY, MS, TN)	1.4172
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5890
7. West South Central (AR, LA, OK, TX)	1.6294
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7048
9. Pacific (AK, CA, HI, OR, WA)	1.6157

We intend to update the preceding CMI values in the FY 2016 final rule to reflect the updated FY 2014 MedPAR file, which would contain data from additional bills received through March 2015.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG–based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2016, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2013 (that is October 1, 2012 through September 30, 2013), which are the latest cost report data available at the time this proposed rule was developed.

We are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2015, must have, as the number of discharges for its cost reporting period that began during FY 2013, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,370
2. Middle Atlantic (PA, NJ, NY)	10,398
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,220
4. East North Central (IL, IN, MI, OH, WI)	7,951
5. East South Central (AL, KY, MS, TN)	7,439
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,858
7. West South Central (AR, LA, OK, TX)	5,355
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,480
9. Pacific (AK, CA, HI, OR, WA)	8,588

We intend to update these numbers in the FY 2016 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2016 (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2016, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2016 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident to bed ratio.

D. Proposed FY 2016 Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) (§ 412.106)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment

is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

2. Impact on Medicare DSH Payment Adjustment of the Continued Implementation of New OMB Labor Market Area Delineations

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951), we implemented the revised OMB labor market area delineations (which are based on 2010 Decennial Census data) for the FY 2015 wage index. (In this proposed rule, we refer to these revised OMB labor market area delineations as the ''new OMB delineations.'') We stated that this implementation would have an impact on the calculation of Medicare DSH payments to certain hospitals. Hospitals that are designated as rural with less than 500 beds and that are not rural referral centers (RRCs) are subject to a maximum DSH payment adjustment of 12 percent. Accordingly, hospitals with less than 500 beds that are currently in urban counties that became rural when we adopted the new OMB delineations, and that did not become RRCs, are subject to a maximum DSH payment adjustment of 12 percent. (We note that urban hospitals are only subject to a maximum DSH payment adjustment of 12 percent if they have less than 100 beds.)

Under the regulation at 42 CFR 412.102, a hospital located in an area that is reclassified from urban to rural, as defined in the regulations, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years. Specifically, the regulations state that, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the DSH payments as applicable to the hospital before its redesignation from urban to rural and the DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the DSH payments applicable to the hospital before its redesignation from urban to rural and the DSH payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

We note that we no longer make a distinction between the urban standardized amount and the rural standardized amount. Rather, hospitals receive the same standardized amount, regardless of their geographic designation. Accordingly, in the FY 2015 IPPS/LTCH PPS final rule, we revised the regulation at § 412.102 to remove references to the urban and rural standardized amounts.

The provisions of § 412.102 continue to apply with respect to the calculation of the DSH payments to hospitals that are currently located in urban counties that became rural under our adoption of the new OMB delineations. Specifically, the regulations state that, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the DSH payments as applicable to the hospital before its redesignation from urban to rural and the DSH payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the DSH payments applicable to the hospital before its redesignation from urban to rural and the DSH payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

For the purposes of ratesetting, calculating budget neutrality, and modeling payment impacts for this FY 2016 proposed rule, any hospital that was previously urban but changed to rural status in FY 2015 as a result of the adoption of the new OMB labor market area delineations will have its DSH payments modeled such that the payment equals the amount of the rural DSH payments plus one-third of the difference between the urban DSH payments and the rural DSH payments.

3. Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) Under Section 3133 of the Affordable Care Act

a. General Discussion

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a new section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.

Medicare DSH payments are calculated under a statutory formula that considers the hospital's Medicare utilization attributable to beneficiaries who also receive Supplemental Security Income (SSI) benefits and the hospital's Medicaid utilization. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive a disproportionate share hospital payment made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such a subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for each fiscal year. Therefore, this factor

amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who are uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment), minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf*.).

For FY 2018 and subsequent years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS, and the percent of individuals who are uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. Therefore, for FY 2018 and subsequent years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in that fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

b. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to *such subsection (d) hospitals* an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status on the cost report for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement

with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.

• *SCHs* that are paid under their hospital-specified rate are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *MDHs,* up until the expiration of the MDH program on March 31, 2015, were paid under the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Therefore, MDHs were eligible to receive Medicare DSH payments and uncompensated care payments if their disproportionate patient percentage was at least 15 percent. We applied the same process to determine MDH eligibility for Medicare DSH and uncompensated care payments, as we did for all other IPPS hospitals, through March 31, 2015 (79 FR 50007). Consistent with our policy of including a pro rata share of the uncompensated care payment amount for a period as part of the Federal rate payment in the comparison of payments under the hospital-specific rate and the Federal rate, for MDH payments for the first 6 months of FY 2015, we will include a pro rata share of the uncompensated care payment amount that reflects the period of time the hospital was paid under the MDH program for its discharges occurring on or after October 1, 2014, and before April 1, 2015 (79 FR 50008). Beginning April 1, 2015, all hospitals that previously qualified for MDH status no longer have MDH status under current law. Therefore, starting April 1, 2015, we determine eligibility for these hospitals as we do for all other IPPS hospitals.

If the MDH program were to be extended beyond its current expiration date of March 31, 2015, similar to how it was extended from October 1, 2013, to March 31, 2014, under the Pathway for SGR Reform Act (Pub. L. 113–67) and from April 1, 2014, to March 31, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), MDHs would continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). Because MDHs are paid based on the IPPS Federal rate and, therefore, are eligible to receive Medicare DSH payments if their disproportionate patient percentage is at least 15 percent, if the MDH program is extended beyond its current expiration date of March 31, 2015, we would continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status on the cost report for that payment year. In addition, as we do for all IPPS hospitals, we would calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 would be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

These policies for MDHs would only apply in FY 2016 if the MDH program is extended, by statute, beyond its current expiration date of March 31, 2015.

• *IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).

• *Hospitals participating in the Rural Community Hospital Demonstration Program* under section 410A of the Medicare Modernization Act do not receive DSH payments and, therefore, are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new DSH payment methodology (78 FR 50625 and 79 FR 50008). There are 20 hospitals currently participating in the demonstration.

c. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision simply by revising the claims payment methodologies to adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the final rule that can be found on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

d. Uncompensated Care Payments

As we have discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the

data sources and methodologies for computing each of these factors, our final policies for FY 2014 and FY 2015, and our proposed policies for FY 2016.

(1) Calculation of Proposed Factor 1 for FY 2016

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that it is a factor equal to the difference between (i) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) if this section did not apply for such fiscal year (as estimated by the Secretary); and (ii) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payment that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be ''estimated by the Secretary.'' Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2015, in order to determine Factor 1 in the uncompensated care payment formula for FY 2016, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act through rulemaking. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2016.

Therefore, in order to determine the two elements of Factor 1 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), in FYs 2014 and 2015, we used the most recently available projections of Medicare DSH payments for the applicable fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost report with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

For purposes of calculating Factor 1 and modeling the impact of this provision for this FY 2016 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's February 2015 Medicare DSH estimates, which are based on data from the December 2014 update of the Medicare Hospital Cost Report Information System (HCRIS), 2012 cost report data provided to CMS by IHS hospitals, and the FY 2015 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2015 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are not subject to the provisions of section 1886(r) of the Act, these hospitals were excluded from the February 2015 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified DSH payment (or 25 percent of DSH payments that would be made without regard to section 1886(r)), Maryland hospitals participating in the Maryland All-Payer Model and hospitals participating in the Rural Community Hospital Demonstration that do not receive DSH payments also are excluded from the Office of the Actuary's Medicare DSH estimates.

Using the data sources discussed above, the Office of the Actuary uses the most recently submitted Medicare cost report data to identify current Medicare DSH payments and the most recent DSH payment adjustments provided in the IPPS Impact File, and applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The February 2015 Office of the Actuary estimate for Medicare DSH payments for FY 2016, without regard to the application of section 1886(r)(1) of the Act, is approximately $13.338 billion. This estimate excludes Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and hospitals participating in the Rural Community Hospital Demonstration, as indicated earlier. Therefore, based on the February 2015 estimate, the estimate for empirically justified Medicare DSH payments for FY 2016, with the application of section 1886(r)(1) of the Act, is $3.335 billion (25 percent of the total amount estimated). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2016 is $10,003,425,327.39 ($13,337,900,436.52 minus $3,334,475,109.13). We are inviting public comments on our proposed calculation of Factor 1 for FY 2016.

The Office of the Actuary's estimates for FY 2016 begin with a baseline of $11.632 billion in Medicare DSH expenditures for FY 2012. The following table shows the factors applied to update this baseline through the current estimate for FY 2016:

FACTORS APPLIED FOR FY 2013 THROUGH FY 2016 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2012 BASELINE

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH payments (in billion)
2013	1.028	0.9844	1.014	1.0139	1.040394	$12.102
2014	1.009	0.9595	1.015	0.9993	0.98197	$11.884
2015	1.014	0.9885	1.005	1.0485	1.056207	$12.552
2016	1.011	1.0012	1.005	1.0446	1.062645	$13.338

In this table, the discharge column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FYs 2013 and 2014 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2015 is based on preliminary data for 2015. The discharge figure for FY 2016 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare FFS and also Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2013 and 2014 are based on actual data adjusted by a completion factor. The FY 2015 and FY 2016 increases are based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the increase in rates for the *Cape Cod* litigation and the reduction in rates for the 2-midnight stay policy). In addition, the ''other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act.

The next table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding percentage adjustment	Total update percentage
2013	2.6	−0.1	−0.7	−1.0	2.8
2014	2.5	−0.3	−0.5	−0.8	0.9
2015	2.9	−0.2	−0.5	−0.8	1.4
2016	2.7	−0.2	−0.6	−0.8	1.1

Note: All numbers are based on the FY 2016 President's Budget projections.

(2) Calculation of Proposed Factor 2 for FY 2016

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (I) who are uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (II) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(i)(I) of the Act further indicates that the percent of individuals under 65 without insurance in 2013 must be the percent of such individuals who are uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment). The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office ''*before* a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . .'' (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf.*)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including

unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure ''the percent of individuals under the age of 65 who are uninsured'' and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the applicable year with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals ''who are uninsured in the most recent period for which data is available (as so calculated).'' In the FY 2014 and FY 2015 IPPS/LTCH PPS final rules (78 FR 50634 and 79 FR 50014), we used the same data source, the most recent available CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, for this FY 2016 IPPS/LTCH PPS proposed rule, we used the CBO's January 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf*) to calculate the percent of individuals without insurance. The CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2015 is 87 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2015 is 13 percent (that is, 100 percent minus 87 percent.) Similarly, the CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2016 is 89 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 available for this proposed rule is 11 percent (that is, 100 percent minus 89 percent.)

The calculation of the proposed Factor 2 for FY 2016, employing a weighted average of the CBO projections for CY 2015 and CY 2016, is as follows:

- CY 2015 rate of insurance coverage (January 2015 CBO estimate): 87 percent.
- CY 2016 rate of insurance coverage (January 2015 CBO estimate): 89 percent.
- FY 2016 rate of insurance coverage: (87 percent * .25)+(89 percent * .75) = 88.5 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent
- Percent of individuals without insurance for FY 2016 (weighted average): 11.5 percent

$1-((0.115-0.18)/0.18) = 1-0.3611 = 0.6389$ (63.89 percent)

0.6389 (63.89 percent) − .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.6369 or 63.69 percent

0.6369 = Factor 2

Therefore, the proposed Factor 2 for FY 2016 is 63.69 percent. Our proposal for Factor 2 is subject to change if more recent CBO estimates of the insurance rate become available at the time of the preparation of the final rule. We are inviting public comments on our proposed calculation of Factor 2 for FY 2016.

The FY 2016 Proposed Uncompensated Care Amount is: $\$10,003,425,327.39 \times 0.6369 = \$6,371,181,591.01$.

FY 2016 Proposed Uncompensated Care Total Available	$6,371,181,591.01

(3) Calculation of Proposed Factor 3 for FY 2016

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of (i) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on the Worksheet S–10 and the completeness of these

data, we did not propose to use data from the Worksheet S–10 to determine the amount of uncompensated care for FY 2014, the first year this provision was in effect, or for FY 2015. We instead employed the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively, to determine Factor 3. We believed that this alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. We also indicated that we were expecting reporting on the Worksheet S–10 to improve over time and remained convinced that the Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals gain greater experience and are submitting more accurate and consistent data through this reporting mechanism.

For FY 2016, we believe it remains premature to propose the use of Worksheet S–10 for purposes of determining Factor 3 and, therefore, are proposing to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively) to determine Factor 3. We believe this methodology would give hospitals more time to learn how to submit accurate and consistent data through Worksheet S–10, as well as give CMS more time to continue to work with the hospital community and others to develop the appropriate clarifications and revisions to Worksheet S–10 to ensure standardized and consistent reporting of all data elements. Accordingly, we are proposing that, for FY 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with § 412.106(b)(2)(i) and (b)(4). We still intend to propose through future rulemaking the use of the Worksheet S–10 data for purposes of determining Factor 3. We are inviting public comments on this proposal to continue to use insured low-income days (that is, to use data for Medicaid and Medicare SSI patient days determined in accordance with § 412.106(b)(2)(i) and (b)(4) as a proxy as permitted by statute) to determine Factor 3 for FY 2016.

As we did for the FY 2014 IPPS/LTCH PPS proposed rule and FY 2015 IPPS/LTCH proposed rule, we will publish on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2016 (that is, hospitals that we project would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. Hospitals will have 60 days from the date of public display of this FY 2016 IPPS/LTCH PPS proposed rule to review these tables and notify CMS in writing of a change in a hospital's subsection (d) hospital status, such as if a hospital has closed or converted to a CAH. Comments can be submitted to the CMS inbox at *Section3131DSH@cms.hhs.gov*. After the publication of the FY 2016 IPPS/LTCH final rule, hospitals will have until August 31, 2015, to review and submit comments on the accuracy of these tables. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2015, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2015.

The statute also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital *for a period selected by the Secretary.* Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) *for such period.* In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments using the most recently available historical data and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), we finalized a policy to use the most recently available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios. This is consistent with the policy we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638) of calculating the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data (including the most recently available data that may be used to update the SSI ratios) with respect to a Federal fiscal year. In other words, we use data from the most recently available full year cost report for the Medicaid days, the most recent cost report data submitted to CMS by IHS hospitals, and the most recently available SSI ratios (that is, latest available SSI ratios before the beginning of the Federal fiscal year) for the Medicare SSI days. Therefore, to estimate Factor 3 for FY 2015, we used data from the most recently available full year cost report and the most recent cost report data submitted to CMS by IHS hospitals for the Medicaid days and the most recently available SSI ratios, which for FY 2015 were data obtained from the 2011/2012 cost reports and the 2010 cost report data submitted by IHS hospitals for the Medicaid days, and the FY 2012 SSI ratios for the Medicare SSI days.

Since the publication of the FY 2015 IPPS/LTCH PPS final rule, we have been informed by the hospital community that they are experiencing difficulties with submitting accurate data for Medicaid days within the timeframes noted in the Provider Reimbursement Manual, Part 2 for a variety of reasons, such as their ability to receive eligibility data from State Medicaid agencies. (As outlined in Section 104, Chapter 1, of the Provider Reimbursement Manual, Part 2, a hospital generally has 5 months after the close of its cost reporting period to file its cost report.) In addition, we have been informed that there is variation in the ability of hospitals and MACs, respectively, to submit and accept amended cost report data in time for the computation of Factor 3. While we continue to believe that it is important to use data that are as recent as possible, we recognize that from time to time the balance between recency and accuracy may require refinement. In the case of Factor 3, because we make prospective determinations of the uncompensated

care payment without reconciliation, we believe that it would increase the accuracy of the data used to determine Factor 3, and accordingly each eligible hospital's allocation of the overall uncompensated care amount, if we provided hospitals with more time to submit these data and MACs with more time to consider these submitted data before they are used in the computation of Factor 3. As we described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), it is not possible for us to wait for a later database update of the cost report data to calculate the final Factor 3 amount for the final rule because this could cause delay in the publication of the final rule. Therefore, we are unable to provide hospitals additional time to submit supplemental data, or for their MAC to consider and accept those data as applicable and appropriate. One alternative would be to use slightly older data within the most recent extract of the hospital cost report data in the HCRIS database. We believe that this would allow hospitals more time to submit data and MACs more time to consider and accept such data as applicable and appropriate.

Therefore, for the computation of Factor 3 for FY 2016, we are proposing to hold constant the cost report years used to calculate Factor 3 and to use data from the 12-month 2012 or 2011 cost reports and, in the case of IHS hospitals, the 2012 cost report data submitted to CMS by IHS hospitals. However, because a more recent HCRIS database is available at the time of this rulemaking, we are proposing that we continue to use the most recent HCRIS database extract available to us at the time of this annual rulemaking cycle. We note that, as in prior years, if the more recent of the two cost reporting periods does not reflect data for a 12-month period, we would use data from the earlier of the two periods so long as that earlier period reflects data for a period of 12 months. If neither of the two periods reflects 12 months, we would use the period that reflected a longer amount of time. We are proposing to codify this change for FY 2016 by amending the regulations at § 412.106(g)(1)(iii)(C). We are inviting public comments on this proposal, which we describe more fully below.

For the FY 2015 IPPS/LTCH PPS final rule, we used the more recent of the full year 2012 or full year 2011 data from the March 2014 update of the hospital cost report data in the HCRIS database and cost report data submitted to CMS by IHS hospitals as of March 2014 to obtain the Medicaid days to calculate Factor 3. In addition, we used the FY 2012 SSI ratios published on the following CMS Web site to calculate Factor 3: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.

In contrast, under our proposal, for FY 2016, we would use the more recent of the full year 2012 or full year 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database and the 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. In addition, to calculate Factor 3 for FY 2016, we anticipate that, under our proposal discussed above, we would use the FY 2013 SSI ratios to be published on the following CMS Web site when they become available: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. For illustration purposes, in Table 18 associated with this proposed rule (which is available via the Internet on the CMS Web site), we compute Factor 3 using the more recent of the full year 2012 or 2011 data from the December 2014 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and the FY 2012 SSI ratios published on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. We anticipate using the more recent of the full year 2012 or 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and the FY 2013 SSI ratios to determine the final Factor 3 for FY 2016.

For subsequent years, if we propose and finalize a policy of using insured low-income days in computing Factor 3, we intend to continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle, and to use the subsequent year of cost reports as applicable using the methodology described above (that is, to advance the 12-month cost reports by 1 year). We note that, starting with the 2013 cost reports, data for IHS hospitals will be included in the HCRIS. Therefore, if an IHS hospital has a 12-month 2013 cost reporting period in the HCRIS database, we will not need to use the 2012 data separately submitted to CMS by the IHS hospital. For example, if we finalize for FY 2017, a policy under which Factor 3 is determined on the basis of insured low-income days, this approach would result in the use of the more recent of the 12-month 2013 or 2012 cost reports in the most recent HCRIS database extract available at the time of rulemaking. In addition, for any subsequent years in which we finalize a policy to use insured low-income days to compute Factor 3, our intention would be to continue to use the most recently available SSI ratio data to calculate Factor 3 at the time of annual rulemaking. We believe that it is appropriate to state our intentions regarding the specific data we would use in the event Factor 3 is determined on the basis of low-income insured days for subsequent years to provide hospitals with as much guidance as possible so they may best consider how and when to submit cost report information in the future. We note that we will make proposals with regard to our methodology for calculating Factor 3 for subsequent years through notice-and-comment rulemaking.

We are proposing to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers for FY 2016 and subsequent fiscal years. In order to confirm mergers and ensure the accuracy of the data used to determine each merged hospital's uncompensated care payment, we will publish a table on the CMS Web site, in conjunction with the issuance of each Federal fiscal year's IPPS/LTCH PPS proposed and final rules, that contains a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of each year's IPPS/LTCH PPS proposed rule to review these tables and notify CMS in writing of any inaccuracies. After the publication of the IPPS/LTCH PPS final rule, hospitals will have until August 31 of that year (for FY 2016, the deadline is August 31, 2015) to review and submit comments on the accuracy of these tables for the applicable fiscal year. Comments can be submitted to our inbox at *Section3133DSH@cms.hhs.gov* through August 31, and any changes to Factor 3 will be posted on the CMS Web site prior to the start of the applicable fiscal year on October 1. We are inviting public comments on our proposal to continue these policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers as described above.

E. Hospital Readmissions Reduction Program: Proposed Changes for FY 2016 Through FY 2017 (§§ 412.150 through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new

section 1886(q) to the Act. Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program,'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those applicable hospitals may be reduced to account for certain excess readmissions.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to ''applicable hospitals'' will be adjusted to account for excess readmissions. In accordance with section 1886(q)(1) of the Act, payments for discharges from an ''applicable hospital'' will be an amount equal to the product of the ''base operating DRG payment amount'' and the adjustment factor for the hospital for the fiscal year. That is, ''base operating DRG payments'' are reduced by a hospital-specific adjustment factor that accounts for the hospital's excess readmissions. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as the payment amount that would otherwise be made under section 1886(d) of the Act (determined without regard to section 1886(o) of the Act [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act. Paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act refer to outlier payments, IME payments, DSH adjustment payments, and add-on payments for low-volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining the payment amount that would otherwise be made under section 1886(d) of the Act for certain hospitals, including policies for SCHs and for MDHs for FY 2013. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374), we finalized policies to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' with respect to those hospitals.

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of (i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. It states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. Section 1886(q)(3)(C) of the Act establishes the floor adjustment factor, which is set at 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act defines the terms ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as the sum, for applicable conditions of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1. The ''excess readmissions ratio'' is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of actual-over-expected readmissions; specifically, the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of ''applicable condition,'' ''expansion of applicable conditions,'' ''applicable hospital,'' ''applicable period,'' and ''readmission.'' The term ''applicable condition'' (which is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666)) is defined as a condition or procedure selected by the Secretary among conditions and procedures for which: (i) Readmissions represent conditions or procedures that are high volume or high expenditures and (ii) measures of such readmissions have been endorsed by the entity with a contract under section 1890(a) of the Act and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital). Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 2015, to the extent practicable, to expand the applicable conditions beyond the three conditions for which measures have been endorsed to the additional four conditions that have been identified by the MedPAC in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary.

Section 1886(q)(5)(C) of the Act defines ''applicable hospital,'' that is, a hospital subject to the Hospital Readmissions Reduction Program, as a subsection (d) hospital or a hospital that is paid under section 1814(b)(3) of the Act, as the case may be. The term ''applicable period,'' as defined under section 1886(q)(5)(D) of the Act, means, with respect to a fiscal year, such period as the Secretary shall specify. As explained in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), the ''applicable period'' is the period during which data are collected in order to calculate various ratios and payment adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the public reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for *all* hospital inpatients (not just Medicare patients) for a broad range of both subsection (d) and nonsubsection (d) hospitals in order to calculate the hospital-specific readmission rates for all such hospital inpatients and to publicly report these ''all-patient'' readmission rates.

2. Regulatory Background

The payment adjustment factor set forth in section 1886(q) of the Act did not apply to discharges until FY 2013. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which will be used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of ''readmission'' and ''applicable period,'' and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmission for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmission payment

adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the ''applicable conditions'' for FY 2015 and subsequent fiscal years, and clarification of the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), we made refinements to the readmissions measures and related methodology for applicable conditions for FY 2015 and subsequent fiscal years, expanded the ''applicable conditions'' for FY 2017 and subsequent fiscal years, discussed the maintenance of technical specifications for quality measures, and described a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)). We also specified the applicable period for FY 2015 and made changes to the calculation of the aggregate payments for excess readmissions to include two additional applicable conditions for the FY 2015 payment determination.

3. Overview of Proposed Policies Changes for the FY 2016 and FY 2017 Hospital Readmissions Reduction Program

In this proposed rule, we are proposing to—

- Make a refinement to the pneumonia readmissions measure, which would expand the measure cohort, for the FY 2017 payment determination and subsequent years (section IV.E.4. of the preamble of this proposed rule); and
- Adopt an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years (section IV.E.9. of the preamble of this proposed rule).

4. Proposed Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure Cohort for the FY 2017 Payment Determination and Subsequent Years

a. Background

In this proposed rule, for the FY 2017 payment determination and subsequent years, we are proposing a refinement of the currently National Quality Forum (NQF) endorsed CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) (hereafter referred to as the CMS 30-Day Pneumonia Readmission Measure (NQF #0506)), which expands the measure cohort. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria, and we are proposing an expansion to this set of hospitalizations. The previously adopted CMS 30-day Pneumonia Readmission Measure (NQF #0506) included hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For measure cohort details of the currently implemented measure, we refer readers to the measure methodology report and measure risk adjustment statistical model on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. Including such patients would better represent the complete population of a hospital's patients who are receiving clinical management and treatment for pneumonia, as well as to ensure the measure includes more complete and comparable populations across hospitals. In addition, use of comparable populations would reduce measurement bias resulting from different coding practices seen across hospitals. We believe that measure results derived from refinement of the measure cohort in the manner we are proposing would improve the measure's assessment of avoidable readmissions and more accurately reflect quality and outcome for pneumonia patients. The determination to refine the measure cohort was based on our evaluation of both the frequency and variation in utilization of these diagnosis codes, and as such coding practices have been described in recently published studies. The rationale for expanding the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) is further described in section VIII.A.6.b. of the preamble of this proposed rule under our discussion of proposed refinements for the Hospital IQR Program.

b. Overview of Measure Cohort Change

The proposed measure refinement would expand the cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, and assessment of the outcome of readmission remain unchanged.

The proposed refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) with this expanded measure cohort was reviewed by the Measure Applications Partnership (MAP), which conditionally supported use of the measure update for the Hospital Readmissions Reduction Program pending NQF review of the measure update and appropriate consideration under the NQF sociodemographic status pilot, if required, as detailed in its Pre-Rulemaking 2015 MAP Recommendations Report available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. This measure will be submitted to NQF for reendorsement when the appropriate project has its call for measures in 2015.

We note that during the MAP Hospital Workgroup and MAP Coordinating Committee in-person meetings, some members discussed the benefit of a phased approach that would first allow for public reporting of the refined measure before implementing it in a pay-for-performance program in order to allow providers to gain experience with the measure refinement, while other members expressed concern that this would delay implementation of an improved measure and also cause

alignment issues and potential confusion among providers. The MAP supported the use of the measure refinement without stipulating prior public reporting as a condition of support. However, we acknowledge the importance of this consideration and took it into account when determining to propose implementation of the measure refinement in the Hospital Readmissions Reduction Program beginning with the FY 2017 payment determination.

We considered other options in proposing when to implement the refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program, including the option to implement the measure refinement beginning with the FY 2018 payment determination. Delaying implementation of the measure refinement until FY 2018 would allow hospitals to gain more experience with the impact of the measure refinement on their measure results and excess readmissions ratios. However, it also would mean delaying use of an improved measure that we believe will better represent the complete population of a hospital's pneumonia patients and better reflect comparable pneumonia patients across hospitals. Delaying implementation of the measure refinement for the Hospital Readmissions Reduction Program could also potentially increase confusion among hospitals as well as raise alignment issues with other CMS hospital inpatient quality reporting and payment programs that use the same measure.

After considering these options, we are proposing to begin with the FY 2017 payment determination to implement the refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in the Hospital Readmissions Reduction Program. We believe that after weighing the considerations, the proposed measure refinement should be incorporated into the Hospital Readmissions Reduction Program as soon as statutorily and operationally feasible, primarily because improving the measure in the manner we are proposing will greatly improve the measure's assessment of quality and outcome for pneumonia patients and, therefore, its implementation should not be unnecessarily delayed.

c. Risk Adjustment

The risk adjustment and statistical modeling approach as well as the measure calculation remain unchanged from the previously adopted measure. However, we did confirm the use of current risk-adjustment variables in the expanded measure cohort by confirming their association with the outcome. We also examined additional risk variables leading to the addition of a few additional risk variables in the measure. For the full measure specifications of the proposed refinement of the measure cohort, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

d. Anticipated Effects of Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure (NQF #0506) Cohort

Using administrative claims data for FY 2015 (that is, discharges between July 2010 and June 2013), we analyzed and simulated the effect of the proposed measure cohort refinements on the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) as if these changes had been applied for the Hospital Readmissions Reduction Program FY 2015 payment determination. We note that these statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for FY 2015, nor for FY 2016. Rather, we are proposing to apply these changes to the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2017 payment determination and subsequent years. Based on our analysis, we anticipate that expanding the measure cohort to include a broader population of patients would add a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases), to the CMS 30-Day Pneumonia Readmission Measure (NQF #0506). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51672), we established that if a hospital has fewer than 25 eligible cases for a measure, we will assign the hospital to a separate category indicating that the number of cases is too small to reliably indicate how well the hospital is performing. These cases are still used to calculate the measure. However, for hospitals with fewer than 25 eligible cases, the hospital's readmission rates and interval estimates will not be publicly reported for the measure. The increase in the size of the measure cohort proposed in this proposed rule would change results for many hospitals and would change the number of hospitals that have greater than 25 cases.

The previously adopted pneumonia readmission measure cohort for the Hospital Readmissions Reduction Program included 976,471 patients and 3,137 hospitals for FY 2015. We noted the following effects for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) if the expanded cohort had been applied for FY 2015: (1) The expansion of the readmission cohort would include an additional 634,519 patients (representing a 65 percent increase, for a total measure cohort of 1,610,990 patients); (2) an additional 42 hospitals (representing a 1.3 percent increase) would meet the minimum 25 patient cases volume threshold over the 3-year applicable period and would be publicly reported for the measure; (3) patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission would represent 40 percent of the total expanded measure cohort; (4) the national observed readmission rate would increase by 0.9 absolute percentage points; and, (5) the proposed cohort refinement would affect the excess readmissions ratios for some hospitals. A detailed description of the refinement to the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) and the effects of the measure update are available on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

e. Calculating the Excess Readmissions Ratio

The proposed refinement of the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) would use the same methodology and statistical modeling approach as the previously adopted CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the Hospital Readmissions Reduction Program, as well as the other Hospital Readmissions Reduction Program measures. We published a detailed description of how the readmission measures estimate the excess readmissions ratios in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

We note that the set of hospitals for which this refined measure would be calculated for the Hospital Readmissions Reduction Program differs from those used in calculations for the Hospital IQR Program. The Hospital Readmissions Reduction Program includes only subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act (and, if not waived from participating, those hospitals paid under section 1814(b)(3) of the Act), while the

Hospital IQR Program calculations include non-IPPS hospitals, such as CAHs, cancer hospitals, and hospitals located in the Territories of the United States. However, we believe that adoption of the refinement to the measure cohort for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) would be appropriate for both programs.

In summary, we are proposing a refinement of the NQF endorsed CMS 30-Day Pneumonia Readmission Measure (NQF #0506), which expands the measure cohort, in the Hospital Readmissions Reduction Program for the FY 2017 payment determination and subsequent years.

We are inviting public comment on this proposal.

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our Web site in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet Web site on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*.

6. Floor Adjustment Factor for FY 2016 (§ 412.154(c)(2))

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of (i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor, which is set at 0.97 for FY 2015 and subsequent fiscal years. We codified the floor adjustment factor at § 412.154(c)(2) of the regulations (77 FR 53386).

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), the adjustment factor is either the greater of the ratio or, for FY 2015 and subsequent fiscal years, a floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2015 and subsequent fiscal years, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

7. Proposed Applicable Period for FY 2016

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

Consistent with the definition specified at § 412.152, we established that the applicable period for FY 2014 under the Hospital Readmissions Reduction Program is the 3-year period from July 1, 2009, to June 30, 2012. That is, we determined the excess readmissions ratios and calculate the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2014 using data from the 3-year time period of July 1, 2009 through June 30, 2012, as this was the most recent available 3-year period of data upon which to base these calculations (78 FR 50669).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 40 through 50041), for FY 2015, consistent with the definition specified at § 412.152, we finalized an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2010 through June 30, 2013. That is, we determined the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2015 using data from the 3-year time period of July 1, 2010 through June 30, 2013.

In this proposed rule, for FY 2016, consistent with the definition specified at § 412.152, we are proposing an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2011 through June 30, 2014. In other words, we are proposing that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 using data from the 3-year time period of July 1, 2011 through June 30, 2014.

8. Proposed Calculation of Aggregate Payments for Excess Readmissions for FY 2016

a. Background

Under the Hospital Readmissions Reduction Program the ''base operating DRG payment amount'' defined at § 412.152 is used both to determine the readmission adjustment factor that accounts for excess readmissions under section 1886(q)(3) of the Act and to determine which payment amounts will be adjusted to account for excess readmissions under section 1886(q) of the Act. Consistent with section 1886(q)(2) of the Act, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53383), under the regulations at § 412.152, we define the ''base operating DRG payment amount'' and specify that it does not include adjustments or add-on payments for IME, DSH, outliers and low-volume hospitals as required by section 1886(q)(2) of the Act. Furthermore, consistent with section 1886(q)(2)(B)(i) of the Act, for SCHs and for MDHs for FY 2013, the definition of ''base operating DRG payment amount'' at § 412.152 excludes the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate.

For FY 2015 and subsequent years, for purposes of calculating the payment adjustment factors and applying the payment methodology, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50041 through 50048), we finalized our policy that the base operating DRG payment amount for MDHs includes the difference between the hospital-specific payment rate and the Federal payment rate (as applicable). Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess

readmissions and (ii) the aggregate payments for all discharges. The definition of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges,'' as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) are codified at § 412.154(c)(2) of the regulations (77 FR 53387).

Section 1886(q)(4) of the Act sets forth the definitions of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as for a hospital for an applicable period, the sum, for applicable conditions of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1. We codified this definition of ''aggregate payments for excess readmissions'' under the regulations at § 412.152 as the product, for each applicable condition, of: (1) The base operating DRG payment amount for the hospital for the applicable period for such condition; (2) the number of admissions for such condition for the hospital for the applicable period; and (3) the excess readmissions ratio for the hospital for the applicable period minus 1 (77 FR 53675).

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition. The methodology for the calculation of the excess readmissions ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). ''Aggregate payments for excess readmissions'' is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program (as described in further detail later in this section).

The term ''aggregate payments for all discharges'' is defined at section 1886(q)(4)(B) of the Act as for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period. ''Aggregate payments for all discharges'' is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. We codified this definition of ''aggregate payments for all discharges'' under the regulations at § 412.152 (77 FR 53387).

We finalized the inclusion of one additional applicable condition, Patients Readmitted Following Coronary Artery Bypass Graft (CABG) Surgery, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50033 through 50039) effective for FY 2017. We will address the inclusion of this additional measure in the calculation of the readmissions payment adjustment for FY 2017 in the FY 2017 rulemaking.

b. Proposed Calculation of Aggregate Payments for Excess Readmissions for FY 2016

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. ''Aggregate payments for excess readmissions'' (the numerator) is defined as the sum, for applicable conditions of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

For FY 2016, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2011, and no later than June 30, 2014. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

The FY 2011 through FY 2014 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and detailed instructions for how to order the data sets. Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

- If using the U.S. Postal Service: Centers for Medicare and Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.
- If using express mail: Centers for Medicare and Medicaid Services, OFM/Division of Accounting—RDDC, Mailstop C#–07–11, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For this FY 2016 proposed rule, we are proposing to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2011, and no later than June 30, 2014. However, we note that, for the purpose of modeling the proposed FY 2016 readmissions payment adjustment factors for this proposed rule, we use excess readmissions ratios for applicable hospitals from the FY 2015 Hospital Readmissions Reduction Program applicable period. For the FY 2016 final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2016 applicable period of July 1, 2011 to June 30, 2014, before they are made public under our policy regarding the reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

In this proposed rule, for FY 2016, we are proposing to use MedPAR data from July 1, 2011 through June 30, 2014. Specifically, in this proposed rule, we are using the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011 with discharges dates that are on or after July 1, 2011, the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012, the March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013, and the December 2014

update of the FY 2014 MedPAR file to identify claims within FY 2014 with discharge dates no later than June 30, 2014. For the final rule, we are proposing to use the same MedPAR files as listed above for claims within FY 2011, FY 2012 and FY 2013. For claims within FY 2014, we are proposing to use in the final rule the March 2015 update of the FY 2014 MedPAR file.

In order to identify the admissions for each condition, to calculate the aggregate payments for excess readmissions for an individual hospital, for FY 2016, we are proposing to identify each applicable condition using the ICD–9–CM codes used to identify applicable conditions to calculate the excess readmissions ratios. (Although the compliance date for the ICD–10–CM and ICD10–PCS code sets is October 1, 2015 (79 FR 45128 through 45134), these proposed policies apply to data periods prior to this compliance date.) Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50041 through 50048) for a discussion of how we identify the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2015. For FY 2016, we are proposing to follow this same approach.

In this proposed rule, for FY 2016, we are proposing to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2015 for the current applicable conditions. For FY 2016, in order to have the same types of admissions to calculate aggregate payments for excess readmissions as is used to calculate the excess readmissions ratio, we are proposing to identify admissions for the AMI, HF, PN, THA/TKA, COPD applicable conditions, for the purposes of calculating aggregate payments for excess readmissions as follows:

- We would exclude admissions that are identified as an applicable condition if the patient died in the hospital, as identified by the discharge status code on the MedPAR claim.
- We would exclude admissions identified as an applicable condition for which the patient was transferred to another provider that provides acute care hospital services (that is, a CAH or an IPPS hospital), as identified through examination of contiguous stays in MedPAR at other hospitals.
- We would exclude admissions identified as an applicable condition for patients who are under the age of 65, as identified by linking the claim information to the information provided in the Medicare Enrollment Database.
- For conditions identified as AMI, we would exclude claims that are same day discharges, as identified by the admission date and discharge date on the MedPAR claim.
- We would exclude admissions for patients who did not have Medicare Parts A and B FFS enrollment in the 12 months prior to the index admission, based on the information provided in the Medicare Enrollment Database.
- We would exclude admissions for patients without at least 30 days post-discharge enrollment in Medicare Parts A and B FFS, based on the information provided in the Medicare Enrollment Database.
- We would exclude all multiple admissions within 30 days of a prior index admission's discharge date, as identified in the MedPAR file, consistent with how multiple admissions within 30 days of an index admission are excluded from the calculation of the excess readmissions ratio.

These exclusions are consistent with our current methodology, which was established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048).

Furthermore, we would only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C (Medicare Advantage) would not be included in this calculation), consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2016, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This policy is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology. The tables below list the ICD–9–CM codes we are proposing to use to identify each applicable condition to calculate the aggregate payments for the excess readmissions proposal for FY 2016. These ICD–9–CM codes also would be used to identify the applicable conditions to calculate the excess readmissions ratios, consistent with our established policy (76 FR 51673 through 51676).

ICD–9–CM CODES TO IDENTIFY PNEUMONIA (PN) CASES

ICD–9–CM code	Description of code
480.0	Pneumonia due to adenovirus.
480.1	Pneumonia due to respiratory syncytial virus.
480.2	Pneumonia due to parainfluenza virus.
480.3	Pneumonia due to SARS-associated coronavirus.
480.8	Viral pneumonia: Pneumonia due to other virus not elsewhere classified.
480.9	Viral pneumonia unspecified.
481	Pneumococcal pneumonia [streptococcus pneumoniae pneumonia].
482.0	Pneumonia due to klebsiella pneumoniae.
482.1	Pneumonia due to pseudomonas.
482.2	Pneumonia due to hemophilus influenzae [h. influenzae].
482.30	Pneumonia due to streptococcus unspecified.
482.31	Pneumonia due to streptococcus group a.
482.32	Pneumonia due to streptococcus group b.
482.39	Pneumonia due to other streptococcus.
482.40	Pneumonia due to staphylococcus unspecified.
482.41	Pneumonia due to staphylococcus aureus.
482.42	Methicillin Resistant Pneumonia due to Staphylococcus Aureus.
482.49	Other staphylococcus pneumonia.

ICD–9–CM CODES TO IDENTIFY PNEUMONIA (PN) CASES—Continued

ICD–9–CM code	Description of code
482.81	Pneumonia due to anaerobes.
482.82	Pneumonia due to escherichia coli [e.coli].
482.83	Pneumonia due to other gram-negative bacteria.
482.84	Pneumonia due to legionnaires' disease.
482.89	Pneumonia due to other specified bacteria.
482.9	Bacterial pneumonia unspecified.
483.0	Pneumonia due to mycoplasma pneumoniae.
483.1	Pneumonia due to chlamydia.
483.8	Pneumonia due to other specified organism.
485	Bronchopneumonia organism unspecified.
486	Pneumonia organism unspecified.
487.0	Influenza with pneumonia.
488.11	Influenza due to identified novel H1N1 influenza virus with pneumonia.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE (HF) CASES

ICD–9–CM code	Code description
402.01	Hypertensive heart disease, malignant, with heart failure.
402.11	Hypertensive heart disease, benign, with heart failure.
402.91	Hypertensive heart disease, unspecified, with heart failure.
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease.
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified failure and chronic kidney disease stage V or end stage renal disease.
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease.
428.xx	Heart Failure.

ICD–9–CM CODES TO IDENTIFY ACUTE MYOCARDIAL INFARCTION (AMI) CASES

ICD–9–CM code	Description of code
410.00	AMI (anterolateral wall)—episode of care unspecified.
410.01	AMI (anterolateral wall)—initial episode of care.
410.10	AMI (other anterior wall)—episode of care unspecified.
410.11	AMI (other anterior wall)—initial episode of care.
410.20	AMI (inferolateral wall)—episode of care unspecified.
410.21	AMI (inferolateral wall)—initial episode of care.
410.30	AMI (inferoposterior wall)—episode of care unspecified.
410.31	AMI (inferoposterior wall)—initial episode of care.
410.40	AMI (other inferior wall)—episode of care unspecified.
410.41	AMI (other inferior wall)—initial episode of care.
410.50	AMI (other lateral wall)—episode of care unspecified.
410.51	AMI (other lateral wall)—initial episode of care.
410.60	AMI (true posterior wall)—episode of care unspecified.
410.61	AMI (true posterior wall)—initial episode of care.
410.70	AMI (subendocardial)—episode of care unspecified.
410.71	AMI (subendocardial)—initial episode of care.
410.80	AMI (other specified site)—episode of care unspecified.
410.81	AMI (other specified site)—initial episode of care.
410.90	AMI (unspecified site)—episode of care unspecified.
410.91	AMI (unspecified site)—initial episode of care.

ICD–9–CM CODES TO IDENTIFY CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) CASES

ICD–9–CM code	Description of code
491.21	Obstructive chronic bronchitis; With (acute) exacerbation; acute exacerbation of COPD, decompensated COPD, decompensated COPD with exacerbation.
491.22	Obstructive chronic bronchitis; with acute bronchitis.
491.8	Other chronic bronchitis. Chronic: tracheitis, tracheobronchitis..
491.9	Unspecified chronic bronchitis.

ICD–9–CM CODES TO IDENTIFY CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) CASES—Continued

ICD–9–CM code	Description of code
492.8	Other emphysema; emphysema (lung or pulmonary): NOS, centriacinar, centrilobular, obstructive, panacinar, panlobular, unilateral, vesicular. MacLeod's syndrome; Swyer-James syndrome; unilateral hyperlucent lung.
493.20	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, unspecified.
493.21	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with status asthmaticus.
493.22	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with (acute) exacerbation.
496	Chronic: nonspecific lung disease, obstructive lung disease, obstructive pulmonary disease (COPD) NOS. NOTE: This code is not to be used with any code from categories 491–493.
518.81 *	Other diseases of lung; acute respiratory failure; respiratory failure NOS.
518.82 *	Other diseases of lung; acute respiratory failure; other pulmonary insufficiency, acute respiratory distress.
518.84 *	Other diseases of lung; acute respiratory failure; acute and chronic respiratory failure.
799.1 *	Other ill-defined and unknown causes of morbidity and mortality; respiratory arrest, cardiorespiratory failure.

** Principal diagnosis when combined with a secondary diagnosis of AECOPD (491.21, 491.22, 493.21, or 493.22).*

ICD–9–CM CODES TO IDENTIFY TOTAL HIP ARTHROPLASTY/TOTAL KNEE ARTHROPLATY (THA/TKA) CASES

ICD–9–CM code	Description of code
81.51	Total hip arthroplasty.
81.54	Total knee arthroplasty.

For FY 2016, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2011 to June 30, 2014, to identify applicable conditions based on the same ICD–9–CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions discussed above. To calculate aggregate payments for excess readmissions, we are proposing to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD and THA/TKA) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the five applicable conditions, we are proposing to sum the base operating DRG payments amounts by each condition, resulting in five summed amounts, one amount for each of the five applicable conditions. We are proposing to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We are proposing to then sum the resulting products which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio). Because this calculation is performed separately for each of the five conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to aggregate payments for excess readmissions (and therefore a payment reduction under the Hospital Readmissions Reduction Program). We note that we are not proposing any changes to our existing methodology to calculate ''aggregate payments for all discharges'' (the denominator of the ratio).

We are proposing the following methodology for FY 2016 as displayed in the chart below.

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2016

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI × (Excess Readmissions Ratio for AMI–1)] + [sum of base operating DRG payments for HF × (Excess Readmissions Ratio for HF–1)] + [sum of base operating DRG payments for PN × (Excess Readmissions Ratio for PN–1)] + [sum of base operating DRG payments for COPD) × (Excess Readmissions Ratio for COPD–1)] + [sum of base operating DRG payments for THA/TKA × (Excess Readmissions Ratio for THA/TKA–1)].

* We note that if a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Proposed Readmissions Adjustment Factor for FY 2016 is the higher of the ratio or 0.9700.

* Based on claims data from July 1, 2011 to June 30, 2014 for FY 2016.

We are inviting public comment on these proposals.

9. Proposed Extraordinary Circumstance Exception Policy for the Hospital Readmissions Reduction Program Beginning in FY 2016 and for Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28117), we welcomed public comment on whether a potential waiver or exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances should be implemented, and the policy and operational considerations of such an extraordinary circumstance exception policy for the Hospital Readmissions

Reduction Program. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048), we indicated that we received many comments in support of CMS establishing a formal extraordinary circumstance exception policy under the Hospital Readmissions Reduction Program. We also previously indicated that any specific proposals related to the implementation of an extraordinary circumstance exception policy would be proposed through notice-and-comment rulemaking. After further consideration of commenters' support of CMS establishing an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program, we agree with commenters that it may be possible for a hospital to experience a certain period of time during which it is not able to submit all of its claims (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control, and that a policy for taking into account such a circumstance should be proposed. Section 1886(q)(5)(D) of the Act permits the Secretary to determine the ''applicable period'' for readmissions data collection, and we believe that the statute allows us to determine that the period not include times when hospitals may encounter extraordinary circumstances.

In developing this proposed extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program beginning in FY 2016 and for subsequent years, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.140(c)(2) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital VBP Program, to the extent feasible.

We considered the feasibility and implications of excluding data for certain readmission measures for a limited period of time from the calculations for a hospital's excess readmissions ratios for the applicable performance period. By minimizing the data excluded from the program, the proposed policy would enable affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continue to meet applicable measure minimum threshold requirements. We believe that this approach could help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program.

b. Requests for an Extraordinary Circumstance Exception

Based upon our prior experience with the Hospital IQR Program and the Hospital VBP Program, we anticipate the need to provide exceptions to only a small number of hospitals affected by a natural disaster or other extraordinary circumstance. During the review of a hospital's request for an extraordinary circumstance exception, we would maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We do not intend to allow a hospital to use this proposed policy and the request process to seek exclusion from the Hospital Readmissions Reduction Program in its entirety for a given fiscal year(s) solely because of experiencing an extraordinary circumstance. Rather, we intend to provide relief for a hospital whose ability to accurately or timely submit all of its claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital.

We are proposing that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. We believe that the 90-calendar day timeframe is an appropriate period of time for a hospital to determine whether to submit an extraordinary circumstance exception request. It is also the same length of time as the current time period allowed under the Hospital VBP Program. Under this proposed policy, a hospital would be able to request a Hospital Readmissions Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the HAC Reduction Program (if the proposed extraordinary circumstance exception policy for the HAC Reduction Program as described in section IV.G.8. of the preamble of this proposed rule is adopted). The extraordinary circumstance exception request form would be made available on the QualityNet Web site.

The following minimum set of information would be required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other 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 exception, including:

++ CMS program name (for example, the Hospital Readmissions Reduction Program, the Hospital VBP Program, or the Hospital IQR Program);

++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and

++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;

- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information would be subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS would: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision. Under the proposed policy, we would review each request for an extraordinary circumstance exception on a case-by-

case basis at our discretion. To the extent feasible, we also would review such a request in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

The proposed policy would not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site. This provision also would align with the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

We are inviting public comment on this proposal.

F. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule with comment period (78 FR 75120 through 75121); and the FY 2015 IPPS/LTCH PPS final rule with comment period (79 FR 50048 through 50087).

We have also codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2016 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573) and refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2016 program year is 1.75 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2016 is $1,489,397,095, based on the December 2014 update of the FY 2014 MedPAR file. We intend to update this estimate for the FY 2016 IPPS/LTCH PPS final rule, using the March 2015 update of the FY 2014 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS) (77 FR 53573 through 53576). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2016, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16 of this proposed rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPSs from the FY 2015 program year. These FY 2015 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 2.5797595162. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available via the Internet on the CMS Web site) to reflect changes based on the March 2015 update to the FY 2014 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2016 will continue to be based on historic FY 2015 Hospital VBP Program TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2016 program year until after the FY 2016 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2016, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2016 program year. We expect that Table 16B will be posted on the CMS Web site in October 2015.

2. Proposed Retention, Removal, Expansion, and Updating of Quality Measures for the FY 2018 Program Year

a. Retention of Previously Adopted Hospital VBP Program Measures for the FY 2018 Program Year

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized our proposal to readopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, if we propose and finalize the removal of a measure). We stated our belief that this policy would facilitate measure adoption for the Hospital VBP Program for future program years, as well as align the Hospital VBP Program with the Hospital IQR Program (77 FR 53592). We are not proposing to change our current policy of readopting measures from the prior program year for each successive program year.

b. Proposed Removal of Two Measures

One consideration in determining whether a measure should be retained or removed from the program is based on an analysis of whether the measure is ''topped-out.'' We have adopted two criteria for determining the ''topped-out'' status of Hospital VBP measures:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- Truncated coefficient of variation ≤0.10.

In this proposed rule, we are proposing to remove the IMM–2 Influenza Immunization and AMI–7a Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival measures, effective for the FY 2018 program year. We believe that removing these measures will continue to ensure that we make valid statistical comparisons through our finalized scoring methodology, while reducing the reporting burden on participating hospitals.

(1) Proposed Removal of IMM–2 Influenza Immunization Measure

Based on our evaluation of the most recently available data, we believe that IMM–2 is ''topped-out.'' As we have discussed in prior rulemaking, measuring hospital performance on ''topped-out'' measures will have no meaningful effect on a hospital's TPS, given that performance on ''topped-out'' measures is generally so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

As discussed further in section VIII.A.3.b. of the preamble of this proposed rule, we believe that this measure should continue to be part of the Hospital IQR Program measure set because it is the only measure that addresses the Best Practices to Enable Healthy Living goal in the CMS Quality Strategy and priority of the same name in the National Quality Strategy.

We are inviting public comment on this proposal.

(2) Proposed Removal of AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival Measure

Our evaluation of the most recently available data shows that AMI–7a is not widely reported by hospitals, and that many hospitals have less than the minimum number of cases required for reporting because most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. We are proposing to remove AMI–7a because collection of the measure data is burdensome to hospitals and measure data are infrequently reported. Therefore, we do not believe that its continued adoption under the Hospital VBP Program will advance our quality improvement goals. As discussed in section VIII.A.3.b. of the preamble of this proposed rule, we also are proposing to remove this measure under the Hospital IQR Program.

We are inviting public comment on this proposal.

c. Proposed New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure (CTM–3) (NQF #0228)

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the CMS Quality Strategy, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

The 3-Item Care Transition Measure (CTM–3) is an NQF-endorsed measure. We adopted this measure in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516). Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *http://www.caretransitions.org/documents/CTM3Specs0807.pdf*. Specifications for the Care Transition Measure as used in the HCAHPS Survey can be found in the current HCAHPS Quality Assurance Guidelines, *http://www.hcahpsonline.org/qaguidelines.aspx*.

The CTM–3 measure adds three questions to the HCAHPS Survey, as follows:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
  - ☐ I was not given any medication when I left the hospital

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50065 through 50066), we stated that we were considering proposing to add the CTM–3 measure from the HCAHPS Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PCCEC/CC) domain of the FY 2018 Hospital VBP Program, and we sought public comments on this topic. We specifically sought public comments on how the new CTM–3 dimension should be included in the scoring methodology that we have adopted for the PCCEC/CC domain.

Based on other public comments last year, we agreed to release additional information about the validity, reliability, and statistical properties of the CTM–3 measure when we proposed the measure (79 FR 50066). We made this information publicly available in 2014 through the NQF reendorsement process of the HCAHPS Survey (NQF #0166), available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*.

We note that the MAP supported the inclusion of the CTM–3 measure in the Hospital VBP Program in its MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*. The MAP noted that the addition of the CTM–3 measure will fill a gap in measuring care transitions.

We are proposing this measure for the Hospital VBP Program based on the MAP recommendation, our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period for that measure. We believe that the proposed addition of the CTM–3 measure to the Hospital VBP Program meets the statutory requirements for inclusion in the FY 2018 program year. Finally, we also believe that this measure, in conjunction with the HCAHPS survey, assesses an important component of quality in the acute care inpatient hospital setting. However, we emphasize that HCAHPS scores are designed and intended for use at the hospital level. We do not endorse the use of HCAHPS scores for comparisons within hospitals, such as comparison of HCAHPS scores associated with a particular ward, floor, provider, or nursing staff. Further, the pain domain questions are intended to evaluate patients' experience of their pain management. HCAHPS pain domain results are not designed to judge, or compare, appropriate versus inappropriate provider prescribing behavior.

We are inviting public comment on this proposal.

d. Proposed Removal of Clinical Care—Process Subdomain for the FY 2018 Program Year and Subsequent Years

We have previously adopted three measures for the Clinical Care—Process subdomain for the FY 2017 Hospital VBP Program (for example, 79 FR 50062 (Table on Previously Adopted and New Measures for the FY 2017 Hospital VBP Program)). However, as discussed above, we are proposing to remove the AMI–7a and IMM–2 measures from the Hospital VBP Program, and we are not proposing to adopt any additional measures for the Clinical Care—Process subdomain. If the proposals above are finalized, only one measure, PC–01 Elective Delivery, which measures the incidence of elective births prior to 39 weeks gestation, would remain in the Clinical Care—Process subdomain for the FY 2018 program year. For the reasons outlined below, and if we finalize the removal of the IMM–2 and AMI–7a measures, we are proposing to move PC–01 to the Safety domain and to remove the Clinical Care—Process subdomain beginning with the FY 2018 program year.

As we have stated over the past several years (for example, 79 FR 50084), we desire the Hospital VBP Program to be as inclusive as possible while maintaining and ensuring the reliability of the domains. We believe that the PC–01 Elective Delivery measure continues to be appropriate for the Hospital VBP Program because, in 2012, nearly one million Medicare beneficiaries were women age 45 and under.[54] Further, in 2011, Medicare paid for roughly 14,000 births (79 FR 50060). However, not all hospitals provide maternity services, which would leave these hospitals with no Clinical Care-Process subdomain measures to report in FY 2018 if PC–01 remains the only measure in that subdomain.

We believe that the PC–01 Elective Delivery measure, currently in the Clinical Care—Process subdomain, can appropriately be recategorized as a Safety domain measure. PC–01 addresses a process designed to reduce risk to both the neonate and the mother, thereby making care safer. Guidelines from the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics state elective deliveries should not be performed at <39 weeks gestation unless medically indicated.[55] Evidence has shown that early-term deliveries result in significant short-term neonatal mortality and result in more cesarean deliveries, and longer maternal length of stay.[56] Furthermore, the MAP Hospital Workgroup has included PC–01 as an ''obstetrical adverse event'' measure in its Safety family of measures.[57] As we continue to align our measure categorizations more closely with the CMS Quality Strategy, we are proposing to recategorize PC–01 as a Safety measure in the Safety domain, and for the reasons discussed above, to remove the Clinical Care—Process subdomain beginning with the FY 2018 program year.

Finally, if we finalize our proposal to remove the Clinical Care—Process subdomain, we are proposing to rename the Clinical Care—Outcomes subdomain as simply the Clinical Care domain. We are also proposing to reweight the domains to reflect our proposals, which we detail in section IV.G.7.a. of the preamble of this proposed rule.

We are inviting public comments on these proposals.

e. NHSN Measures Standard Population Data

The NHSN measures are calculated by CDC, and currently include the CAUTI, CLABSI, MRSA bacteremia, CDI, and Colon and Abdominal Hysterectomy SSI measures in the FY 2017 program year and subsequent program years. They measure the occurrence of these HAIs in hospitals participating in the Hospital VBP Program. In order to calculate the NHSN measures for use in both the Hospital IQR Program and the Hospital VBP Program, CDC must go through several steps. First, CDC determines each NHSN measure's number of predicted infections.[58] CDC determines the number of predicted infections using both specific patient care location characteristics (for example, number of days in which a patient in an ICU has a central line) and infection rates that occurred among a standard population (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data'').[59] Finally, for each NHSN measure, CDC calculates the Standardized Infection Ratio (SIR) by comparing a hospital's observed number of HAIs with the number of HAIs predicted for the hospital, adjusting for several risk factors.[60] For more information about the way NHSN measures are calculated, we refer readers to QualityNet's Web page on HAI measures, which may be found at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

As part of routine measure maintenance, CDC is updating the ''standard population data'' to ensure the NHSN measures' number of predicted infections reflect the current state of HAIs in the United States.[61] Currently, CDC calculates the ''standard population data'' for the CAUTI measure based on data it collected in CY 2009.[62] CDC calculates the ''standard population data'' for the CLABSI and Colon and Abdominal Hysterectomy SSI measures based on data it collected in 2006 to 2008.[63] CDC calculates the ''standard population data'' for the MRSA bacteremia and CDI measures based on data it collected in 2010 to 2011.[64] Beginning in 2015, CDC will collect data in order to update the standard population data for all of these NHSN measures (the CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data'').

Because the Hospital VBP Program calculates improvement points using comparisons between data collected from hospitals in a baseline period and data collected in a performance period, the Hospital VBP Program must treat CDC's standard population data update differently than other quality programs. We have determined that we cannot equally compare CDC's ''new standard population data'' to the ''current standard population data'' in order to calculate improvement points. If we do not address the CDC's measure update, we will be unable to compare the baseline and performance periods for NHSN measures in the FY 2017 and FY 2018 program years. To address the

[54] Centers for Medicare & Medicaid Services. (2013). Table I.3—Medicare Enrollment/Demographics. Available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2013_final.pdf*.

[55] Clark, S., Miller, D., Belfort, M., Dildy, G., Frye, D., & Meyers, J. (2009). Neonatal and maternal outcomes associated with elective delivery. [Electronic Version]. *Am J Obstet Gynecol.* 200:156.e1–156.e4.

[56] Glantz, J. (Apr. 2005). Elective induction vs. spontaneous labor associations and outcomes. [Electronic Version]. *J Reprod Med.* 50(4):235–40. Available at: *http://www.researchgate.net/publication/7826004_Elective_induction_vs._spontaneous_labor_associations_and_outcomes*.

[57] MAP Families of Measures: Safety, Care Coordination, Cardiovascular Conditions, Diabetes Final Report, October 2012, p. 46.

[58] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html*.

[59] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html*.

[60] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

[61] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

[62] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6*.

[63] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6*.

[64] Available at: *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#b6*.

problem, we intend to use the ''current standard population data'' to calculate performance standards and calculate and publicly report measure scores until the FY 2019 program year, as depicted in the table below. For the FY 2019 program year and subsequent years, the Hospital VBP Program will use the ''new standard population data'' to calculate performance standards and calculate and publicly report measure scores.

CDC'S STANDARD POPULATION DATA IN THE HOSPITAL VBP PROGRAM

	FY 2017 program year *	FY 2018 program year *	FY 2019 program year **	FY 2020 program year **
NHSN Measures Baseline Periods.	Current standard population data.	Current standard population data.	New standard population data.	New standard population data.
NHSN Measures Performance Periods.	Current standard population data.	Current standard population data.	New standard population data.	New standard population data.

* CDC will use ''current standard population data'' to calculate measure data that we will translate into scores on the measures.
** CDC will use ''new standard population data'' (CY 2015) to calculate measure data that we will translate into scores on the measures.

For a discussion addressing the ''new standard population data'' in the Hospital IQR Program, we refer readers to section VIII.A.4.b. of the preamble of this proposed rule.

f. Summary of Previously Adopted and Newly Proposed Measures for the FY 2018 Program Year

In summary, for the FY 2018 program, we are proposing the following measure set:

FY 2018 PREVIOUSLY ADOPTED AND NEWLY PROPOSED MEASURES

Patient and Caregiver-Centered Experience of Care/Care Coordination Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
CTM–3 *	3-Item Care Transitions Measure.
Clinical Care Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization.
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.
Safety Domain	
CAUTI	National Healthcare Safety Network Catheter-Associated Urinary Tract Infection Outcome Measure.
CLABSI	National Healthcare Safety Network Central Line-Associated Bloodstream Infection Outcome Measure.
Colon and Abdominal Hysterectomy SSI.	Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection Outcome Measure: • Colon • Abdominal Hysterectomy.
MRSA bacteremia	National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
CDI	National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection Outcome Measure.
PSI–90	Patient Safety for Selected Indicators (Composite).
PC–01 **	Elective Delivery.
Efficiency and Cost Reduction Domain	
MSPB–1	Payment-Standardized Medicare Spending Per Beneficiary

* Proposed new measure.
** Proposed to be moved from the Clinical Care—Process subdomain to the Safety domain.

3. Previously Adopted and Newly Proposed Measures for the FY 2019, FY 2021, and Subsequent Program Years

Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable (for example, 76 FR 26490 through 26547; 76 FR 51653 through 51660; 76 FR 74527 through 74547; 77 FR 53567 through 53614; 78 FR 50676 through 50707; 78 FR 75120 through 75121; 79 FR 50048 through 50087). Below, we are signaling our intent to include additional data in certain NHSN measures beginning with the FY 2019 program year, proposing to adopt a new measure beginning with the FY 2021 program year, and summarizing all previously adopted and newly proposed measures.

a. Intent To Propose in Future Rulemaking To Include Selected Ward (Non-Intensive Care Unit (ICU)) Locations in Certain NHSN Measures Beginning With the FY 2019 Program Year

The Hospital VBP Program uses adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores for the CAUTI and CLABSI measures for the FY 2017 and FY 2018 program years (79 FY

50061). In the FY 2014 IPPS/LTCH PPS proposed rule, we proposed under the Hospital IQR Program to expand the collection of CAUTI and CLABSI measures to include several selected ward (non-ICU) locations beginning with events occurring on or after January 1, 2014 (78 FR 27684). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787), after consideration of the public comments received, we deferred the implementation date of the CAUTI and CLABSI measure expansion to selected ward (non-ICU) settings for the Hospital IQR Program from January 1, 2014 to January 1, 2015 (78 FR 50787). Selected ward (non-ICU) locations are defined as adult or pediatric medical, surgical, and medical/surgical wards (79 FY 50061; 78 FR 50787).

In the FY 2015 IPPS/LTCH PPS final rule, we signaled our intent to consider using data from selected ward (non-ICU) locations for the Hospital VBP Program, beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures (79 FR 50061). We intend to propose to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures beginning with the FY 2019 program year in future rulemaking. We intend to propose to adopt a baseline period of January 1, 2015 through December 31, 2015, and a performance period of January 1, 2017 through December 31, 2017, for the CAUTI and CLABSI measures. This expansion of the CAUTI and CLABSI measures would be consistent with the NQF reendorsement update to these measures, which allows application of the measures beyond ICUs (78 FR 50787). We believe this expansion of the measures will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts (78 FR 50787).

We are inviting public comment on this plan to accommodate these measures' expansions in the Hospital VBP Program future rulemaking.

b. Proposed New Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)

Hospital 30-Day, All-Cause, RSMR following COPD Hospitalization (NQF #1893) (MORT–30–COPD) is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following COPD hospitalizations. We adopted this measure in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50792). Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Chronic lower respiratory disease (including COPD) is the third leading cause of death in the United States.[65] Between 1998 and 2008, the number of patients hospitalized annually for acute exacerbations of COPD increased by approximately 18 percent.[66] [67] [68] Moreover, COPD is one of the top 20 conditions contributing to Medicare costs.[69] The median 30-day RSMR following admissions for COPD between July 2010 and June 2013 was 7.8 percent with variation in mortality rates ranging from 5.5 percent to 12.4 percent across over 2,700 hospitals.[70]

The MAP supported the inclusion of the MORT–30–COPD measure in the Hospital VBP Program as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [71] The MAP noted that the addition of the MORT–30–COPD measure would be appropriate as 30-day mortality rate measures for AMI, HF, and PN are already part of the Hospital VBP Program measure set.

We are proposing this measure for the Hospital VBP Program based on the MAP recommendation, our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least 1 year prior to the start of the performance period. In addition, the MORT–30–COPD measure is appropriate for the Hospital VBP Program because it addresses a high volume, high cost condition, and chronic lower respiratory disease (including COPD) is the third leading cause of mortality in the United States. The measure aligns with the CMS Quality Strategy Goal of Effective Prevention and Treatment. Based on the continued high risk of mortality after COPD hospitalizations, we are proposing to add it to the Clinical Care domain for the FY 2021 Hospital VBP Program.

We are inviting public comment on this proposal.

c. Summary of Previously Adopted and Newly Proposed Measures for the FY 2019 and FY 2021 and Subsequent Program Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50063), we finalized our proposal to adopt the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary THA/TKA measures for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50063 through 50065), we also finalized our proposal to adopt the PSI–90 measure for the FY 2019 program year and subsequent years.

FY 2019 PREVIOUSLY ADOPTED MEASURES

	Clinical Care Domain
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty/ Total Knee Arthroplasty.

FY 2019 PREVIOUSLY ADOPTED MEASURES

	Safety Domain
PSI–90	Patient Safety For Selected Indicators (Composite).

In this proposed rule, we are proposing to adopt the MORT–30–COPD measure for the FY 2021 program year and subsequent years.

[65] Hoyert DL, Xu JQ. Deaths: preliminary data for 2011. *Natl Vital Stat Rep*. 2012;61(6):1–65. Hyattsville, MD: National Center for Health Statistics.2012. Available at: *http://www.birthbythenumbers.org/wp-content/uploads/2012/12/prelim-deaths-2011.pdf*.

[66] National Heart L, and Blood Institute, The Morbidity & Mortality: Chart Book on Cardiovascular, Lung and Blood Diseases. 2009; Available at: *http://www.nhlbi.nih.gov/resources/docs/2009_ChartBook.pdf*.

[67] The Centers for Disease Control and Prevention. National Center for Health Statistics Chronic Lower Respiratory Disease. FastStats 2010; Available at: *http://www.cdc.gov/nchs/fastats/copd.htm*.

[68] Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project Statistics on Hospitals Stays. 2009; Available at: *http://hcupnet.ahrq.gov/*.

[69] Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

[70] September 2014 Medicare Hospital Quality Chartbook Performance Report on Outcome Measures. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*.

[71] National Quality Forum ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' found at *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*.

FY 2021 NEWLY PROPOSED MEASURE

	Clinical Care Domain
MORT–30–COPD.	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization.

4. Possible Measure Topics for Future Program Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50066 through 50070), we sought comment on measures that could potentially be used to expand the Efficiency and Cost Reduction domain in the future. We are again seeking comments on this issue. We are interested in expanding the Efficiency and Cost Reduction domain to include a more robust measure set, which may include measures that supplement the MSPB measure with more condition and/or treatment specific episode measures. We encourage comment on efficiency and cost reduction measures already included in the Hospital IQR Program as well as measures we are proposing in section VIII.A.7. of the preamble of this proposed rule for inclusion in the Hospital IQR Program beginning with the FY 2018 payment determination.

5. Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2018 Program Year

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087) for the baseline and performance periods for the Clinical Care—Process, PCCEC/CC, Clinical Care—Outcomes, and Efficiency and Cost Reduction domains that we have adopted for the FY 2017 program year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50692 through 50694, we adopted baseline and performance periods for the 30-day mortality measures for FY 2017, FY 2018, and FY 2019, and for the PSI–90 measure for FY 2017 and FY 2018 (78 FR 50692 through 50694, 50698 through 50699).

b. Proposed Baseline and Performance Periods for the Patient and Caregiver-Centered Experience of Care/Care Coordination Domain for the FY 2018 Program Year

Since the FY 2015 program year, we have adopted a 12-month baseline period and 12-month performance period for measures in the PCCEC/CC domain (77 FR 53598; 78 FR 50692; 79 FR 50072). We continue to believe that a 12-month performance period for the HCAHPS Survey and proposed CTM–3 measure provides us sufficient data on which to score hospital performance, which is an important goal for both CMS and stakeholders. Therefore, for the FY 2018 program year, we are proposing to adopt a 12-month performance period of January 1, 2016 through December 31, 2016 for the PCCEC/CC domain. We also are proposing to adopt a corresponding 12-month baseline period of January 1, 2014 through December 31, 2014 for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

c. Proposed Baseline and Performance Periods for NHSN Measures and PC–01 in the Safety Domain for the FY 2018 Program Year

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for NHSN measures (78 FR 75121; 79 FR 50071). In addition, we adopted the PC–01 measure for the FY 2017 program year with a 12-month baseline period and 12-month performance period (79 FR 50072). We continue to believe that a 12-month performance period provides us with sufficient data on which to score hospital performance on the NHSN measures, as well as the PC–01 measure, in the Safety domain. We also note that 12-month baseline and performance periods are consistent with the reporting periods used for these measures under the Hospital IQR Program. Therefore, for the FY 2018 program year, we are proposing to adopt a performance period of January 1, 2016 through December 31, 2016 for the NHSN measures and the PC–01 measure in the Safety domain. We also are proposing to adopt a corresponding baseline period of January 1, 2014 through December 31, 2014 for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

d. Proposed Baseline and Performance Periods for the Efficiency and Cost Reduction Domain for the FY 2018 Program Year

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for the MSPB–1 measure in the Efficiency and Cost Reduction domain (79 FR 50072; 78 FR 50692). These baseline and performance periods enable us to collect sufficient measure data, while allowing time to calculate and incorporate MSPB–1 measure data into the Hospital VBP Program scores in a timely manner. Therefore, for the FY 2018 program year, we are proposing to adopt a 12-month performance period of January 1, 2016 through December 31, 2016 for the MSPB–1 measure in the Efficiency and Cost Reduction domain. We also are proposing to adopt a corresponding baseline period of January 1, 2014 through December 31, 2014. We note that these proposed baseline and performance periods align with the baseline and performance periods for the PCCEC/CC domain and all measures in the Safety domain with the exception of PSI–90.

We are inviting public comments on these proposals.

e. Summary of Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2018 Program Year

The table below summarizes the proposed baseline and performance periods for the FY 2018 program year (with previously adopted baseline and performance periods for the mortality and PSI composite (PSI–90) measures noted). We note that we have proposed above to remove the Clinical Care—Process subdomain from the Hospital VBP Program beginning with the FY 2018 program year. We note further that these baseline and performance periods would continue to align with the PCCEC/CC domain and the Efficiency and Cost Reduction domain, as well as the periods proposed for certain measures in the Safety domain.

PREVIOUSLY ADOPTED AND PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR

Domain	Baseline period	Performance period
PCCEC/CC: • HCAHPS Survey • CTM–3.	January 1, 2014–December 31, 2014	January 1, 2016–December 31, 2016.

PREVIOUSLY ADOPTED AND PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
Clinical Care:		
Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)*.	October 1, 2009–June 30, 2012	October 1, 2013–June 30, 2016.
Safety:		
• PSI–90*	• July 1, 2010–June 30, 2012	• July 1, 2014–June 30, 2016.
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2014–December 31, 2014	• January 1, 2016–December 31, 2016.
Efficiency and Cost Reduction:		
MSPB–1	January 1, 2014–December 31, 2014	January 1, 2016–December 31, 2016.

*Previously adopted baseline and performance periods.

6. Previously Adopted and Newly Proposed Baseline and Performance Periods for Future Program Years

a. Previously Adopted Baseline and Performance Periods for the FY 2019 Program Year

The table below summarizes the previously adopted baseline and performance periods for the Clinical Care domain and PSI–90 measures for the FY 2019 program year.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN).	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• THA/TKA	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2017.
Safety:		
• PSI–90	• July 1, 2011–June 30, 2013	• July 1, 2015–June 30, 2017.

b. Proposed Baseline and Performance Periods for the PSI–90 Measure in the Safety Domain in the FY 2020 Program Year

The table below summarizes the previously adopted and proposed baseline and performance periods for the FY 2020 program year. In the FY 2020 program year, we are proposing to adopt a performance period of July 1, 2016 to June 30, 2018 for the PSI–90 measure. We are proposing a corresponding baseline period of July 1, 2012 to June 30, 2014. This will allow us to collect 24-months of data from hospitals on the PSI–90 measure.

We are inviting comment on these proposals.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)*.	July 1, 2010–June 30, 2013	July 1, 2015–June 30, 2018.
• THA/TKA*.		
Safety:		
PSI (PSI–90) Measure	July 1, 2012–June 30, 2014	July 1, 2016–June 30, 2018.

*Previously adopted baseline and performance periods.

c. Proposed Baseline and Performance Periods for the Clinical Care Domain for the FY 2021 Program Year

The table below summarizes the proposed baseline and performance periods for the FY 2021 program year. In the FY 2014 IPPS/LTCH PPS and FY 2015 IPPS/LTCH PPS final rules (78 FR 50692 through 50694; 79 FR 50072 through 50073), we adopted baseline and performance periods for the three 30-day mortality measures for the FY 2017, FY 2018, FY 2019, and FY 2020 program years. We adopted baseline and performance periods for the THA/TKA measure for the FY 2019 and FY 2020 program years (79 FR 50073). We adopted this policy in light of the length of the performance period that is needed to collect enough measure data for reliable performance scoring. We continue to believe that we should adopt 36-month baseline and performance periods for the mortality measures when possible to accommodate those durations.

We believe that a similar rationale applies to the new MORT–30–COPD measure that we are proposing to adopt for the Clinical Care domain for the FY

2021 program year. Furthermore, we are attempting to align measurement periods under the Hospital VBP Program with measurement periods under the Hospital IQR Program for the 30-day mortality measures. Therefore, for the FY 2021 program year, we are proposing to adopt a 36-month performance period of July 1, 2016 through June 30, 2019 for all mortality measures (the three previously adopted mortality measures, as well as the proposed MORT–30–COPD measure) in the Clinical Care domain. We also are proposing to adopt a corresponding baseline period of July 1, 2011 through June 30, 2014. We note that the proposed performance periods will align with the reporting periods for the mortality measures in the Hospital IQR Program for the first time.

For the THA/TKA measure in the FY 2021 program year, we are proposing to adopt a 36-month performance period of April 1, 2016 through March 31, 2019. We also are proposing to adopt a corresponding baseline period of April 1, 2011 through March 31, 2014. This baseline and performance period will align with the THA/TKA measure reporting period for the Hospital IQR Program and will make reporting more seamless for hospitals.

We are inviting public comment on these proposals.

PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD).	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• THA/TKA	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.

7. Proposed Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53599 through 53604), we adopted performance standards for the FY 2015 program year and certain FY 2016 program year measures. We also finalized our policy to update performance standards for future program years via notice on the CMS Web site or another publicly available Web site. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50694 through 50698), we revised our regulatory definitions of ''achievement threshold'' and ''benchmark'' at 42 CFR 412.160 and adopted performance standards for additional FY 2016 program year measures. We also adopted an interpretation of ''achievement threshold'' and ''benchmark'' under 42 CFR 412.160 to exclude the numerical values that result when the performance standards are calculated. We have further adopted a policy under which we may update a measure's performance standards for a fiscal year once if we identify data issues, calculation errors, or other problems that would significantly affect the displayed performance standards (79 FR 50079). We refer readers to the FY 2014 IPPS/LTCH PPS final rule for the complete set of FY 2016 performance standards (78 FR 50697 through 50698).

b. Technical Updates

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077 through 50079), we adopted a policy under which we may adopt technical updates to performance standards under the Hospital VBP Program. We adopted this policy by amending the definition of ''performance standards'' under 42 CFR 412.160 of our regulations to enable us to update performance standards' numerical values to incorporate nonsubstantive technical updates made to Hospital VBP Program measures between the time that they are adopted for a particular program year and the time that we actually calculate hospital performance on those measures after the performance period for the program year has concluded. We stated our intent to continue to use rulemaking to adopt substantive updates to measures adopted for the Hospital VBP Program. We stated that examples of changes that we might consider to be substantive include those in which the changes are so significant that the measure is no longer the same measure or when a standard of performance assessed by a measure becomes more stringent. However, we stated our intent to determine what constitutes substantive versus nonsubstantive changes on a case-by-case basis, although we affirmed our intent to be as transparent as possible with stakeholders about any such updates we might adopt.

On January 29, 2015, we announced a technical update to the performance standards that we have adopted for the PSI–90 measure for the FY 2017 program year. The announcement was published on QualityNet and can be viewed at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228774624610*. The update resulted from a more recent AHRQ Quality Indicator software version becoming available. The FY 2017 performance standards were initially calculated using Version 4.4 of the AHRQ software, and the update allowed us to use Version 4.5a for both the performance standards and hospital results.

For more detailed information on the updates implemented in Version 4.5a, we refer readers to the Log of Coding Updates and revisions, posted on QualityNet, available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228695355425*. For more information on differences between Version 4.5a and previous versions of the software, we

refer readers to the AHRQ Web site, available at: *http://qualityindicators.ahrq.gov* or to the AHRQ help desk directly, available at: *QIsupport@ahrq.hhs.gov* or (307) 427–1949.

c. Proposed Performance Standards for the FY 2018 Program Year

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we are proposing to adopt the following additional performance standards for the FY 2018 program year. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2016 IPPS/LTCH PPS final rule. We note further that the MSPB–1 measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

We note further that the performance standards for the NHSN measures, the PSI–90 measure, and the MSPB–1 measure are calculated with lower values representing better performance. This distinction is made in contrast to other measures for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule, the performance standards for the Colon and Abdominal Hysterectomy SSI are computed separately for each procedure stratum, and we will first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections (78 FR 50684).

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2018 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
	Safety Measures		
CAUTI *	National Healthcare Safety Network Catheter-associated Urinary Tract Infection Outcome Measure.	0.916	0.000.
CLABSI *	National Healthcare Safety Network Central line-associated Bloodstream Infection Outcome Measure.	0.401	0.000.
CDI *	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection Outcome Measure.	0.776	0.000.
MRSA bacteremia *	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.	0.766	0.000.
PSI–90 ± *	Patient safety for selected indicators (composite)	0.577321	0.397051.
Colon and Abdominal Hysterectomy SSI *.	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection Outcome Measure.		
	• Colon	• 0.801	• 0.000.
	• Abdominal Hysterectomy	• 0.745	• 0.000.
PC–01	Elective Delivery	0.022989	0.000.
	Clinical Care Measures		
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization *.	0.851458 *	0.871669.*
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure *.	0.881794 *	0.903985.*
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization *.	0.882986 *	0.908124.*
	Efficiency and Cost Reduction Measure		
MSPB–1 *	Payment-Standardized Medicare Spending per Beneficiary.	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
± Previously adopted performance standards.

Based on public comments in the FY 2015 IPPS/LTCH PPS final rule, we are proposing to adopt the ''normalization'' approach to scoring the PCCEC/CC domain, which will introduce only minor changes to the original scoring formula, as follows. For purposes of the HCAHPS Base Score, the new CTM–3 dimensions would be calculated in the same manner as the eight existing HCAHPS dimensions. For each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which would be summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0–90 points, as compared to 0–80 points when only eight dimensions were included). The prenormalized HCAHPS Base Score would then be multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions would be of equal weight,

so that, as before, the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated in the same manner as before and would continue to range from 0 to 20 points. The Consistency Points would now consider scores across all nine of the PCCEC/CC dimensions. The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and will range from 0 to 100 points, as before.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2018 PROGRAM YEAR PATIENT AND CAREGIVER-CENTERED EXPERIENCE OF CARE/CARE COORDINATION DOMAIN

HCAHPS Survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	52.85	78.45	86.70
Communication with Doctors	59.48	80.56	88.59
Responsiveness of Hospital Staff	37.91	65.22	80.35
Pain Management	50.17	70.26	78.44
Communication about Medicines	45.50	63.38	73.61
Hospital Cleanliness & Quietness	43.43	65.58	79.25
Discharge Information	62.00	86.50	91.58
3-Item Care Transition *	27.28	51.33	62.18
Overall Rating of Hospital	36.94	70.15	84.72

* Newly proposed measure.

We are inviting public comments on these proposed performance standards.

d. Previously Adopted Performance Standards for Certain Measures for the FY 2019 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50065), we adopted the PSI–90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year. As with the PSI–90, MSPB–1, and NHSN measures described above, the THA/TKA measure is calculated with lower values representing better performance. Therefore, in the FY 2015 IPPS/LTCH PPS final rule we adopted the following performance standards for the FY 2019 program year (79 FR 50077):

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN SAFETY AND CLINICAL CARE DOMAIN MEASURES FOR THE FY 2019 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Safety Measures		
PSI–90 *	Patient Safety for Selected Indicators (Composite)	0.853715	0.589462
	Clinical Care Measures		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization.	0.850671	0.873263
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.883472	0.908094
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.882334	0.909460
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.	0.032229	0.023178

* Lower values represent better performance.

e. Previously Adopted and Newly Proposed Performance Standards for Certain Measures for the FY 2020 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50063 through 50065), we adopted the PSI–90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077), we also adopted the following performance standards for the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA measures for the FY 2020 program year. In this proposed rule, we are proposing performance standards for the PSI–90 measure for the FY 2020 program year as set forth below:

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Safety Domain		
PSI–90*	Patient Safety for Selected Indicators (Composite)	0.778761	0.545903
	Clinical Care Domain		
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization.	0.853715	0.875869
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.881090	0.906068
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.882266	0.909532
THA/TKA * ±	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.	0.032229	0.023178

* Lower values represent better performance.
± Previously adopted performance standards.

f. Proposed Performance Standards for Certain Measures for the FY 2021 Program Year

We are proposing the following performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN, and the proposed MORT–30–COPD):

PROPOSED PERFORMANCE STANDARDS FOR CLINICAL CARE DOMAIN MEASURES FOR THE FY 2021 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Clinical Care Measures		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Hospitalization.	0.860355	0.879714
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization.	0.883803	0.906144
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0.886443	0.91067
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization.	0.860355	0.879714
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty/Total Knee Arthroplasty.	0.03089	0.022304

* Lower values represent better performance.

8. Proposed FY 2018 Program Year Scoring Methodology

a. Proposed Domain Weighting for the FY 2018 Program Year for Hospitals That Receive a Score on All Domains

In the FY 2015 IPPS/LTCH PPS final rule, we adopted the following domains and domain weights for the FY 2017 program year for hospitals that receive a score in all newly aligned domains:

DOMAIN WEIGHTS FOR THE FY 2017 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight
Safety	20 percent.
Clinical Care	30 percent.
• Clinical Care—Outcomes	• 25 percent.
• Clinical Care—Process	• 5 percent.
Efficiency and Cost Reduction	25 percent.
Patient and Caregiver-Centered Experience of Care/Care Coordination	25 percent.

For the FY 2018 program year, we are proposing to remove two ''topped-out'' measures from the Clinical Care—Process subdomain. In addition, we are proposing to move one measure (PC–01) from the Clinical Care—Process subdomain to the Safety domain and to remove the Clinical Care—Process subdomain.

If these proposals are adopted, the Safety domain will include seven measures for the FY 2018 program year, including PC–01, which would be new to that domain. Because we are proposing to move one measure to the Safety domain, and because we continue to believe that hospitals should be provided strong incentives to perform well on measures of patient safety, we are proposing to increase the Safety domain's weight by 5 percentage points. We are proposing to adopt the following FY 2018 program year domain weighting for hospitals receiving a score on all proposed newly-aligned domains:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2018 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight
Safety	25 percent.
Clinical Care	25 percent.
Efficiency and Cost Reduction	25 percent.
Patient and Caregiver-Centered Experience of Care/Care Coordination	25 percent.

We are inviting public comments on the proposed domain weights.

b. Proposed Domain Weighting for the FY 2018 Program Year for Hospitals Receiving Scores on Fewer Than Four Domains

In prior program years, we finalized a policy that hospitals must have received domain scores on all finalized domains in order to receive a TPS. However, because the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with additional domains, we considered whether it was appropriate to continue this policy.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53606 through 53607), we finalized our proposal that, for the FY 2015 program year and subsequent years, hospitals with sufficient data to receive at least two out of the four domain scores that existed for the FY 2015 program year (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also finalized our proposal that, for hospitals with at least two domain scores, TPSs would be reweighted proportionately to the scored domains to ensure that the TPS is still scored out of a possible 100 points and that the relative weights for the scored domains remain equivalent to the weighting which occurs when there are scores in all four domains. We believe that this approach allows us to include relatively more hospitals in the Hospital VBP Program while continuing to focus on reliably scoring hospitals on their quality measure performance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50701 through 50702), we continued this approach for the FY 2016 program year and subsequent program years for purposes of eligibility for the program.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), we adopted a policy that, for the FY 2017 program year and subsequent years, hospitals must receive domain scores on at least three quality domains in order to receive a TPS. We stated our belief that, by adopting this policy, we will continue to allow as many hospitals as possible to participate in the program while ensuring that reliable TPSs result. We also finalized a policy that hospitals with sufficient data on at least three of four domains for FY 2017 will have their TPSs proportionately reweighted. Finally, in the FY 2015 IPPS/LTCH PPS final rule, we adopted case minimums for the FY 2016 program year and subsequent years (79 FR 50085 through 50086).

Under these policies, in order to receive a TPS for the FY 2018 program year:

- Hospitals must meet the requirements to receive an HCAHPS Survey measure score in order to receive a PCCEC/CC domain score. Hospitals must report a minimum number of 100 HCAHPS surveys for a hospital to receive a PCCEC/CC domain score (76 FR 26530).
- Hospitals must meet the requirements to receive a MSPB–1 measure score in order to receive an Efficiency and Cost Reduction domain score. Hospitals must report a minimum number of 25 cases for the MSPB–1 measure (77 FR 53609 through 53610).
- Hospitals must receive a minimum of two measure scores within the Clinical Care domain. Hospitals must report a minimum number of 25 cases for each of the mortality measures (77 FR 53609 through 53610).
- Hospitals must receive a minimum of three measure scores within the Safety domain.

++ Hospitals must report a minimum of three cases for any underlying indicator for the PSI–90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609).

++ Hospitals must report a minimum of one predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 10 cases for the PC–01 measure (76 FR 26530).

We are not proposing any changes to the minimum numbers of cases and measures that we have adopted above. However, because we are proposing to remove the Clinical Care—Process subdomain from the Hospital VBP Program effective with the FY 2018 program year, we considered whether we should revisit our finalized requirement that hospitals must receive scores on at least three domains in order to receive a TPS. However, we continue to believe that this requirement appropriately balances our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures. We are not proposing to change this requirement at this time. We welcome public comments on whether we should consider adopting a different policy on this topic. We will continue to proportionately reweight hospitals' TPSs when they have sufficient data on only three domains.

G. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program.

2. Statutory Basis for the HAC Reduction Program

Section 3008 of the Affordable Care Act added section 1886(p) to the Act to provide an incentive for certain hospitals to reduce the incidence of HACs. Section 1886(p) of the Act requires the Secretary to make an adjustment to payments to ''applicable hospitals'' effective beginning on October 1, 2014, and for subsequent program years. Section 1886(p)(1) of the Act sets forth the requirements by which payments to ''applicable hospitals'' will be adjusted to account for HACs with respect to discharges occurring during FY 2015 or later. For hospitals with HAC scores in the top quartile relative to other applicable hospitals for a given fiscal year, the amount of Medicare payment is reduced to 99 percent of the amount of payment that would otherwise apply to discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable. Section 1886(p)(2)(A) of the Act defines ''applicable hospitals'' as subsection (d) hospitals that meet certain criteria. Section 1886(p)(2)(B)(i) of the Act defines these criteria and specifies that the payment adjustment would apply to an applicable hospital that ranks in the top quartile (25 percent) of all subsection (d) hospitals, relative to the national average, of conditions acquired during the applicable period, as determined by the Secretary. Section 1886(p)(2)(B)(ii) of the Act requires the Secretary to establish and apply a risk-adjustment methodology in calculating HAC scores for each hospital.

Sections 1886(p)(3) and (p)(4) of the Act define ''hospital-acquired conditions'' and ''applicable period,'' respectively. The term ''hospital-acquired condition'' means ''a condition identified in subsection 1886(d)(4)(D)(iv) of the Act and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.'' The term ''applicable period'' means, with respect to a fiscal year, a period specified by the Secretary.

Section 1886(p)(5) of the Act requires that, prior to FY 2015 and each subsequent fiscal year, the Secretary provide confidential reports to each applicable hospital with respect to the HAC Reduction Program scores for the applicable period, to give the hospitals an opportunity to review and correct the data. Section 1886(p)(6)(A) of the Act sets forth the reporting requirements by which the Secretary would make information available to the public regarding HACs for each applicable hospital. Section 1886(p)(6)(B) of the Act requires the Secretary to ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the HAC scores of the applicable hospital prior to such information being made public. Section 1886(p)(6)(C) of the Act requires that, once corrected, the HAC scores be posted on the *Hospital Compare* Web site (*http://www.medicare.gov/hospitalcompare/search.html*) in an easily understandable format.

Section 1886(p)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(p) of the Act. These determinations include: what qualifies as an applicable hospital; the specifications of a HAC; the Secretary's determination of the ''applicable period''; the provision of confidential reports submitted to the applicable hospital; and the information publicly reported on the *Hospital Compare* Web site.

3. Overview of Previous HAC Reduction Program Rulemaking

For a further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104). These policies describe the general framework for implementation of the HAC Reduction Program including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

4. Implementation of the HAC Reduction Program for FY 2016

We are not proposing any changes to the above described policies for the implementation of the HAC Reduction Program for FY 2016. However, we are reminding readers that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50101 through 50102), we finalized the following measures for use in the FY 2016 program: AHRQ PSI–90 Composite and CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI) and Colon and Abdominal Hysterectomy Surgical Site Infection (SSI). We are not proposing to add or remove any measures for FY 2016.

We are providing an update on NQF proceedings for three of the measures previously finalized for the FY 2016 program: PSI–90 Composite; CLABSI; and CAUTI. For FY 2016, we are retaining the AHRQ PSI–90 Composite measure (in Domain 1) that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717). As we noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50090), the AHRQ PSI–90 Composite measure is undergoing NQF maintenance review. The PSI–90 Composite measure currently consists of eight component indicators: PSI–3 Pressure ulcer rate; PSI–6 Iatrogenic pneumothorax rate; PSI–7 Central venous catheter-related blood stream infections rate; PSI–8 Postoperative hip fracture rate; PSI–12 Postoperative pulmonary embolism/Deep vein thrombosis rate; PSI–13 Postoperative sepsis rate; PSI–14 Wound dehiscence rate; and PSI–15 Accidental puncture and laceration rate.

As part of the NQF maintenance review process, AHRQ is considering the addition of PSI–9 Perioperative hemorrhage rate, PSI–10 Perioperative physiologic metabolic derangement rate, and PSI–11 Post-operative respiratory failure rate measures, or a combination of these three measures, to the PSI–90 Composite measure. We consider the potential inclusion of additional component measures in the PSI–90 Composite measure to be a significant change to the measure and, if that occurs, we would engage in notice-and-comment rulemaking prior to requiring the reporting of the revised composite for the HAC Reduction Program. At this time, the AHRQ PSI–90 Composite measure is continuing to undergo NQF maintenance review. No changes have been finalized. Therefore, we are not proposing any changes to this measure at this time.

Similarly, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50090), we noted that the CDC NHSN CAUTI and CLABSI measures in Domain 2 that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717) for inclusion in FYs 2015, 2016 and 2017 were undergoing NQF maintenance review. We stated in the FY 2015 IPPS/LTCH PPS final rule that if there are significant changes to these measures, we would engage in notice-and-comment rulemaking prior to requiring the reporting of the revised

measures. These measures have now completed the NQF maintenance review process, and modified versions of the measures were reendorsed by NQF on November 10, 2014.[72] We note that reendorsed versions of the CDC NHSN CLABSI and CAUTI measures included a new statistical option for calculating the measure result, the Adjusted Ranking Metric (ARM), in addition to the standardized infection ratio (SIR) statistical option. For FY 2016, we will continue use of the CDC NHSN CLABSI and CAUTI measures as previously finalized for the program with use of the SIR. We will be working with CDC in the future to determine if the newly available ARM would be appropriate for use in the HAC Reduction Program. If we determine at a later time that the ARM is appropriate for use in the HAC Reduction Program and provides an advantage to the existing measure result (the SIR), we will propose this change in notice-and-comment rulemaking.

We also note that we anticipate providing hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2016 Total HAC Score in late summer 2015 via the *QualityNet Secure Portal*.[73] In order to have access to their hospital-specific reports, hospitals must register for a *QualityNet Secure Portal* account. We did not make any changes to the review and correction policies for FY 2016. Hospitals have a period of 30 days after the information is posted to the *QualityNet Secure Portal* to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year.

5. Proposed Changes for Implementation of the HAC Reduction Program for FY 2017

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50102), we finalized the following measures for use in the FY 2017 program: AHRQ PSI–90 Composite and CDC NHSN CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia, and *Clostridium difficile* (CDI). We are not proposing any changes to this measure set for FY 2017. We also are not proposing to make any changes to the measures from how they were finalized for use in the FY 2016 program (CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI) or FY 2017 program (MRSA Bacteremia and CDI).

For FY 2017, we are proposing three changes to existing program policies: (1) The dates of the time period used to calculate hospital performance; (2) the addition of a narrative rule used in the methodology to calculate the Domain 2 score; and (3) the relative contribution of Domain 1 (patient safety) and Domain 2 (infection) to the Total HAC Score. Each proposal is described in more detail below.

a. Proposed Applicable Time Period for the FY 2017 HAC Reduction Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified policy at 42 CFR 412.170 that provided that there will be a 2-year applicable time period to collect data used to calculate the Total HAC Score.

For FY 2017, we are proposing to continue similar 2-year time periods for the calculation of HAC Reduction Program measure results. For the Domain 1 measure (AHRQ PSI–90 Composite measure), we would use the 24-month period from July 1, 2013 through June 30, 2015. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017. For the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we would use data from CYs 2014 and 2015.

We are seeking public comment on the proposal to use these updated time periods for calculation of measure results for the FY 2017 program.

b. Proposed Narrative Rule Used in Calculation of the Domain 2 Score for the FY 2017 HAC Reduction Program

We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723) that there will be instances in which applicable hospitals may not have data on all Domain 1 and 2 measures, and, therefore, a set of narrative rules was finalized to determine how to score each Domain. The scoring rules were finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723 through 50725) and clarified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50096 through 50098). For FY 2017, we will follow the rules as previously finalized. As described below, we also are proposing an additional narrative rule for use beginning in the FY 2017 program year. This additional narrative rule would be applicable to calculation of the Domain 2 score and would treat each Domain 2 measure independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable).

We note that the current narrative rules for Domain 2 assign a score for each Domain 2 measure and the measure scores are averaged to provide a Domain 2 Score. For the FY 2015 and FY 2016 HAC Reduction Program, if a hospital reports data for at least one of the Domain 2 measures, its Domain 2 Score is based solely on the measure(s) the hospital reported and the hospital is not assigned the maximum number of points for any nonreported measure(s). This approach was employed for the FY 2015 and 2016 HAC Reduction Program because the applicable periods for the Domain 2 measures for those program years (the FY 2015 period was January 1, 2012 through December 31, 2013, and the FY 2016 period was January 1, 2013 through December 31, 2014) occurred, at least in part, prior to the announcement of the HAC Reduction Program with the publication of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) in August 2013. The proposed applicable period for Domain 2 measures in the FY 2017 program (CYs 2014 and 2015) occurs in its entirety after the HAC Reduction Program was announced. This means hospitals were notified of the impact that not reporting these data would have on their Total HAC Score before the FY 2017 reporting period began (that is, before January 1, 2014). Therefore, we are proposing for FY 2017 and subsequent program years that each Domain 2 measure be treated independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable). For instance, if a hospital does not submit data for the Colon and Abdominal Hysterectomy SSI measure and does not have a valid waiver for nonreporting, the measure would receive a score of 10. This score of 10 would then be combined with the measure scores the hospital received for data reported on the other FY 2017 Domain 2 measures (CLABSI and CAUTI) to calculate the hospital's total Domain 2 score. The rationale for this proposed change in methodology is to encourage hospitals to submit all available data on all measures in the program and to further encourage hospitals to reduce all HACs included in the program.

We are inviting public comments on our proposal to implement the score calculations discussed above in FY 2017

[72] National Quality Forum. Measures search. Available at: *http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1122&print=0&entityTypeID=1* and *http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1121&print=0&entityTypeID=1*.

[73] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598*.

and subsequent years, as well as our proposal for an additional narrative rule that would treat each Domain 2 measure independently when determining if a score of 10 (maximal score) should be assigned to the measure for nonsubmission of data without a waiver (if applicable).

c. Proposed Domain 1 and Domain 2 Weights for the FY 2017 HAC Reduction Program

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50102), we finalized for FY 2016 a methodology for calculating a Total HAC Score for each hospital by determining a score for each domain, then multiplying each domain score by a weight (Domain 1—AHRQ Patient Safety Indicators, 25 percent; Domain 2—CDC NHSN measures, 75 percent), and adding together the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)).

For FY 2017, we are proposing to adjust the weighting of Domains 1 and 2 so that the weight of Domain 1 would be 15 percent and the weight of Domain 2 would be 85 percent. We are proposing to decrease the Domain 1 weight for two reasons. First, with the implementation of the CDC MRSA Bacteremia and CDI measures in the FY 2017 program, we believe the weighting of both domains needs to be adjusted to reflect the addition of the fifth and sixth measure in Domain 2. Second, among the public comments on the FY 2014 and FY 2015 IPPS/LTCH PPS final rules that were considered, MedPAC and other stakeholders recommended that Domain 2 should be weighted more than Domain 1 because they believed the CDC NHSN chart-abstracted measures were more reliable and actionable than claims-based measures. We are inviting public comments on this proposal to decrease the Domain 1 weight from 25 percent to 15 percent and increase the Domain 2 weight from 75 percent to 85 percent for FY 2017.

6. Proposed Measure Refinements for the FY 2018 HAC Reduction Program

a. Proposal to Include Select Ward (Non-Intensive Care Unit (ICU)) Locations in Certain CDC NHSN Measures Beginning in the FY 2018 Program Year

We are proposing measure refinements to the CDC NHSN CLABSI and CAUTI measures that were previously adopted for the HAC Reduction Program to include select ward (non-ICU) locations beginning in FY 2018. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50719), we adopted the CLABSI and CAUTI measures inclusive of pediatric and adult patients in ICUs for the HAC Reduction Program beginning with FY 2015. We noted at that time that the Hospital IQR Program finalized data collection for these measures for adult and pediatric patients in medical, surgical and medical/surgical wards (also referred to as select ward locations), in addition to ICU locations, effective beginning January 1, 2015, and that we would propose the additional locations for the HAC Reduction Program in the future.

The refined CAUTI and CLABSI measures that include select ward locations in addition to ICU locations were endorsed by the NQF in 2012. The MAP 2015 final recommendations indicated that the CLABSI and CAUTI measures with ICU and select ward locations be included in the HAC Reduction Program.[74] We note that during the MAP Hospital Workgroup meeting (December 9–10, 2014) and the MAP Coordinating Committee meeting (January 26–27, 2015), some members discussed the benefit of reporting the modified measures publicly before including them in a payment program in order to allow providers and CMS to gain experience with the modified measures. Other members expressed concern that this could delay implementation of an improved measure[75]. The MAP supported the use of the refined measures without stipulating prior public reporting as a condition of support. However, we acknowledge the importance of this consideration and took it into account when considering the timing of implementing the expanded measure in the HAC Reduction Program.

We considered a number of options for when to begin using the refined measures in the HAC Reduction Program. The CDC NHSN measure data used in the HAC Reduction Program are obtained from data that hospitals report as part of their participation in the Hospital IQR program. Therefore, due to the timing of the Hospital IQR Program including select ward locations (beginning January 1, 2015), the FY 2017 HAC Reduction Program, using the applicable period of CYs 2014 and 2015 for the CDC NHSN measures, is the first time data from select ward locations could be included in the program. However, using select ward location data in the FY 2017 program would result in hospitals with ICU locations having the opportunity to contribute 2 years of data, while hospitals without ICU locations would have the opportunity to contribute 1 year of data for measure result calculation. We believe this systematically unequal distribution of data could introduce bias in the program and should be avoided. If the introduction of select ward location data for the CLABSI and CAUTI measures is delayed until the FY 2018 HAC Reduction Program (applicable period would likely be CYs 2015 and 2016), all hospitals, regardless of whether or not they have ICUs, would have the opportunity to contribute 2 years of data for measure result calculations.

In addition, delaying implementation until FY 2018 would allow CMS and providers to gain some experience with the impact that the inclusion of these data would have on a hospital's HAC Reduction Program scores. We also considered the possibility of further delaying implementation of the refined measures until the FY 2019 program (applicable period would likely be CYs 2016 and 2017) in order to not include the first year of reporting (CY 2015) in a payment program measure calculation.

After considering these three options, we are proposing to include data from pediatric and adult medical ward, surgical ward, and medical/surgical ward locations in addition to data from adult and pediatric ICU locations for the CDC NHSN CLABSI and CAUTI measures beginning with the FY 2018 HAC Reduction Program. This option balances our belief that the refinement of the CLABSI and CAUTI measures to include select ward locations results in an improved measure that more accurately captures hospital-wide performance regarding these HACs with the need to provide hospitals with the opportunity to submit data for the full period of performance and the desire to gain experience with the refined measures before incorporating them into the HAC Reduction Program. We also believe this measure refinement will allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts (78 FR 50787).

We are inviting public comment on our proposal.

b. Update to CDC NHSN Measures Standard Population Data

In this section, we provide information regarding upcoming changes to the standard population data that are used to calculate the SIR for the CDC NHSN measures. These changes are occurring as part of routine measure maintenance.

[74] Available at: *http://www.qualityforum.org/map/*.

[75] Ibid.

The CDC NHSN measures are used to monitor hospital performance on prevention of healthcare-associated infections (HAIs). For each NHSN measure, CDC calculates the SIR, which compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusting for several risk factors.[76] The predicted number of infections is determined using patient care location characteristics (for example, the number of central line days) and infection rates that occurred among a standard population during a specified time period (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data''). For example, CDC currently uses data collected in CY 2009 for the CAUTI measure to determine the standard population data.[77] For more information about the method by which NHSN measures are calculated, we refer readers to QualityNet's Web page on HAI measures, which may be found at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

As part of routine measure maintenance, CDC will be updating the standard population data to ensure the NHSN measures' number of predicted infections reflects the current state of HAIs in the United States.[78] Beginning January 1, 2015, CDC started collecting data to use in updating the standard population data for HAI measures. (The CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data.'') Measure results using infections reported in CY 2016 will reflect the use of the new standard population data. It is anticipated that the new standard population data will affect the HAC Reduction Program beginning in FY 2018 when the applicable period for the CDC NHSN measures included in the program is likely to include CY 2015 and CY 2016.

7. Maintenance of Technical Specifications for Quality Measures

Technical specifications for AHRQ's PSI–90 Composite measure in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. We are not proposing any changes to this policy at this time.

8. Proposed Extraordinary Circumstance Exception Policy for the HAC Reduction Program Beginning in FY 2016 and for Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28142), we welcomed public comment on whether a potential waiver or exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances should be implemented, and the policy and operational considerations of such an extraordinary circumstance exception policy for the HAC Reduction Program. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50101), we indicated that we received many comments in support of CMS establishing a formal extraordinary circumstance exception policy under the HAC Reduction Program. We also previously indicated that any specific proposals related to the implementation of an extraordinary circumstance exception policy would be proposed through notice-and-comment rulemaking. After further consideration of commenters' support of CMS establishing an extraordinary circumstance exception policy for the HAC Reduction Program, we agree with commenters that it may be possible for a hospital to experience a certain period of time during which it is not able to accurately collect quality measure data and/or to report those data in a timely manner due to an extraordinary circumstance beyond its control, and that a policy for taking into account such a circumstance should be proposed.

In developing this proposed extraordinary circumstance exception policy for the HAC Reduction Program beginning in FY 2016 and for subsequent years, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital VBP Program, to the extent feasible.

We considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC score for the applicable performance period. By minimizing the data excluded from the program, the proposed policy would enable affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continue to meet applicable measure minimum threshold requirements. We believe that this approach could help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program.

b. Requests for an Extraordinary Circumstance Exception

Based upon our prior experience with the Hospital IQR Program and the Hospital VBP Program, we anticipate the need to provide exceptions to only a small number of hospitals affected by a natural disaster or other extraordinary circumstance. During the review of a hospital's request for an extraordinary circumstance exception, we will maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We do not intend to allow a hospital to use this proposed policy and the request process to seek exclusion from the HAC Reduction Program in its entirety for a given fiscal year(s) solely because of experiencing an extraordinary circumstance. Rather, we intend to provide relief for a hospital whose ability to accurately collect quality measure data and/or to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. Section 1886(p)(4) of the Act permits the Secretary to determine the ''applicable period'' for HAC data

[76] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

[77] Available at: *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf*; and *http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html*.

[78] Available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf*.

collection, and we believe that the statute allows us to determine that the period not include times when hospitals may encounter extraordinary circumstances.

We are proposing that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. We believe that the 90-calendar day timeframe is an appropriate period of time for a hospital to determine whether to submit an extraordinary circumstance exception request. It is also the same length of time as the current time period allowed under the Hospital VBP Program. Under this proposed policy, a hospital would be able to request a HAC Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the Hospital Readmissions Reduction Program (if an extraordinary circumstance exception policy is adopted for the Hospital Readmissions Reduction Program as described in section IV.E.9. of the preamble of this proposed rule). The extraordinary circumstance exception request form would be made available on the QualityNet Web site (*https://www.qualitynet.org/*).

The following minimum set of information would be required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other 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 exception, including:

++ CMS program name (for example, the HAC Reduction Program, the Hospital VBP Program, or the Hospital IQR Program);

++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and

++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;

- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information would be subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS would: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of the CMS decision. Under the proposed policy, we would review each request for an extraordinary circumstance exception on a case-by-case basis at CMS' discretion. To the extent feasible, we also would review such a request in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

The proposed policy would not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited, to issuing memos, emails, and notices on the QualityNet Web site at: *https://www.qualitynet.org/*. This provision also would align with the Hospital IQR Program's extraordinary circumstances extension or exemption policy, as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651).

We are inviting public comment on this proposal.

H. Proposed Elimination of the Simplified Cost Allocation Methodology for Hospitals (§ 412.302)

1. Background

The Medicare hospital cost report employs a cost-finding methodology to allocate direct and indirect costs using statistics appropriate to each department within a hospital. The costs of nonrevenue-producing cost centers (general service or overhead cost centers) are allocated to each other and to the revenue-producing cost centers using statistical bases and related statistics that measure the amount of service furnished by each cost center to the other cost centers (42 CFR 413.24(b) and (d)). In this regard, cost-finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished (42 CFR 413.24(b)(1)).

In the FY 1997 IPPS final rule (61 FR 46214 through 46215), CMS implemented the simplified cost allocation methodology at 42 CFR 412.302(d)(4) for hospitals as an alternative to the standard cost-finding methodology. The simplified cost allocation methodology reduces the number of statistical bases that a hospital must maintain. Under the simplified cost allocation methodology, a hospital must use a prescribed list of statistical bases, without deviation, as set forth in the Provider Reimbursement Manual (PRM) (CMS Pub. 15–2), Section 4020, Form CMS–2552. The simplified cost allocation methodology was devised in response to concerns expressed by the hospital industry over 20 years ago regarding the high costs of the recordkeeping required under the cost reporting rules. Since implementation of the simplified cost allocation methodology, there have been advances in technology of recordkeeping for hospitals, resulting in less arduous and costly recordkeeping and a diminished need for hospitals to use the simplified cost allocation methodology. It was expected that, although use of the simplified cost allocation methodology by hospitals would result in reduced recordkeeping costs, it also would likely result in reduced Medicare payments to hospitals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we created standard cost centers for Magnetic Resonance Imaging (MRI) and computed tomography (CT) scans, and required that hospitals report the costs and charges for these services under new cost centers on the Medicare cost report Form CMS–2552–10. The new standard cost centers for MRIs and CT scans were effective for cost reporting periods beginning on or after May 1, 2010.

Beginning in FY 2014, we started to calculate the MS–DRG relative weights using 19 CCRs, including distinct CCRs

for MRIs and CT scans. In addition, beginning in the CY 2014 OPPS, we started to calculate the OPPS relative payment weights using distinct CCRs for MRIs and CT scans. Some stakeholders expressed concern that CMS was not appropriately determining the cost of advanced imaging for inpatient and outpatient hospital services because, when the costs of hospitals that use the simplified cost allocation methodology are included in cost determinations, less precise CCRs are generated. In response to public comments on the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27486) and the CY 2014 OPPS/ASC proposed rule (78 FR 43547), in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50521 through 50523) and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74843 through 74847), we encouraged hospitals to use the statistical basis of ''dollar value'' for the costs of capital-related movable equipment, especially for costly MRI and CT imaging equipment, to support a more precise cost allocation and, therefore, more precise CCRs. However, a hospital that may have obtained an approval from a MAC under section 2313 of CMS Pub. 15–1 to use the simplified cost allocation methodology was restricted by the prescribed statistical basis of ''square footage'' for costs of capital-related movable equipment. In those instances, we recommended that hospitals use the statistical basis of the dollar value or use the ''Direct Assignment of General Service Cost'' method by requesting MAC approval in accordance with section 2307 of CMS Pub. 15–1.

In this proposed rule, we are proposing to eliminate the simplified cost allocation methodology because, as discussed above, the allocation of the costs of capital-related movable equipment using this methodology yields less precise calculated CCRs. Currently, less than 1 percent of hospitals have elected to use the simplified cost allocation methodology. Based on FY 2013 data, only 9 of 1,269 CAHs and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology. Furthermore, we believe that advances in technology have reduced the cost of recordkeeping, which has allowed hospitals to maintain accurate statistical data and afforded them the flexibility to change to a more precise allocation methodology.

2. Proposed Changes

The regulations applicable to the election of the simplified cost allocation methodology are located in 42 CFR 412.302. For the reasons set forth in section IV.H.1. of the preamble of this proposed rule, we are proposing to amend § 412.302 by revising paragraph (d)(4) to eliminate a hospital's ability to elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552 for cost reporting periods beginning on or after October 1, 2015.

I. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing ''rural community'' hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming (source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left nine hospitals participating at that time. In 2008, we announced a solicitation for up to six additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient hospital services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left seven of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008) participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, changing the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension period, unless the hospital makes an election to discontinue participation.

In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for the initial 5-year period. The Affordable Care Act also allows not more than 30 rural

community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that were eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, similarly citing a relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating in the demonstration.

In addition, section 410A(c)(2) of Public Law 108–173 required that, in conducting the demonstration program under this section, the Secretary must ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality.

Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past 11 IPPS final rules, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FYs 2005 through 2015 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, and 79 FR 50141, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

In general terms, in each of these previous years, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. Prior to FY 2013, we used finalized, or settled, cost reports, as available, and ''as submitted'' cost reports for hospitals for which finalized cost reports were not available. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to these cost amounts. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we used ''as submitted'' cost reports (for cost reporting periods ending in CY 2010) for each hospital participating in the demonstration in estimating the costs of the demonstration. In addition, in FY 2013, we incorporated different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. Finally, in each of the previous years, an annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services also was applied. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rules for FYs 2012, 2013, 2014, and 2015, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2009, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. The reasonable cost-based methodology authorized by section 410A of Public Law 108–173, as amended, is hereafter referred to as the ''reasonable cost methodology.'' (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an earlier given year from ''as submitted'' cost reports that were submitted by the hospitals prior to the inception of the demonstration.) We then updated the estimated cost described above to the current year by multiplying it by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustment. For the FY 2010 IPPS/RY 2010 LTCH PPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs

of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we included in the budget neutrality offset amount an amount in addition to the estimate of the demonstration costs in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

Following upon the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we continued to propose a methodology for calculating the budget neutrality offset amount to account for both the estimated demonstration costs in the upcoming fiscal year and an amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), we adopted changes to the methodology for calculating the budget neutrality offset amount in an effort to further improve and refine the methodology. We noted that the revised methodology varied, in part, from the methodology finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51705). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology we used for FY 2013. We noted that, although we made changes to certain aspects of the budget neutrality offset amount calculation for FY 2013, several core components of the methodology remained unchanged. For example, we continued to include in the budget neutrality offset amount the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier year (which would be determined once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50739 through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be $52,589,741. This amount was comprised of two distinct components: (1) The final resulting difference between the estimated reasonable cost amount to be paid under the demonstration to the 22 participating hospitals in FY 2014 for covered inpatient hospital services, and the estimated amount that would otherwise be paid to such hospitals in FY 2014 without the demonstration (this amount was $46,549,861); and (2) the amount by which the actual costs of the demonstration for FY 2007, as shown in the finalized cost reports for the hospitals that participated in the demonstration during FY 2007, exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount, $6,039,880, was derived from finalized cost reports for cost reporting periods beginning in FY 2007 for the 9 hospitals that participated in the demonstration during that year).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), we stated the methodology for determining the budget neutrality adjustment factor to be applied to the FY 2015 national IPPS payment rates as follows.

Step 1: For each of the participating hospitals, we identified the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for the hospital's cost reporting period ending in CY 2012). Because ''as submitted'' cost reports ending in CY 2012 were the most recent available cost reports, we believe they were an accurate predictor of the costs of the demonstration in FY 2015.

Because section 410A of Public Law 108–173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we included the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2012 reasonable cost amount for covered inpatient hospital services under the demonstration. As indicated above, we used ''as submitted'' cost reports for the hospital's cost reporting period ending in CY 2012 for this calculation.

We summed the two above-referenced amounts to calculate the general total estimated FY 2012 reasonable cost amount for covered inpatient hospital services for all participating hospitals.

We multiplied this sum (that is, the general total estimated FY 2012 reasonable cost amount for covered inpatient hospital services for all participating hospitals) by the FY 2013, FY 2014, and FY 2015 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. We then multiplied the product of the general total estimated FY 2012 reasonable cost amount for all participating hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for FYs 2013 through 2015—the result was the general total estimated FY 2015 reasonable cost amount for covered inpatient hospital services for all participating hospitals.

We used the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and was used because it is intended to reflect the tendency of hospitals' inpatient caseloads to increase. Because inpatient caseloads for small hospitals may fluctuate, we incorporated into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the participating hospitals, we identified the general estimated amount that would otherwise be paid in FY 2012 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2012) if the demonstration had not been implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we identified the estimated amount that generally would otherwise be paid for these services and included it in the total FY 2012 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration. We summed these two amounts to calculate the estimated FY 2012 total payments that generally would otherwise be paid for covered inpatient hospital services for all participating hospitals without the demonstration.

We multiplied the above amount (that is, the estimated FY 2012 total payments that generally would otherwise be paid for covered inpatient hospital services for all participating hospitals without the demonstration) by the FYs 2013 through 2015 IPPS applicable percentage increases. This methodology differs from Step 1, in which we applied the market basket percentage increases to the sum of the hospitals' general total FY 2012 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. Hospitals participating in the demonstration would be participating under the IPPS payment methodology if they were not in the demonstration. Then we multiplied the product of the estimated FY 2012 total payments that generally would otherwise be made without the demonstration and the IPPS applicable percentage increases for the years involved by a 3-percent annual volume adjustment for FYs 2013 through 2015. The result represented the general total estimated FY 2015 costs that would otherwise be paid without the demonstration for covered inpatient hospital services to the participating hospitals.

Step 3: We subtracted the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 2015 if the demonstration were not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all participating hospitals for covered inpatient hospital services for FY 2015). For the FY 2015 IPPS/LTCH PPS final rule, the resulting difference was $54,177,144 (79 FR 50145). This estimated amount was based on the specific assumptions identified regarding the data sources used, that is, ''as submitted'' recently available cost reports.

Also, in the FY 2015 IPPS/LTCH PPS final rule, we calculated the amount by which the actual costs of the demonstration in FY 2008 (that is, the costs of the demonstration for the 10 hospitals that participated in FY 2008, as shown in these hospitals' finalized cost reports for the cost report period beginning in that fiscal year), exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule. This amount, calculated for the FY 2015 final rule, was $10,389,771 (79 FR 50145).

Therefore, the total budget neutrality offset amount applied to the FY 2015 IPPS rates was $64,566,915. This was the sum of two separate components: (1) The difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to the participating hospitals in FY 2015 without the demonstration ($54,177,144); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2008 for the hospitals that participated in the demonstration during FY 2008) exceed the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule ($10,389,771).

2. Proposed FY 2016 Budget Neutrality Offset Amount

In this FY 2016 IPPS/LTCH PPS proposed rule, in general, we are proposing to use the established methodology used in FY 2015 (as discussed earlier), with some modifications as discussed below, for determining the budget neutrality offset amount to be applied to the FY 2016 national IPPS rates to reflect the costs of the demonstration. We are proposing to use ''as submitted'' cost reports ending in CY 2013 as the basis for estimating the reasonable cost amounts for covered services under the demonstration, as well as the amounts that would be paid absent the demonstration. As in previous years' rules, we believe that because these are the most recent available cost reports, they will be an accurate predictor of these amounts.

Although the proposed methodology for FY 2016 is similar to that for the past several rules, we note that the demonstration will have begun to phase out by the beginning of FY 2016, and because of this, we believe additional calculations would be appropriate. The 7 ''originally participating hospitals,'' that is, those hospitals that began the demonstration between 2005 and 2009, will have ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. Therefore, we are proposing that the financial experience of these hospitals would not factor into the estimated reasonable cost amount and the estimated amounts that would otherwise be paid without the demonstration for FY 2016.

The participation period for the 15 hospitals that entered the demonstration following upon the Affordable Care Act amendments and that are still participating in the demonstration will end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016, through December 31, 2016. As further discussed below, our proposed methodology for estimating the reasonable cost amounts for covered inpatient hospital services under the demonstration, as well as the amounts that would otherwise be paid without the demonstration, would reflect the fact that some of the hospitals within this cohort will participate in the demonstration for only a fraction of the 12 months in FY 2016. Eleven of these 15 hospitals are scheduled to end the demonstration on or before September 30, 2016; eight of these 11 hospitals are scheduled to end the demonstration prior to September 30, 2016.

For each of these 8 hospitals, we are proposing that the FY 2016 estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration derived from the ''as submitted'' cost reports for cost reporting periods ending in CY 2013 be prorated according to the ratio of the number of months between October 1, 2015 and the end of the hospital's cost reporting period in relation to the entire 12-month period. (For example, if a hospital's cost reporting period end date is June 30, 2016, the factor to be multiplied by the estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration from the calendar year end 2013 cost report is 0.75.) For the 7 hospitals that would end the demonstration on either September 30, 2016 or December 31, 2016, estimates of these amounts would correspond to the amounts indicated in the calendar year end 2013 cost reports.

We note that the 7 hospitals that started the demonstration between FYs 2005 and 2009 also will have ended their participation on a rolling basis during FY 2015. In the FY 2015 IPPS/LTCH PPS final rule, in accordance with the policy we finalized in the FY 2015 IPPS/LTCH PPS final rule, we based the estimate of the cost of the demonstration for FY 2015 on the financial experience as indicated on these hospitals' CY 2012 ''as submitted'' cost reports (as discussed earlier) without making any

adjustment to reflect the fact that hospitals would be ending at different points during FY 2015. We believe this methodology was reasonable because only 5 hospitals are ending their participation in the demonstration before September 30, 2015, out of the 22 hospitals on which the estimate of the cost of the demonstration for that year was based. Furthermore, as discussed previously, the methodology stated in this and previous rules for determining the costs of the demonstration in a given fiscal year entails the comparison of the actual costs of the demonstration as determined from finalized cost reports for that fiscal year (when they are available) to the estimated amount identified for that fiscal year in the corresponding fiscal year's final rule. Consistent with this policy, this second step will be used to reconcile any differences between the estimated and actual demonstration costs for FY 2015 once finalized cost reports for cost reporting periods beginning in FY 2015 are available. Although we believe that our methodology for estimating costs for FY 2015 was reasonable, for FY 2016, we are proposing a more refined methodology to estimate the costs of the demonstration; that is, one that entails prorating, as discussed above, the estimated reasonable cost amount and the estimated amounts that would otherwise be paid without the demonstration as indicated on the ''as submitted'' cost reports for cost reporting periods ending in CY 2013 based on the number of months that each hospital will have participated in the demonstration during FY 2016.

Similar to previous years, we are proposing the methodology for calculating the budget neutrality offset amount to proceed in several steps, as follows.

Step 1: For each of the 15 hospitals that will be participating in the demonstration during FY 2016, we are proposing to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services for the period of participation during FY 2016 based on ''as submitted'' cost reports ending in CY 2013. As discussed above, we are proposing that the basis of this estimate for each hospital scheduled to participate for part of FY 2016 would be the fraction of the number of months that the hospital will be participating out of the 12 months within FY 2016 multiplied by the reasonable cost amount for covered inpatient hospital services indicated on the ''as submitted'' cost report ending in CY 2013.

Given that 8 hospitals will be participating in the demonstration for part of FY 2016, we believe that such a methodology of prorating represents an appropriate refinement to the methodology established in previous rules for estimating the reasonable cost amount paid under the demonstration because each hospital's relevant cost experience, respectively, which this estimated amount reflects, would apply for the specific number of months for which it is participating in the demonstration in FY 2016. We believe that applying the relevant fraction, representing the number of months that the hospital will have participated during FY 2016 out of the 12 months in the fiscal year, will lead to more precise estimates.

Because section 410A of Public Law 108–173 stipulates that swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we are proposing to include the cost of these services, as reported on the ''as submitted'' cost reports ending in CY 2013 for the hospitals that provided swing-bed services in CY 2013, similarly prorated by the fraction of the number of months that the hospital will be participating out of the total number of months within FY 2016.

Similar to the methodology applied in FY 2015, we are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2013 reasonable cost amount for covered inpatient hospital services for all participating hospitals. Next, we are proposing to multiply the derived sum by the FY 2014, FY 2015, and FY 2016 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. For this proposed rule, the current estimate of the FY 2016 IPPS market basket percentage increase provided by the CMS Office of the Actuary is specified in section IV.A. of the preamble of this proposed rule. We are proposing to use the final FY 2016 IPPS market basket percentage increase in the final rule. We are proposing to multiply this product of the prorated reasonable cost amount for all 15 hospitals (based on CY 2013 ''as submitted'' cost reports) and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for FYs 2014, 2015, and 2016. The result is the proposed total estimated FY 2016 reasonable cost amount for covered inpatient hospital services for all hospitals participating in FY 2016.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2014 through 2016 to the reasonable cost amount derived from CY 2013 cost reports described earlier to model the estimated FY 2016 reasonable cost amount under the demonstration. We are proposing to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and is being used because it is intended to reflect the tendency of hospitals' inpatient caseloads to increase. Because inpatient caseloads for small hospitals may fluctuate, we are proposing to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 15 hospitals that will be participating in FY 2016, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2016 under applicable payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2013) if the demonstration was not implemented. Similar to Step 1, we are proposing that the basis of this estimate for each hospital participating for part of FY 2016 would be the fraction of the number of months that the hospital will be participating out of the 12 months within FY 2016 multiplied by the estimated amount that would otherwise be paid for these services as indicated on the ''as submitted'' cost report ending in CY 2013. We believe that such a methodology of prorating represents an appropriate refinement to the methodology established in previous rules for estimating the amount that otherwise would be paid without the demonstration because each hospital's relevant costs and claims experiences, respectively, which this estimated amount reflects, would apply for the specific number of months for which it is participating in the demonstration in FY 2016. As we stated in Step 1, we believe that applying the relevant fraction, representing the number of months that the hospital will have participated during FY 2016 out of the 12 months in the fiscal year, will lead to more precise estimates.

Similarly, as in Step 1, for the hospitals that provide swing-bed services, we are proposing to include the amount that would otherwise be paid for these services without the demonstration, as reported on the ''as

submitted'' cost reports ending in CY 2013 for the hospitals that provided swing-bed services in CY 2013. We are proposing to prorate, as appropriate, the estimated amount that would otherwise be paid for these services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2013) by the fraction of the number of months that the hospital will be participating in FY 2016 out of the total number of months within FY 2016, and include this amount in the total FY 2013 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration.

Similar to the methodology applied in FY 2015, we are proposing to sum these two amounts and multiply the derived sum by the FYs 2014, 2015, and 2016 IPPS applicable percentage increases. For this proposed rule, the current estimate of the FY 2016 IPPS applicable percentage increase is specified in section IV.A. of the preamble of this proposed rule. (We are proposing to use the final FY 2016 applicable percentage increase in the final rule.) This methodology differs from Step 1, in which we are proposing to apply the IPPS market basket percentage increases to the sum of the hospitals' general total FY 2013 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate update factors to estimate the amounts that would generally otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. We are proposing then to multiply this product by a 3-percent annual volume adjustment for FYs 2014, 2015, and 2016. The result represents the proposed general total estimated FY 2016 amount that would otherwise be paid for covered inpatient hospital services without the demonstration to the hospitals that would be participating in FY 2016.

Step 3: We are proposing to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 2016 if the demonstration had not been implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all participating hospitals for covered inpatient hospital services for FY 2016). We are proposing that the resulting difference would represent one component of the estimated amount for which an adjustment to the national IPPS rates would be calculated (as further discussed below).

For this proposed rule, the resulting difference is $26,195,949. This estimated amount is based on the specific assumptions identified regarding the data sources used, that is, ''as submitted'' recently available cost reports. If updated data become available prior to the FY 2016 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to estimate the costs for the demonstration program in FY 2016. Therefore, the estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

Step 4: We are proposing to include in the budget neutrality offset amount the amount by which the actual demonstration costs corresponding to an earlier given year (which would be determined once we have finalized cost reports for that year) differs from the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. (In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50145), we calculated the amount by which the actual costs of the demonstration in FY 2008 exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule. The corresponding differences for FYs 2005, 2006, and 2007 were identified and included in the budget neutrality offset amounts in previous years' IPPS final rules.) Currently, finalized cost reports for cost reporting periods beginning in FY 2009 are available for the 10 hospitals that completed a cost report period starting in FY 2009. These cost reports have been issued by the MACs as finalized, and they have been subject to review processes specific to the calculations for cost-based payment as determined by the payment methodology for the demonstration. We note that CMS has issued a notice of reopening for several of these cost reports pertaining to an issue that affects hospitals nationwide. However, it is not yet known if, or to what extent, the calculations for budget neutrality under the demonstration would be affected in the event of a reopening of these cost reports. Until such a determination is made, we believe that it would be appropriate to use these cost reports this year for our calculations under Step 4 for FY 2016 in order to take into account the actual costs of the demonstration for FY 2009 as soon as possible and to enhance the accuracy of the budget neutrality offset calculation.

Therefore, in this proposed rule, we are identifying the difference between the total cost of the demonstration as indicated on these finalized FY 2009 cost reports and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule, and we are proposing to adjust the current year's budget neutrality offset amount by that difference. If there is a reopening that necessitates a recalculation for any of these reports, we would conduct another calculation once the affected cost reports are revised and finalized to determine the difference between the cost of the demonstration as reflected on the revised and finalized cost reports and the amount that was included in the budget neutrality offset amount for FY 2009 as identified in the FY 2009 IPPS final rule (taking into account any amount already included in the finalized budget neutrality offset amount in the FY 2016 IPPS/LTCH PPS final rule that reflects an adjustment based on FY 2009 cost reports). If finalized cost reports for demonstration hospitals that participated in FY 2010 or FY 2011 are available prior to the FY 2016 IPPS/LTCH PPS final rule, we intend to adjust the budget neutrality offset amount for FY 2016 for any amounts by which the finalized costs of the demonstration for the year (FY 2010 or FY 2011) differ from the amounts included in the budget neutrality offset amount as finalized in the respective year's IPPS final rule that indicate the estimated cost of the demonstration for that fiscal year.

As further discussed below, we note that, for this proposed rule, Step 4 would result in the amount indicating the actual cost of the demonstration for FY 2009 (determined from the current finalized FY 2009 cost reports described in Step 4) being less than the amount that was originally identified in the FY 2009 IPPS final rule as the estimated cost of the demonstration. Therefore, we are proposing to include that component as a negative adjustment to the budget neutrality offset amount for the current fiscal year (as explained below).

Step 5: The total budget neutrality offset amount that we are proposing to apply in determining the budget neutrality adjustment to the FY 2016 IPPS rates would use the sum of the amounts derived in Steps 3 and 4. Each of these amounts represents a discrete calculation, reflecting the two-stage process of ensuring budget neutrality for the demonstration: (1) Estimating the costs of the demonstration prospectively

for the upcoming fiscal year from historical ''as submitted'' cost reports (Step 3), and (2) then retrospectively reconciling the difference between this estimate for a prior fiscal year and the actual costs as recorded on finalized cost reports for the specific fiscal year (Step 4).

Therefore, for this FY 2016 LTCH/LTCH PPS proposed rule, we are proposing to incorporate the following components into the calculation of the total budget neutrality offset:

(a) The amount, derived from Step 3, representing the difference between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to participating hospitals for covered inpatient hospital services for FY 2016 and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This amount would be based on ''as submitted'' cost reports for cost reporting periods ending in CY 2013, and would be prorated according to the number of months that each hospital will have participated in the demonstration in FY 2016 out of the 12-month fiscal year period. This amount is $26,195,949.

(b) The amount, as derived from Step 4, by which the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for the 10 hospitals that completed a cost reporting period beginning in FY 2009) differ from the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule. Analysis of this set of cost reports shows that the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule exceeds the actual cost of the demonstration by $8,457,452.

For FY 2016, the total budget neutrality offset amount that we are proposing to apply is: The amount determined under item (a) of Step 5 ($26,195,949) minus the amount determined under item (b) of Step 5 ($8,457,452) or $17,738,497. We are proposing to subtract the amount under item (b) from that under item (a) because the amount under item (b) represents the amount by which the budget neutrality offset finalized in the FY 2009 IPPS final rule exceeded the actual costs of the demonstration for FY 2009. Accordingly, we are proposing to reduce the budget neutrality offset amount for FY 2016 by that amount.

If updated data become available prior to the FY 2016 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2016. Therefore, the amount of the budget neutrality offset may change in the FY 2016 IPPS/LTCH PPS final rule based on the availability of updated data. In addition, similar to previous years, we are proposing that if finalized cost reports for all of the demonstration hospitals that participated in an applicable year (FY 2010 or FY 2011) are available prior to the FY 2016 IPPS/LTCH PPS final rule, we would adjust the budget neutrality offset amount to reflect the difference between the actual cost of the demonstration for the year (FY 2010 or FY 2011) and the budget neutrality offset amount applicable to such year as finalized in the respective year's final rule, as explained in Step 4. The resulting total would be the amount for which an adjustment to the national IPPS rates would be made.

We are inviting public comments on our proposals discussed above.

Finally, we are considering whether to propose in future rulemaking that the calculation of the final costs of the demonstration for a fiscal year reflect that some of the participating hospitals would otherwise have been eligible for the payment adjustment for low-volume hospitals in that fiscal year if they had not participated in the demonstration. Our policy under the demonstration is that hospitals participating in the demonstration are not able to receive the low-volume payment adjustment in addition to the reasonable cost-based payment authorized by section 410A of Public Law 108–173. We refer readers to CMS Change Request 7505, dated July 22, 2011, available on the CMS Web site at: *http://www.cms.gov*. Section 1886(d)(12) of the Act provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective FY 2005 (69 FR 49099 through 49102). We note that sections 3125 and 10314 of the Affordable Care Act provided for temporary changes in the qualifying criteria and payment adjustment for low-volume hospitals for FYs 2011 and 2012, which were further extended by subsequent legislation through March 31, 2015 (79 FR 49998 through 50001). These temporary changes increased the number of hospitals that are eligible to receive the low-volume hospital payment adjustment.

To the extent a hospital would have received a low-volume hospital payment adjustment if it had not participated in the demonstration, we believe it would be reasonable to take this into account in future rulemaking in determining what the hospital would have otherwise been paid in an applicable year without the demonstration. Because this payment adjustment has not been factored into the estimation of payments that otherwise would have been paid under the demonstration, such a proposal would require detailed consideration of the data sources and methodology that would be used to determine which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and to estimate the amount of the adjustment. We are inviting public comments on this issue.

J. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy (§ 412.4)

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004

MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. In the preamble to the FY 2006 IPPS final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Proposed Changes to the Postacute Care Transfer MS–DRGs

Based on our annual review of MS–DRGs, we have identified two proposed new MS–DRGs that we are proposing to include on the list of MS–DRGs subject to the postacute care transfer policy. As we discuss in section II.G. of the preamble of this proposed rule, in response to public comments and based on our analysis of FY 2014 MedPAR claims data, we are proposing to make changes to MS–DRGs, effective for FY 2016.

As discussed in section II.G.3.b. of the preamble of this proposed rule, we are proposing to modify the MS–DRG assignment of certain cardiovascular procedures currently assigned to MS–DRGs 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC), 248 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent with MCC or 4+ Vessels/Stents), 249 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent without MCC), 250 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC), and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent without MCC) to improve the clinical homogeneity of these MS–DRGs and reflect the resource cost of specialized equipment. We are proposing to create new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and to reassign the procedures performed within the heart chambers using intracardiac techniques from their current assignment in MS–DRGs 246 through 251 to the two proposed new MS–DRGs.

To improve clinical coherence for the various cardiovascular procedures currently assigned to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively), as discussed in section II.G.3.e. of the preamble of this proposed rule, we also are proposing to delete MS–DRGs 237 and 238 and to create five new proposed MS–DRGs: Proposed new MS DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively) would contain the more complex, more invasive aortic and heart assist procedures currently assigned to MS–DRGs 237 and 238. Proposed new MS–DRGs 270 (Other Major Cardiovascular Procedures with MCC), 271 (Other Major Cardiovascular Procedures with CC), and 272 (Other Major Cardiovascular Procedures without CC/MCC) would include the less complex, less invasive cardiovascular procedures currently assigned to MS–DRGs 237 and 238.

In light of these proposed changes to the MS–DRGs for FY 2016, according to the regulations under § 412.4(c), we evaluated these proposed MS–DRGs against the general postacute care transfer policy criteria using the FY 2014 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to reassess MS–DRGs when proposing reassignment of procedures and/or diagnostic codes that would result in material changes to an MS–DRG. As a result of our review, we are proposing to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 273 and 274. Existing MS–DRGs 246 through 251 do not currently qualify for the postacute care transfer policy and would not meet the review criteria for FY 2016. Proposed new MS–DRGs 268 through 272 also would not qualify for postacute care transfer policy status.

PROPOSED LIST OF MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2016

Proposed new MS–DRG	Proposed MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,395)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.8005%)	Postacute care transfer policy status
268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.	4,464	2,178	268	*6.0036	NO.
269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.	19,382	3,617	0	*0	NO.
270	Other Major Cardiovascular Procedures with MCC.	15,141	5,964	719	*4.7487	NO.
271	Other Major Cardiovascular Procedures with CC.	10,368	4,027	532	*5.1312	NO.
272	Other Major Cardiovascular Procedures without CC/MCC.	4,785	*880	54	*1.1285	NO.

PROPOSED LIST OF MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2016—Continued

Proposed new MS–DRG	Proposed MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,395)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.8005%)	Postacute care transfer policy status
273	Percutaneous Intracardiac Procedures with MCC.	6,602	2,654	646	9.7849	YES.
274	Percutaneous Intracardiac Procedures without MCC.	15,812	2,445	140	*0.8854	YES.**

*Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.
**As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

Finally, we have determined that proposed new MS–DRGs 273 and 274 also would meet the criteria for the special payment methodology. Therefore, we are proposing that the two proposed new MS–DRGs would be subject to the MS–DRG special payment methodology, effective FY 2016.

PROPOSED LIST OF MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY FOR FY 2016

Proposed new MS–DRG	Proposed MS–DRG Title	Geometric mean length of stay	Average charges of 1-day discharges	50 percent of average charges for all cases within MS–DRG	Special payment policy status
273	Percutaneous Intracardiac Procedures with MCC	6.0	$67,126	$60,588	YES.
274	Percutaneous Intracardiac Procedures without MCC ..	2.7	0	0	YES.*

*As described in the policy at 42 CFR 412.4(d)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

The proposed postacute care transfer status and special payment policy status of these MS–DRGs are reflected in Table 5 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site.

K. Short Inpatient Hospital Stays

Over the past few years, stakeholders have expressed a variety of concerns related to Medicare policies on short inpatient hospital stays, long outpatient stays that include observation services, and Medicare policies with respect to when payment for short hospital stays is appropriate under Medicare Part A. CMS has taken steps to address such concerns. As we announced on April 1, 2015, CMS recovery auditors are not permitted to conduct patient status reviews for claims with dates of admission of October 1, 2013 through April 30, 2015.

In addition, on December 30, 2014, we announced a number of changes to the Recovery Audit Program. Such modifications included changing the recovery auditor ''look-back period'' for patient status reviews to 6 months from the date of service in cases where a hospital submits the claim within 3 months of the date that it provides the service. Several other program improvements were included in this announcement. We have established limits on additional documentation requests (ADRs) that are based on a hospital's compliance with Medicare rules, incrementally applied ADR limits for providers that are new to recovery auditor reviews, and diversified ADR limits across all types of claims for a certain provider. We also have established a requirement that recovery auditors must complete complex reviews within 30 days, and failure to do so will result in the loss of the recovery auditor's contingency fee. In addition, we will require recovery auditors to wait 30 days before sending a claim to the MAC for adjustment. This 30-day period will allow the provider to submit a discussion period request before the MAC makes any payment adjustments. These changes will be effective with the next Recovery Audit Program contract awards.

Despite these planned alterations to the Recovery Audit Program, we note that hospitals and physicians continue to voice their concern with parts of the 2-midnight rule finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954). Therefore, we are considering this feedback carefully, as well as recent MedPAC recommendations, and expect to include a further discussion of the broader set of issues related to short inpatient hospital stays, long outpatient stays with observation services, and the related -0.2 percent IPPS payment adjustment in the CY 2016 hospital outpatient prospective payment system proposed rule that will be published this summer.

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. The IPPS for capital-related costs was initially implemented in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period established to phase in the IPPS for hospital inpatient

capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at § 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

C. Proposed Annual Update for FY 2016

The proposed annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2016 is discussed in section III. of the Addendum to this proposed rule.

We note that, in section II.D. of the preamble of this proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we are proposing for FY 2016 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA. Because section 631 of the ATRA requires CMS to make a recoupment adjustment only to the operating IPPS standardized amount, we are not proposing a similar adjustment to the national or Puerto Rico capital IPPS rates (or to the operating IPPS hospital-specific rates or the Puerto Rico-specific standardized amount). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110–90.

VI. Proposed Changes for Hospitals Excluded From the IPPS

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applies as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed above.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), we will continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2016 and

subsequent fiscal years. Accordingly, for FY 2016, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2016 percentage increase in the FY 2010-based IPPS operating market basket.

For this FY 2016 proposed rule, based on IHS Global Insight, Inc.'s 2015 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2016 is 2.7 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2016 rate-of-increase percentage that would be applied to the FY 2015 target amounts in order to calculate the FY 2016 target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.7 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2016.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2016

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: Specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section VII. of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, a LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless a LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to the FY 2014 rulemaking cycle. In addition, in this proposed rule, we discuss the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, and the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–97), enacted on March 27, 2014, both of which affect the LTCH

PPS. In section VII.B. of the preamble of this proposed rule, we discuss our proposals to implement the provisions of section 1206(a) of Public Law 113–67, which amended section 1886(m) of the Act by adding paragraph (6) and established, among other things, patient-level criteria for payments under the LTCH PPS for implementation beginning with FY 2016, and our proposed changes to the calculation of the greater than 25-day average length of stay criteria, consistent with the statute, in section VII.F. of the preamble of this proposed rule. In section VII.E. of the preamble of this proposed rule, we are proposing technical clarifications relating to our implementation of the new statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities (subject to certain defined exceptions) and the new statutory moratorium on bed increases in existing LTCHs under section 1206(b)(2) of Public Law 113–67, as amended.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv)(I) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 412.507). In light of our proposed implementation of section 1206(a) of Public Law 113–67, we now need to also address beneficiary charges in the context of the new site neutral payment rate. Therefore, in section VII.B.7.c. of the preamble of this proposed rule, we are proposing to amend the existing regulations relating to the limitation on charges to address beneficiary charges under this new LTCH PPS payment rate.

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred 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 (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial ''in such unusual cases as the Secretary finds appropriate'' (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of electronic health record (EHR) technology certified under the ONC Health Information Technology (HIT) Certification Program developed to support secure, interoperable, health information exchange. The HIT Policy Committee (a Federal Advisory Committee) has recommended areas in which HIT certification under the ONC HIT Certification Program would help support providers that are eligible for the Medicare and Medicaid EHR Incentive Programs, such as long-term care and postacute care hospitals and behavioral health care providers. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and could enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this proposed rule). More information on the ONC HIT Certification Program and efforts to

develop standards applicable to LTCHs can be found by accessing the following Web sites and resources:

- *http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf*;
- *http://www.healthit.gov/facas/FACAS/health-it-policy-committee/hitpc-workgroups/certificationadoption*;
- *http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG*; and
- *http://wiki.siframework.org/Longitudinal+Coordination+of+Care*.

B. Proposed Application of the Site Neutral Payment Rate (Proposed New § 412.522)

1. Overview

Section 1206 of Public Law 113–67 mandates significant changes to the payment system for LTCHs beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Under the current LTCH PPS, all discharges are paid under the LTCH PPS standard Federal payment rate (that is, payments calculated under the existing regulations, including adjustments, in Subpart O of 42 CFR part 412). Section 1206 requires the establishment of an alternate ''site neutral'' payment rate for Medicare inpatient discharges from an LTCH that fail to meet certain statutorily defined criteria. Discharges that meet the criteria will continue to be paid the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria will be paid at a new site neutral payment rate, as described below. We note that, for the remainder of this section, the phrase ''LTCH PPS standard Federal payment rate case'' refers to a LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate under section 1886(m)(6)(A)(ii) of the Act as discussed in section VII.B.3. of the preamble of this proposed rule, and the phrase ''site neutral payment rate case'' refers to a LTCH PPS case that does *not* meet the statutory patient-level criteria and, therefore, will be paid the applicable site neutral payment rate in accordance with section 1886(m)(6)(A)(i) of the Act, as discussed in section VII.B.4. of the preamble of this proposed rule.

Under section 1886(m)(6)(A) of the Act as added by section 1206(a) of Public Law 113–67, beginning in cost reporting periods starting on or after October 1, 2015, all LTCH discharges are paid according to the site neutral payment rate unless certain criteria are met. For LTCH cases that meet the criteria for exclusion, the site neutral payment rate does not apply and payment will be made without regard to the provisions of section 1886(m)(6) of the Act. For cases that meet the criteria for exclusion from the site neutral payment rate, payment will continue to be based on the LTCH PPS standard Federal payment rate as determined in § 412.523. As discussed in section VII.B.3. of the preamble of this proposed rule, under section 1886(m)(6)(A)(ii) of the Act, the criteria for exclusion from the site neutral payment rate are: (1) The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; (2) admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital; and (3) the immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to in this proposed rule as the ICU criterion) or the discharge from the LTCH is assigned to a MS–LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours (referred to in this proposed rule as the ventilator criterion).

In this section of the proposed rule, we discuss our proposals to implement the required changes to the LTCH PPS payment rate, as well as other related policy proposals in accordance with section 1206(a) of Public Law 113–67 under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA.

2. Proposed Application of the Site Neutral Payment Rate Under the LTCH PPS

For FY 2016, we are proposing to add a new section to the regulations under 42 CFR part 412 Subpart O (proposed new § 412.522) to establish the site neutral payment rate required by section 1886(m)(6) of the Act as added by section 1206(a)(1) of Public Law 113–67. Specifically, section 1886(m)(6) of the Act requires that, beginning in cost reporting periods occurring on or after October 1, 2015, all LTCH discharges will be paid under the site neutral payment rate unless certain criteria are met. All LTCH discharges that meet the criteria for exclusion from the site neutral payment rate will continue to be paid the LTCH PPS standard Federal payment rate. Accordingly, in this proposed rule, under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA and in accordance with section 1206(a) of Public Law 113–67, we are proposing to implement the statutory criteria for excluding cases from the site neutral payment rate under proposed new § 412.522(b), as well as establish the requirements for determining the site neutral payment rate for a given LTCH discharge under proposed new § 412.522(c). In addition, we are proposing to make conforming changes to paragraph (a)(2) of § 412.521 to include the new site neutral payment rate established in accordance with proposed new § 412.522 as a method of payment under the LTCH PPS. We also are proposing a technical change to the language in § 412.521(a)(2) that currently refers to the Federal payment rate by changing the term from ''Federal payment rate'' to ''standard Federal payment rate'' in order to provide consistent terminology when referring to such a payment.

3. Criteria for Exclusion From the Site Neutral Payment Rate

a. Statutory Provisions

As stated earlier, section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning in cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges are paid according to the site neutral payment rate unless certain criteria are met. In general, under section 1886(m)(6)(A)(ii) of the Act, the criteria for exclusion from the site neutral payment rate are: the discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital; and the immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to in this proposed rule as the ICU criterion) or the discharge from the LTCH is assigned to an MS–LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours (referred to in this proposed rule as the ventilator criterion). Below we present our proposals to implement the statutory criteria for exclusion from the site neutral payment rate under sections 1886(m)(6)(A)(ii)(I) and (II) of the Act. b. Proposed Implementation of the Criterion for a Principal Diagnosis Relating to a Psychiatric Diagnosis or to Rehabilitation

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that in order for an LTCH discharge to be excluded from payment under the site neutral payment rate, the LTCH discharge cannot have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation. To implement this criterion, under the broad authority of section 123(a)(1) of the BBRA, as amended by section 307(b)

of the BIPA and in accordance with section 1206(a) of Public Law 113–67, we are proposing to identify cases with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation using specific MS–LTC–DRGs that we believe indicate such principal diagnoses. We are inviting public comments on our proposal to identify these cases using specific MS–LTC–DRGs that we believe indicate such principal diagnoses, including the specific MS–LTC–DRGs presented under this proposed approach.

As discussed in section VII.C.2. of the preamble of this proposed rule, the MS–LTC–DRG patient classifications are, by extension, the same as the MS–DRG patient classifications used under the IPPS. The process of developing the MS–DRGs, and by extension the MS–LTC–DRGs, began by dividing all possible principal diagnoses into mutually exclusive principal diagnosis areas, referred to as Major Diagnostic Categories (MDCs). In general, a case is assigned to an MDC based on the patient's principal diagnosis before the case is assigned to an MS–DRG. Once the MDCs were defined, each MDC was evaluated to identify which patient characteristics would be expected to result in similar hospital resource consumption. Because the presence of a surgical procedure that required the use of the operating room would have a significant effect on the type of hospital resources used to treat a patient, most MDCs were initially divided into surgical DRGs and medical DRGs. Some surgical and medical DRGs were further differentiated based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC). (For additional information and details on the development of the MS–DRG classifications, we refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43764 through 43765).)

As such, Medicare LTCH discharges are classified into MS–LTC–DRGs based primarily on the patient's principal diagnosis, as well as up to 24 additional diagnoses, and up to 25 procedures performed during the LTCH stay. Within a small number of MS–LTC–DRGs, classification is also based on the patient's age, sex, and discharge status. The diagnosis and procedure information is currently reported by the hospital using codes from the ICD–9–CM coding system. For FY 2015, the MS–DRGs Version 32 are being used under the IPPS and the MS–LTC–DRGs Version 32 are being used under the LTCH PPS, which are based on ICD–9–CM codes. However, hospitals are required to use the ICD–10–CM/PCS coding system beginning October 1, 2015. As discussed in section II.G.1.a. of the preamble of this proposed rule, the anticipated transition to ICD–10 necessitated the development of an ICD–10–CM/PCS version of the MS–DRGs. To this end, CMS undertook a variety of activities, including a project to convert the ICD–9-based MS–DRGs to ICD–10 MS–DRGs using the General Equivalence Mappings (GEMs). The GEMs provide a map between ICD–9–CM and ICD–10 codes (78 FR 50549). For additional details on the various efforts taken by CMS in preparation for the transition from ICD–9–CM to ICD–10–CM/PCS, we refer readers to section II.G.1. of the preamble of this proposed rule or the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

For FY 2016, we are proposing to use the ICD–10 MS–DRGs Version 33 under the IPPS and the ICD–10 MS–LTC–DRGs Version 33 under the LTCH PPS. Specifically, as discussed in section II.G.1.b. of the preamble of this proposed rule, we are proposing the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–based MS–DRGs Version 32 as part of the proposed MS–DRG updates (and by extension the MS–LTC–DRG updates, as discussed in section VII.C.2. of the preamble of this proposed rule) for FY 2016. We are inviting public comments on how well the ICD–10 MS–DRGs Version 32 (and by extension MS–LTC–DRGs Version 32) replicates the logic of the MS–DRGs Version 32 (and by extension MS–LTC–DRGs Version 32) based on ICD–9–CM codes. In addition, we are inviting public comments on the translations from ICD–9–CM to ICD–10–CM/PCS with regard to our proposal to identify LTCH discharges with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation using specific ICD–10 MS–LTC–DRGs that we believe indicate such principal diagnoses, particularly the validity of the specific MS–LTC–DRGs listed under this proposed approach discussed below in this section. (We note that, for the remainder of the section, when we refer to MS–DRGs Version 33 (or by extension MS–LTC–DRGs), we are referring to the ICD–10-based MS–DRGs Version 33 (and by extension MS–LTC–DRGs), unless otherwise stated. Similarly, when we refer to MS–DRGs Version 32 (or by extension MS–LTC–DRGs), we are referring to the ICD–9-based MS–DRGs Version 32 (and by extension MS–LTC–DRGs), unless otherwise stated).

In this proposed rule, we are proposing under proposed new § 412.522(b)(1)(i) to identify LTCH discharges with principal diagnoses relating to a psychiatric diagnosis or to rehabilitation based on the MS–LTC–DRG assignment in accordance with § 412.513 of the regulations. In developing this proposal, we began by examining which ICD–9–CM diagnosis codes appropriately identify a principal diagnosis related to a psychiatric diagnosis or to rehabilitation. Next, we determined which MS–DRGs (and by extension, MS–LTC–DRGs) those ICD–9-based diagnosis codes grouped to using Version 32 of the ICD–9–CM MS–DRG Definitions Manual, which shows the valid principal diagnoses for each MDC and the MS–DRG assignment for each of those principal diagnoses. We believe that the resulting list of MS–LTC–DRGs Version 32 are indicative of an LTCH discharge with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation because the classification of a Medicare discharge into a MS–LTC–DRG is predominantly based on the patient's principal diagnosis.

As stated above and as discussed in greater detail in section II.G.1. of the preamble of this proposed rule, in preparation for the implementation of ICD–10, we have developed ICD–10-based MS–LTC–DRGs. Under the ICD–10 MS–DRGs Version 32 (and by extension the ICD–10 MS–LTC–DRGs Version 32), the same list of ICD–10 MS–LTC–DRGs are indicative of an LTCH discharge with a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation. As stated earlier in this section, for FY 2016, we are proposing to use the ICD–10 MS DRGs Version 33 under the IPPS and the ICD–10 MS–LTC–DRGs Version 33 under the LTCH PPS. Therefore, for FY 2016, we are proposing that an LTCH discharge assigned to one of the following proposed ICD–10 MS–LTC–DRGs Version 33 would identify a case with a principal diagnosis relating to a psychiatric diagnosis:

- MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnosis of Mental Illness);
- MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction);
- MS–LTC–DRG 881 (Depressive Neuroses);
- MS–LTC–DRG 882 (Neuroses except Depressive);
- MS–LTC–DRG 883 (Disorders of Personality & Impulse Control);
- MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation);
- MS–LTC–DRG 885 (Psychoses);
- MS–LTC–DRG 886 (Behavioral & Developmental Disorders);
- MS–LTC–DRG 887 (Other Mental Disorder Diagnoses);

• MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama);
• MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy);
• MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); and
• MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC).

We also are proposing that, for FY 2016, an LTCH discharge assigned to one of the following proposed ICD–10 MS–LTC–DRGs Version 33 would identify an LTCH discharge with a principal diagnosis relating to rehabilitation:

• MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and
• MS–LTC–DRG 946 (Rehabilitation without CC/MCC).

Under these proposals, for FY 2016, an LTCH discharge grouped to any of the proposed MS–LTC–DRGs listed above would not meet the criteria under proposed new § 412.522(b)(1)(i) to be excluded from the site neutral payment rate.

c. Proposed Addition of Definition of a ''Subsection (d) Hospital'' to LTCH Regulations

The site neutral payment rate established in section 1206(a) of Public Law 113–67 includes several references to ''subsection (d) hospitals.'' The term ''subsection (d) hospital'' is defined in section 1886(d)(1)(B) of the Act and generally means a hospital located in 1 of the 50 States or the District of Columbia other than a psychiatric hospital, a rehabilitation hospital, a children's hospital, an LTCH, or a cancer hospital. Section 1886(m)(6)(D) of the Act, as added by section 1206(a)(1) of Public Law 113–67, also specifies that any reference in that paragraph to a ''subsection (d) hospital'' is deemed to include a ''subsection (d) Puerto Rico hospital.'' Section 1886(d)(9)(A) of the Act states that, as used in that section, the term ''subsection (d) Puerto Rico hospital'' means a hospital that is located in Puerto Rico and that would be considered a subsection (d) hospital (as defined in paragraph (d)(1)(B)) if it were located in 1 of the 50 States.

As part of our proposed implementation of section 1206(a) of Public Law 113–67, and under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to add a definition of the term ''subsection (d) hospital'' under § 412.503 that would be applicable to the LTCH regulations under proposed new § 412.522. Specifically, we are proposing to define a ''subsection (d) hospital'' under § 412.503, for purposes of proposed new § 412.522, as a hospital defined in section 1886(d)(1)(B) of the Act, and includes any hospital that is located in Puerto Rico that would be defined as a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act if it were located in 1 of the 50 States. We believe that this proposed definition is consistent with definitions used in the statute, and would provide additional clarity in the proposed regulations presented in this proposed rule to implement the site neutral payment rate policies required by section 1206(a) of Public Law 113–67.

d. Proposed Interpretation of ''Immediately Preceded'' by a Subsection (d) Hospital Discharge

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that, in order to be excluded from payment under the site neutral payment rate, the LTCH discharge must meet the ICU criterion at section 1866(m)(6)(A)(iii) of the Act or the ventilator criterion at section 1866(m)(6)(A)(iv) of the Act, which are discussed in greater detail below. Both the ICU criterion and the ventilator criterion require that the LTCH admission be immediately preceded by a discharge from a subsection (d) hospital.

For purposes of the ICU criterion and the ventilator criterion at sections 1866(m)(6)(A)(iii) and (iv) of the Act, under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we are proposing that the phrase ''immediately preceded'' by a discharge from a subsection (d) hospital means a Medicare patient is discharge from the subsection (d) hospital immediately prior to the patient's admission to an LTCH. A Medicare patient discharge from the subsection (d) hospital to any other setting, including home, an IRF, an IPF, or a SNF would not be considered to be ''immediately preceded'' by a discharge from a subsection (d) hospital, nor fulfill the ICU criterion or the ventilator criterion in order to qualify for exclusion from the site neutral payment rate. We believe that this proposed policy, which would be codified at new proposed § 412.522(b)(1)(ii), would appropriately identify an LTCH admission that was immediately preceded by a discharge from a subsection (d) hospital. Under this proposal, we are proposing to determine an applicable Medicare patient discharge from a subsection (d) hospital (as defined at proposed § 412.503) by using the subsection (d) hospital's discharge date on the Medicare claim and the LTCH admission date on the Medicare claim for the LTCH's discharge. We also are proposing, for purposes of evaluation of the exclusion from the site neutral payment rate, that the discharge from a subsection (d) hospital must use Patient Discharge Status Code 63, which signifies a patient was discharged or transferred to an LTCH, or Patient Discharge Status Code 91, which signifies a patient was discharged/transferred to a Medicare-certified LTCH with a planned acute care hospital inpatient readmission on hospital claims submitted for the LTCH's discharge to be eligible for exclusion from the site neutral payment rate. We are proposing that a Medicare patient discharge that occurred on the same date as the LTCH admission (or, in certain rare circumstances, that occurred the date before the date of the LTCH admission) that has a patient discharge status code on the subsection (d) hospital claim that indicates discharge or transfer to an LTCH would fulfill the immediately preceded portion of the requirements to be excluded from the site neutral payment rate. Under this proposal, discharges from subsection (d) hospitals reporting a patient discharge status code other than 63 or 91 on the hospital's claim could not serve as a basis for a discharge meeting the immediately preceded by a subsection (d) hospital discharge requirement for exclusion from the site neutral payment rate. We believe that it is appropriate to include discharges from a subsection (d) hospital that occur on the date before the date of the LTCH admission (that is, essentially within 1 calendar day of the LTCH admission) under our proposed interpretation of the term ''immediately preceded'' in order to account for those rare circumstances where a patient is discharged from a subsection (d) hospital before the midnight census, but was not admitted to the LTCH until after the midnight census of that date of discharge. As we expect that the vast majority of LTCH admissions would occur on the same date as the discharge from the subsection (d) hospital, and only in rare instances would the LTCH admission occur on the date after the discharge date from the subsection (d) hospital, increased frequency in LTCH admissions on the date after the IPPS discharge date would raise concerns that could merit further scrutiny.

We note that this proposed interpretation of ''immediately preceded'' by a subsection (d) hospital would work in tandem with our existing interrupted stay policy at § 412.531.

Although we are not proposing to make any changes to our existing interrupted stay policy, we are making reference to it only to illustrate the consistency between our proposed policy and our existing program policies. The interrupted stay policy is a payment adjustment that was included under the LTCH PPS from the inception. In this discussion, we use the terms ''interrupted stay'' and ''interruption of stay'' interchangeably. An interruption of stay occurs when, during the course of an LTCH hospitalization, the patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment or service that is not available at the LTCH for a specified period followed by readmittance to the same LTCH. As we stated when we established the interrupted stay policy (67 FR 50187), we believe that the readmission to the LTCH represents a continuation of the initial interrupted treatment, rather than a new admission. If an interruption of stay occurred, payment for both ''halves'' of the LTCH discharge would be bundled, and Medicare would make a single payment based on the second date of discharge. The interruption of stay policy treats the second part of an interrupted stay as a ''continuation'' of the initial stay, not a separate LTCH admission. Based on this policy and the requirements of section 1206(a) of Public Law 113–67, in order for an LTCH discharge to be excluded from the site neutral payment rate and, therefore, receive payment based on the LTCH PPS standard Federal payment rate, the initial LTCH admission must be immediately preceded by a subsection (d) hospital discharge. Any interruption of stay defined under § 412.531 would not invalidate the immediately preceded status for the LTCH admission because we historically have treated interrupted stays as one stay. We believe that this interpretation of ''immediately preceded'' in the context of the existing interrupted stay policy is consistent with our historical treatment of LTCH cases involving interrupted stays.

e. Proposed Implementation of the Intensive Care Unit (ICU) Criterion

Section 1886(m)(6)(A)(iii)(I) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ICU criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital that included at least 3 days in an intensive care unit (ICU), as determined by the Secretary. Furthermore, section 1886(m)(6)(A)(iii)(II) of the Act states that, in determining ICU days, the Secretary shall use data from revenue center codes 020X or 021X (or such successor codes as the Secretary may establish). Revenue center codes are reported on the hospital claim (Form CMS–1450 that is also known as the UB–04), which is a uniform institutional provider bill suitable for use in billing multiple third party payers, that is developed and maintained by the National Uniform Billing Committee (NUBC). (We refer readers to Chapter 25, subsection 70.1 of the Medicare Claims Processing Manual (Pub. 100–4).) The revenue code description for revenue center code 020X is for intensive care, and the revenue code description for revenue center code 021X is for coronary care. Both revenue center codes are used to bill Medicare for services provided by ''intensive care units (ICUs)'' as defined under our existing definition at § 413.53(d) of the regulations. Both of these revenue code descriptions are further divided into subcategories that form a revenue center code series. For billing purposes, the ''X'' in the revenue code descriptions for revenue center codes 020X and 021X refers to one of the subcategories available for that revenue center code series. (For additional information on the use of revenue center codes 020X and 021X, we refer readers to Chapter 25, subsection 75.4 of the Medicare Claims Processing Manual (Pub. 100–4) and the NUBC's Web site at: *http://www.nubc.org.*)

To implement the ICU criterion specified at section 1886(m)(6)(A)(iii) of the Act, we are proposing under proposed new § 412.522(b)(2) that the discharge from the subsection (d) hospital that immediately preceded (as previously discussed in section VII.B.3.d. of the preamble of this proposed rule) the admission to the LTCH includes at least 3 days in an ICU (as defined in § 413.53(d) of the regulations). Consistent with the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we are proposing that at least 3 days must be reported on the hospital claim submitted by the subsection (d) hospital using revenue center codes 020X or 021X, the use of which must be consistent with our definition of an ICU under § 413.53(d) in order to fulfill the ICU criterion to be excluded from the site neutral payment rate. We believe that this proposal is consistent with the statute and appropriate because it would ensure that payment for discharges made under the LTCH PPS standard Federal payment rate are for services provided to critically ill beneficiaries who require long-term acute hospitalization.

In developing our proposal for the implementation of the ICU criterion at section 1886(m)(6)(A)(iii) of the Act, we examined current hospital coding practices and the use of revenue center codes 020X and 021X, including the subcategory codes, as reported on the Medicare claims for IPPS hospitals. We do not expect a change in general hospital coding practices regarding revenue center code categories 020X and 021X as a result of this proposal. However, we will continue to monitor such coding practices and may propose to revise the ICU criterion regulations in the future if data from revenue center code series for revenue center codes 020X and 021X indicate that any of the subcategories are not consistent with services provided by ICUs as defined under § 413.53(d).

As previously noted with regard to our proposed implementation of the ''immediately preceded'' requirement, our proposed implementation of the ICU criterion would also work in tandem with our existing interruption of stay policy. Again, we note that we are not proposing to make any changes to the existing interrupted stay policy, and we are referencing it only to illustrate the consistency between our proposed policy and our existing program policies. (For a description of our existing interrupted stay policy, we refer readers to the discussion in section VII.B.3.d. of the preamble of this proposed rule.) As previously noted, LTCH cases involving interrupted stays are treated as a single continuous LTCH stay. As such, under our proposal, the discharge from a subsection (d) hospital that immediately precedes the initial LTCH admission would determine whether the ICU criterion is met. Under our proposal, compliance with the ICU criterion would be based exclusively on the number of days the beneficiary spent in the immediately preceding subsection (d) hospital's ICU prior to being initially admitted to the LTCH. If, during the intervening period of an interrupted LTCH stay, a beneficiary spends any number of days in the ICU of a subsection (d) hospital, those days would not be considered in the evaluation of the LTCH discharge for purposes of meeting the ICU criterion because such care would not have immediately preceded the initial admission to the LTCH. Conversely, if the subsection (d) hospital discharge that immediately preceded the initial LTCH admission meets the ICU criterion (that is, includes at least 3 ICU days), and the period of time relating to an intervening interrupted stay does not include any days in a subsection (d)

hospital's ICU, the ICU criterion would still be met because the initial portion of the LTCH admission fulfilled the ICU criterion for exclusion from the site neutral payment rate. We believe that this proposed interpretation of the ICU criterion in the context of the existing interrupted stay policy is consistent with our historical treatment of LTCH cases involving interrupted stays.

f. Proposed Implementation of the Ventilator Criterion

Section 1886(m)(6)(A)(vi) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ventilator criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital (as discussed in section VII.B.3.d. of the preamble of this proposed rule), and the LTCH discharge must be assigned to an MS–LTC–DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH. As we discussed in section VII.B.3.b. of the preamble of this proposed rule, cases are assigned to MS–LTC–DRGs based, in part, on procedures performed during the beneficiary's LTCH stay, which are reported on a Medicare claim using procedure codes. We are proposing that, for the purposes of a discharge being excluded from the site neutral payment rate, the discharge must use the applicable procedure code to indicate that at least 96 hours of ventilator services were received during the LTCH stay. Currently, under the ICD–9–CM coding system, procedure code 9672 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) is used to describe such long-term mechanical ventilator services provided during a hospital stay, including an LTCH stay. As discussed in sections II.G.1.a. and VII.C. of the preamble of this proposed rule, the use of the ICD–10–CM/PCS coding system will be required beginning October 1, 2015. Under the ICD–10–PCS coding system, procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) describes such long-term mechanical ventilator services provided during a hospital stay, including an LTCH stay. Therefore, we believe that it would be appropriate and consistent with the requirements at section 1886(m)(6)(A)(vi)(II) of the Act to require LTCHs, effective with discharges in cost reporting periods beginning on or after October 1, 2015, to report procedure code 5A1955Z on hospital claims to indicate that the beneficiary received at least 96 hours of ventilator services during the LTCH stay as a condition of the LTCH discharge being eligible for exclusion from the site neutral payment rate based on the ventilator criterion. Under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA and in accordance with section 1206(a) of Public Law 111–67, under proposed new § 412.522(b)(3), we are proposing to require LTCHs to report ICD–10–PCS procedure code 5A1955Z on their claims to indicate that the beneficiary received at least 96 hours of ventilator services during the LTCH stay as a condition of that discharge being eligible for exclusion from the site neutral payment rate based on the ventilator criterion.

Under this proposal, any LTCH discharges that do not report this procedure code on the claim submitted for payment would not meet the ventilator criterion. In developing this proposal, we recognized that many of the discharges reporting procedure code 5A1955Z (that is, those cases involving at least 96 hours of mechanical ventilation services) are grouped into one of six MS–LTC–DRGs. However, discharges grouped into these six MS–LTC–DRGs are not necessarily limited to cases involving beneficiaries who have received at least 96 hours of mechanical ventilation services. In addition, there are some cases that do involve at least 96 hours of mechanical ventilation that are correctly assigned to MS–LTC–DRGs other than the six MS–LTC–DRGs mentioned; for example, those cases grouped based on surgical hierarchy. Given the variance of possible MS–LTC–DRG assignments based on the procedure code indicating the receipt of at least 96 hours of mechanical ventilator services and the MS–LTC–DRG groupings, we believe that our proposal to determine eligibility for meeting the ventilator criterion under section 1886(m)(6)(A)(vi)(II) of the Act based on the procedure code used is more consistent with the language of the Act as added by Public Law 113–67.

4. Proposed Determination of the Site Neutral Payment Rate (Proposed New § 412.522(c))

a. General

Section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning with cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges are paid according to the site neutral payment rate unless certain criteria are met. In general, section 1886(m)(6)(B)(ii) of the Act specifies that the site neutral payment rate is the lower of the IPPS comparable per diem amount under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case. Consistent with the requirements of section 1886(m)(6)(B)(ii) of the Act, we are proposing under proposed new § 412.522(c)(1) that the site neutral payment rate is the lower of the IPPS comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case determined under § 412.529(d)(2).

Under our proposed calculation of the site neutral payment rate, proposed new § 412.522(c)(1)(i) would provide that the IPPS comparable per diem amount would be calculated using the same method used to determine an amount comparable to the hospital IPPS per diem amount as set forth in the existing regulations at§ 412.529(d)(4), consistent with section 1886(m)(6)(B)(ii)(I) of the Act. Specifically, in the RY 2007 LTCH PPS final rule (71 FR 27852 through 27853), we established a method to determine an amount payable under 42 CFR part 412, subpart O, that is comparable to what would otherwise be paid under the IPPS for the costs of inpatient operating services, which is commonly referred to as the ''the IPPS comparable per diem amount.'' Accordingly, consistent with § 412.529(d)(4), we are proposing to determine the IPPS comparable per diem amount based on the standardized amount determined under § 412.64(c), adjusted by the applicable DRG weighting factors determined under § 412.60 as specified at § 412.64(g). We are proposing to further adjust this amount to account for differences in area wage levels based on geographic location using the applicable IPPS labor-related share and the IPPS wage index for nonreclassified hospitals published in the annual IPPS final rule in accordance with § 412.525(c). For LTCHs located in Alaska and Hawaii, we are proposing that this amount would be further adjusted by the applicable COLA factors established annually during the rulemaking cycle. We also are proposing that the IPPS comparable per diem amount include an adjustment for treating a disproportionate share of low-income patients, consistent with the DSH payment adjustment under § 412.106, as applicable, which would include a proxy adjustment for the uncompensated care payment (78 FR 50765 through 50767). In the case of an LTCH that is a teaching hospital, we are proposing that the IPPS comparable per

diem amount include an IME payment adjustment, consistent with the formula set forth under § 412.105, where the LTCH's IME cap (that is, the limit on the number of full-time equivalent (FTE) residents that may be counted for IME) would be imputed from the LTCH's direct GME cap as set forth at § 413.79(c)(2). In addition, we are proposing that the IPPS comparable per diem amount also include payment for inpatient capital-related costs, based on the capital IPPS Federal rate determined in accordance with § 412.308(c), adjusted by the applicable IPPS DRG weighting factors. We are proposing to further adjust the capital IPPS Federal rate by the applicable geographic adjustment factors based on the geographic location of the LTCH and the COLA factors for LTCHs located Alaska and Hawaii, consistent with § 412.316. In addition, we are proposing to include in this amount the adjustments to the capital IPPS Federal rate for DSH payments in accordance with § 412.320 and IME payments in accordance with § 412.322. Consistent with § 412.529(d)(4)(i)(B) and (C), we are proposing to determine the IPPS comparable per diem amount by dividing the IPPS comparable payment amount described above by the geometric average length of stay of the specific MS–DRG under the IPPS and multiplying that amount by the covered days of the LTCH stay. We are proposing that the IPPS comparable per diem amount be limited to the full comparable amount to what would otherwise be paid under the IPPS.

The IPPS comparable per diem amount described under § 412.529(d)(4) does not include additional payments for extraordinarily high-cost cases under the IPPS outlier policy. Therefore, consistent with the requirements of section 1886(m)(6)(B)(ii)(I) of the Act, under our proposed calculation of the site neutral payment rate under proposed new § 412.522(c)(1), we are proposing to add any high-cost outlier (HCO) payment that may be payable under § 412.525(a) to the IPPS comparable per diem amount. To do so, as discussed in greater detail in section VII.B.7.b. of the preamble of this proposed rule, we also are proposing to revise the HCO policy under existing § 412.525(a) to provide for high-cost outlier payments under the site neutral payment rate calculated under proposed new § 412.522(c). We are proposing that site neutral payment rate cases receive an additional payment for HCOs that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which we are proposing would be the sum of site neutral payment rate for the case and the IPPS fixed-loss amount. We also are proposing that HCO payments for site neutral payment rate cases would be budget neutral and are proposing to apply a budget neutrality factor to the LTCH PPS payments for those cases to maintain budget neutrality. (For additional information on our proposed revised HCO policy in regard to site neutral payment rate cases under § 412.525(a), we refer readers to section VII.B.7.b. of the preamble of this proposed rule.)

Furthermore, under our proposed calculation of the site neutral payment rate, under proposed new § 412.522(c)(1)(ii), we are proposing to calculate 100 percent of the estimated cost of a case by multiplying the LTCH's hospital-specific cost-to-charge ratio (CCR) by the Medicare allowable charges for the LTCH case, which is the same method we use to determine SSO payments under § 412.529(d)(2), as well as HCO payments under the HCO policy under § 412.525(a). Consistent with our existing policies for computing CCRs under the LTCH PPS, we also are proposing to apply the payment policies described under § 412.529(f)(4)(i) through (f)(4)(iii) to the calculation of the estimated cost of the case for site neutral payment rate cases under proposed new § 412.522(c)(1)(ii). Under this proposal, the CCR applied at the time a claim is processed would generally be based on either the most recent settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. CMS may specify an alternative to the CCR otherwise applicable if we believe that the CCR being applied is inaccurate, in accordance with section 150.24 of Chapter 3 of the Medicare Claims Processing Manual (Pub. 100–4), or an LTCH may request an alternate (higher or lower) CCR based on its presentation of substantial evidence in support of that alternate. The CMS Regional Office must approve the request, and the MAC notifies the LTCH whenever a change is made to its CCR. The applicable MAC may also use the statewide average CCR that is established annually by CMS if it is unable to determine an accurate CCR for an LTCH under one of the circumstances specified at existing § 412.529(f)(4)(iii) (that is, in general, for a new LTCH, when the LTCH's CCR exceeds 3 standard deviations from the corresponding national geometric mean CCR, and for a LTCH for which data to calculate a CCR are otherwise not available). These same CCR policies also are applicable under the LTCH PPS HCO policy (§ 412.525(a)(4)(iv)(B) and (a)(4)(iv)(C)).

Currently, under the LTCH PPS, payments for HCO and SSO cases may be subject to reconciliation at cost report settlement under § 412.525(a)(4)(iv)(D) and § 412.529(f)(4)(iv), respectively. Under these policies, reconciliation is based on the CCR calculated using the CCR computed from the settled cost report that coincides with the discharge. Under our existing criteria, reconciliation occurs in instances where a LTCH's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate payments when a claim is processed. We adopted this reconciliation policy for the LTCH PPS HCO and SSO cases because CCRs based on settled cost reports are not available when claims are processed unless significant delays are imposed on the payment of claims. (For additional information, we refer readers to the June 9, 2003 IPPS/LTCH PPS high-cost outlier final rule (68 FR 34507) and sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4).) Given the use of LTCH CCRs to calculate the estimated cost of cases under the proposed site neutral payment rate, we believe that it would be equally appropriate to apply the current CCR reconciliation policy principles to site neutral payment rate payments. Therefore, we are proposing under proposed new § 412.522(c)(4) to reconcile site neutral payment rate payments based on the CCR calculated using the settled cost report that coincides with the discharge. We also are proposing that, at the time of any such reconciliation of site neutral payment rate payments, such payments be adjusted to account for the time value of any underpayments or overpayments. Any adjustment would be based upon a widely available index to be established in advance by the Secretary and would be applied from the midpoint of the cost reporting period to the date of reconciliation. The index that would be used to calculate the time value of money is the monthly rate of return that the Medicare Trust Fund earns, which can be found at: *http://www.ssa.gov/OACT/ProgData/newIssueRates.html*, consistent with our current reconciliation policy described in section 150.27 of Chapter 3 of the Medicare Claims Processing Manual (Pub. 100–4). Furthermore, we are proposing that our existing policies governing CCRs for both HCO (under § 412.525(a)(4)(iv)(A) through (C)) and

SSO payments (under § 412.529(f)(4)(i) through (iii)) would apply to the CCRs used to determine the estimated cost of a case under proposed new § 412.522(c)(4).

b. Proposed Blended Payment Rate for FY 2016 and FY 2017

Section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that will be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. For those discharges, the applicable site neutral payment rate is to be the blended payment rate specified in section 1886(m)(6)(B)(iii) of the Act. For LTCH discharges occurring in cost reporting periods beginning during FY 2018 or later, the applicable site neutral payment rate will be the site neutral payment rate as defined in section 1886(m)(6)(B)(ii) of the Act.

Section 1886(m)(6)(B)(iii) of the Act specifies that the blended payment rate is comprised of 50 percent of the site neutral payment rate for the discharge under section 1886(m)(6)(B)(ii) of the Act and 50 percent of the LTCH PPS standard Federal payment rate that would have applied to the discharge if paragraph (6) of section 1886(m) of the Act had not been enacted. As previously discussed, we are proposing to codify the site neutral payment rate specified under section 1886(m)(6)(B)(ii) of the Act under proposed new § 412.522(c)(1), as adjusted under proposed new § 412.522(c)(2). Under proposed new § 412.522(c)(1), the site neutral payment rate is the lower of the IPPS comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments under § 412.525(a), or 100 percent of the estimated cost of the case determined under § 412.529(d)(2). For purposes of the blended payment rate, we are proposing that the payment rate that would otherwise be applicable if section 1886(m)(6) of the Act had not been enacted would be the LTCH PPS standard Federal payment; which, in light of other proposals presented in this proposed rule, would be the LTCH PPS Federal standard payment rate that is applicable to discharges that meet the criteria for exclusion from the site neutral payment rate under proposed new § 412.522(a)(2). That rate is the LTCH PPS standard Federal payment rate determined under § 412.523. Therefore, consistent with the requirements of section 1886(m)(6)(B)(ii) of the Act, we are proposing under proposed new § 412.522(c)(3), for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015, and on or before September 30, 2017 (that is, discharges occurring in cost reporting periods beginning during FYs 2016 and 2017), the payment amount for site neutral payment rate cases would be a blended payment rate, which would be calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under proposed new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate determined under § 412.523. Under this proposal, the payment amounts determined under proposed new § 412.522(c)(1) (the site neutral payment rate) and under § 412.523 (the LTCH PPS standard Federal rate) would include any applicable adjustments, such as HCO payments, as applicable, consistent with the requirements under § 412.523(d). For example, the portion of the blended payment for the discharge that is based on proposed new § 412.522(c)(3) would include 50 percent of any applicable site neutral HCO payment under our proposed revised HCO payment policy (discussed in detail in section VII.B.7.b. of the preamble of this proposed rule), consistent with proposed new § 412.522(c)(1)(i), which provides for HCO payments under § 412.525(a). Similarly, the portion of the blended payment for the discharge that is based on the LTCH PPS standard Federal payment rate would include any applicable HCO payment under existing § 412.525(a).

c. Proposed LTCH PPS Standard Federal Payment Rate

Section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which specifies that beginning with cost reporting periods starting on or after October 1, 2015, all LTCH PPS discharges are paid according to the site neutral payment rate, unless certain criteria are met. For detailed discussion of our proposals regarding the criteria for exclusion from the site neutral payment rate, we refer readers to section VII.B.3. of the preamble of this proposed rule. For LTCH cases that meet the criteria for exclusion from the site neutral payment rate, section 1886(m)(6)(A)(ii) of the Act specifies that the site neutral payment rate will not apply and payment will be made without regard to requirements of section 1886(m)(6)(A)(ii) of the Act. Consistent with these statutory requirements, we are proposing under proposed new § 412.522(a)(2) that for LTCH discharges that meet the criteria for exclusion from site neutral payment rate under proposed new § 412.522(b), payment will be based on the LTCH PPS standard Federal payment rate as determined in § 412.523. That is, under proposed new § 412.522(a)(2), LTCH PPS standard Federal payment rate cases would continue to be paid based on the LTCH PPS standard Federal payment rate. Under this proposal, all of the existing payment adjustments under § 412.525(d), that is, the adjustments for SSO cases under § 412.529, the adjustments for interrupted stays under § 412.531, and the 25-percent threshold policy under § 412.534 and § 412.536, would still apply if appropriate. In addition, as discussed in greater detail in section VII.B.7.b. of the preamble of this proposed rule, we are proposing that our existing HCO policy would apply to LTCH PPS standard Federal payment rate cases, except that the 8 percent HCO target would be established using only data from LTCH PPS standard Federal payment rate cases.

5. Proposed Application of Certain Existing LTCH PPS Payment Adjustments to Payments Made Under the Site Neutral Payment Rate

Consistent with current LTCH PPS payment policies for adjusting Federal prospective payments, under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we are proposing that certain existing payment adjustments under the special payment provisions set forth at existing § 412.525(d), with the exception of the SSO adjustment described under § 412.525(d)(1). These adjustments include the interrupted stay policy and 25-percent threshold policy. The current payment adjustment under the interrupted stay policy at § 412.531 was developed and implemented prior to the statutory LTCH PPS dual-rate payment structure and contains terms specific to payment based on the LTCH PPS standard Federal payment rate (such as LTC–DRG payment and Federal LTC–DRG prospective payment). Under our proposal, the site neutral payment rate would not be calculated based on the LTCH PPS standard Federal payment rate because the payment would generally be the lower of the IPPS comparable per diem amount (including any applicable outlier payments), or 100 percent of the estimated cost of the case. Consequently, in order to apply the provisions of the existing interrupted stay policy at § 412.531 to site neutral payment rate cases, under proposed new § 412.522(c)(2)(ii), we are proposing to specify that, for purposes of the application of the provisions of 412.531 to LTCH discharges described under § 412.522(a)(1), the LTCH PPS

standard payment-related terms, such as ''LTC–DRG payment'', ''full Federal LTC–DRG prospective payment'', and ''Federal prospective payment,'' mean the site neutral payment rate calculated under proposed new § 412.522(c).

We believe that it is appropriate to apply these adjustments to the site neutral payment rate cases because the site neutral payment rate merely establishes an alternate payment amount under the LTCH PPS, as opposed to creating an exception from the LTCH PPS. Additionally, we believe that the policy concerns upon which these policies were based apply equally to payments made under the LTCH PPS site neutral payment rates and the standard Federal payment rates.

We established the interrupted stay policy to address instances in which a patient is discharged from an LTCH and later readmitted to that LTCH within a certain amount of time. This kind of readmission to the LTCH represents a continuation or resumption of the initial, interrupted treatment, rather than a new admission. (For a discussion of our implementation of the interrupted stay policy, we refer readers to the RY 2003 LTCH PPS final rule (67 FR 56002).) We continue to believe that the interrupted stay policy serves as an effective instrument to protect the Medicare Trust Fund from significant and inappropriate expenditures (78 FR 50768), and we do not believe that the site neutral payment rate will address these concerns unless the interrupted stay policy is applied to site neutral payment rate cases in the same manner as it is applied to standard Federal payment rate cases.

The 25-percent threshold payment adjustment policy was implemented based on analyses of Medicare discharge data that indicated that patterns of patient shifting appeared to be occurring more for provider financial advantage than for patient benefit. In order to discourage such activity, a payment adjustment was applied to LTCH discharges of patients who were admitted to the LTCH from the same referring hospital in excess of an applicable percentage threshold (79 FR 50185). We refer readers to the detailed discussions of the 25-percent threshold payment adjustment policy for LTCH hospital-within-hospitals (HwHs) and LTCH satellite facilities in the FY 2005 IPPS/LTCH final rule (69 FR 49191 through 49214) and its application to all other LTCHs in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944), as well as our discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185 through 50187), for additional details on the 25-percent threshold payment adjustment. We do not believe that the site neutral payment rate will address these patient shifting concerns unless the 25-percent threshold payment adjustment is applied to site neutral payment rate cases in the same manner as it is applied to LTCH PPS standard Federal payment rate cases.

In considering the potential policy proposals, we recognized that there is a current statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under section 1206(b)(1)(A) of Public Law 113–67 that is scheduled to expire in FY 2016. (For a discussion of our implementation of the current statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185 through 50187).) We are proposing to apply all of the payment adjustments to site neutral payment rates in the same manner as they are currently applied (and will continue to be applied for the foreseeable future) to LTCH PPS standard Federal payment rates—including, as applicable, the moratorium on implementing the 25-percent threshold payment adjustment.

We are not proposing to apply the SSO payment adjustment to the site neutral payment rate at this time because, while the policy goal of ensuring patients in an LTCH receive a full course of treatment remains, under our current method of paying for SSOs as described under § 412.529, we pay for SSOs based on the lowest of several payment options, one of which is the LTCH's estimated cost of the case. As described above, site neutral payment rate cases are paid the lower of the IPPS comparable per diem amount, or 100 percent of the estimated cost of the case. Because the estimated cost option is used in determining both SSO payments and site neutral payment rates and both methods make payment based on the lowest of their respective payment options, in most cases, applying our current SSO payment adjustment to site neutral payment rate cases would not affect the resulting LTCH PPS payment made for the discharge. We may consider proposing the application of an alternative SSO payment adjustment in the future if we find evidence that Medicare beneficiaries are not regularly receiving the full course of treatment when such treatment is paid for at the site neutral payment rate.

6. Proposals Relating to the LTCH Discharge Payment Percentage

Section 1886(m)(6)(C) of the Act, as added by section 1206 of Public Law 113–67, imposes several requirements related to an LTCH's discharge payment percentage. As defined by section 1886(m)(6)(C)(iv) of the Act, the term ''LTCH discharge payment percentage'' is a ratio, expressed as a percentage, of Medicare discharges not paid the site neutral payment rate to total number of Medicare discharges occurring during the cost reporting period. In other words, an LTCH's discharge payment percentage would be the ratio of an LTCH's Medicare discharges that meet the criteria for exclusion from the site neutral payment rate (as described under proposed new § 412.522(a)(2)) to an LTCH's total number of Medicare discharges paid under the LTCH PPS (that is, both Medicare discharges paid under the site neutral payment rate and those that meet the criteria for exclusion from the site neutral payment rate, as described under proposed new § 412.522(a)(1) and (2), respectively) during the cost reporting period. Therefore, consistent with the statutory requirement at section 1886(m)(6)(C)(iv) of the Act and under the broad authority under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, under proposed new § 412.522(d)(1), we are proposing to define an LTCH's discharge payment percentage as a ratio, expressed as a percentage, of Medicare discharges excluded from the site neutral payment rate as described under proposed new § 412.522(a)(2) to total Medicare discharges paid under the LTCH PPS (in accordance with 42 CFR part 412, subpart O) during the cost reporting period.

In addition, section 1886(m)(6)(C)(i) of the Act requires that we provide notice to each LTCH of the LTCH's discharge payment percentage (as defined in section 1886(m)(6)(C)(iv) of the Act) for LTCH cost reporting periods beginning during or after FY 2016. Therefore, we are proposing to codify this statutory requirement at proposed new § 412.522(d)(2). Under this proposal, for cost reporting periods beginning on or after October 1, 2015, as required by the statute, we would inform each LTCH of their discharge payment percentage as defined under proposed new § 412.522(d)(1). We plan to develop such a notification process through subregulatory guidance. We also note that, under section 1886(m)(6)(C)(ii) of the Act, for cost reporting periods beginning on or after October 1, 2020, the statute requires that any LTCH whose discharge payment percentage for the period is not at least 50 percent will be informed of such a fact and all of the LTCH's discharges in each successive cost reporting period will be paid the payment amount that

would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital, subject to the process for reinstatement provided for by section 1886(m)(6)(C)(iii) of the Act. Because this statutory requirement is not effective until cost reporting periods beginning on or after October 1, 2020, we are not making any proposals related to the limitation requirement or the process for reinstatement at this time. However, we are inviting public comments on the development and implementation of the process for reinstatement under section 1886(m)(6)(C)(iii) of the Act.

7. Additional LTCH PPS Policy Considerations Related to the Implementation of the Site Neutral Payment Rate Required by Section 1206(a) of Public Law 113–67

As discussed earlier in this section, section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which establishes patient-level criteria for payments made under the LTCH PPS for LTCH discharges occurring during cost reporting periods beginning on or after October 1, 2015 (FY 2016). In the FY 2015 IPPS/LTCH PPS proposed and final rules, we stated our intent to implement the requirements established by section 1206(a) of Public Law 113–67 through notice and comment rulemaking during the FY 2016 IPPS/LTCH PPS rulemaking cycle. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28205 through 28206), we discussed several significant issues arising from the statutory changes to the LTCH PPS required by section 1206(a) of Public Law 113–67, which establishes two distinct payment groups for LTCH discharges under the revised system: Discharges meeting specified patient-level criteria that will be paid under the LTCH PPS standard Federal payment rate and all other patient discharges that will be paid under the site neutral payment rate. In that same proposed rule, we expressed our interest in receiving feedback from LTCH stakeholders on our plans to evaluate whether it would be appropriate to modify any of our historical policies or methodologies as we began to develop proposals to implement the statutory changes to the LTCH PPS. In particular, we solicited public feedback on the policies relating to the MS–LTC–DRG relative payment weights and high-cost outlier payments in preparation of developing proposals to implement the statutory changes to the LTCH PPS beginning in FY 2016. We explained that in setting the payment rates and factors under the LTCH PPS in accordance with requirements of section 1206(a) of Public Law 113–67, for certain LTCH PPS payment adjustments we planned to evaluate whether it would be appropriate to modify our historical methodology to account for the establishment of the two distinct payment rates for LTCH discharges. In particular, we stated our intent to examine whether, beginning in FY 2016, it would continue to be appropriate to include data for all LTCH PPS cases, including site neutral payment rate cases, in the methodology used to set the MS–LTC–DRGs relative payment weights. We also stated our intent to explore the possibility of changes to the current LTCH PPS high-cost outlier payment policy. Given the fact that, for a number of LTCH discharges, payment would be made based on the lower site neutral payment rate (that is, the lesser of an ''IPPS comparable'' payment amount or 100 percent of the estimated cost of the case), we believed that it would be appropriate to evaluate whether a single high-cost outlier threshold could be applied to all LTCH PPS cases (both LTCH PPS standard Federal payment rate and site neutral payment rate cases), or whether it may be more appropriate to have separate high-cost outlier thresholds for each of the two payment rates under the statutory revisions to the LTCH PPS.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50197 through 50198), we summarized the comments we received in response to our request for input from LTCH stakeholders. As we stated in that same final rule, we appreciated the commenters' thoughtful and detailed feedback, particularly those comments regarding the MS–LTC–DRG relative payment weights and the high-cost outlier policy under the new LTCH PPS dual-rate payment structure established by section 1206(a) of Public Law 113–67. In developing the proposals presented in this proposed rule, we considered the recommendations and information provided by those commenters. Below we discuss our policy proposals related to the MS–LTC–DRG payment relative weights and high-cost outlier policy in regard to our proposed implementation policies under the LTCH PPS dual-rate payment structure required by section 1206(a) of Public Law 113–67.

a. MS–LTC–DRG Relative Payment Weights

Under the LTCH PPS, relative payment weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization between the diagnosis-related groups (§ 412.515). Each year, based on the latest available LTCH claims data, we calculate a relative payment weight for each MS–LTC–DRG that represents the resources used for an average inpatient LTCH case assigned to that MS–LTC–DRG to ensure that Medicare patients with conditions or illnesses classified under each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency (79 FR 50170). CMS adjusts the classifications and weighting factors annually to reflect changes in factors affecting the relative use of hospital resources, such as treatment patterns, technology, and the number of discharges (§ 412.517).

Under the new statutory LTCH PPS structure, section 1206(a) of Public Law 113–67 establishes two distinct payment rates for LTCH discharges: Discharges meeting specified patient-level criteria that will be excluded from the site neutral payment rate and all other patient discharges that will be paid under the site neutral payment rate. As discussed in greater detail in section VII.B.4.c. of the preamble of this proposed rule, under proposed new § 412.522(a)(2), we are proposing to pay for LTCH discharges that meet the criteria for exclusion from site neutral payment rate using the LTCH PPS standard Federal payment rate described under § 412.523, as adjusted. In other words, LTCH discharges that meet the specified patient-level criteria would continue to be paid at what we refer to as the ''LTCH PPS standard Federal payment rate.'' In general, the LTCH PPS standard Federal payment rate is calculated by adjusting the LTCH PPS standard Federal payment rate by the applicable MS–LTC–DRG relative payment weight for that Medicare cases. Under proposed new § 412.522(c) (as discussed in greater detail in section VII.B.4.a. of the preamble of this proposed rule), consistent with section 1886(m)(6)((B)(ii) of the Act, we are proposing that the site neutral payment rate is the lower of the IPPS comparable per diem amount (including any applicable outlier payments), or 100 percent of the estimated cost of the case. Under this proposal, the IPPS comparable per diem amount would be determined using the same method to determine SSO payments under the SSO policy at § 412.529(d)(4), and the estimated cost of the case would be determined using the same method to determine estimated costs under the SSO policy at § 412.529(d)(2). We note that the proposed methodology for determining payments for site neutral payment rate cases does not use the LTCH PPS standard Federal payment

rate or the applicable MS–LTC–DRG relative payment weights.

As discussed above, in preparation for this proposed rule, we considered LTCH stakeholder input and evaluated whether it would be appropriate to modify our historical MS–LTC–DRG relative payment weight methodology to account for the establishment of the two distinct payment rates for LTCH discharges under the statutory changes to the LTCH PPS. Specifically, we examined whether our historical methodology, which uses data from all LTCH PPS discharges, should be continued when we calculate the MS–LTC–DRG relative payment weights under the new LTCH PPS dual-rate payment structure, or whether it would be more appropriate to limit the data used to calculate relative payment weights to that obtained from discharges paid based on the LTCH PPS standard Federal payment rate. Our existing methodology for developing the MS–LTC–DRG relative payment weights includes established policies related to the data used to calculate the relative payment weights, the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, the low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, and the calculation of the MS–LTC–DRG relative payment weights with a budget neutrality factor (79 FR 50171). Our most recent discussion of the existing methodology for calculating the MS–LTC–DRG relative payment weights can be found in the FY 2015 IPPS/LTCH final rule (79 FR 50168 through 50176). Our proposed methodology for calculating the FY 2016 MS–LTC–DRG relative payment weights (including a proposal to use only data from the LTCH PPS standard Federal payment rate cases) is discussed in section VII.C.3. of the preamble of this proposed rule.

In response to our solicitation for stakeholder input included in the FY 2015 IPPS/LTCH PPS proposed rule, we received numerous comments that addressed the calculation of the MS–LTC–DRG relative payment weights under the new statutory LTCH PPS structure. In its comment, MedPAC urged CMS to establish ''. . . new relative payment weights for each MS–LTC–DRG based solely on the most recent available standardized data associated with discharges meeting the specified patient-level criteria'' because those discharges under the new law would represent cases treating the most severely ill, incurring higher resource costs that warrant higher LTCH payments. MedPAC also stated that the change in methodology should not result in increased aggregate payments for the cases paid under the LTCH PPS standard Federal payment rate under the new statutory LTCH PPS structure. Most of the other commenters agreed with MedPAC's recommendation that the MS–LTC–DRG relative payment weights under the new statutory structure should be calculated using only the data from cases that meet the statutory patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases), without including data from cases paid the site neutral payment rate. A few commenters conducted their own analyses and found that both relative payment weight approaches (that is, using data from all LTCH PPS cases as compared to using only data from standard Federal payment rate cases) produce MS–LTC–DRG relative payment weights that are similar. In addition, some of the commenters urged CMS to focus on keeping payments for LTCH PPS standard Federal payment rate cases at the same level that would have been in the absence of the statutory changes, or otherwise consider employing a methodology that promotes stability and predictability in the MS–LTC–DRG relative payment weights. Therefore, the overwhelming majority of the preliminary stakeholder feedback we received did not support using data from all LTCH PPS cases to determine the MS–LTC–DRG relative payment weights for the LTCH PPS standard Federal payment rate cases.

We appreciate the commenters' detailed feedback and have taken into consideration their concerns and recommendations in our evaluation the issue of the MS–LTC–DRG relative payment weights under the new LTCH PPS structure required by section 1206(a) of Public Law 113–67. As part of our evaluation, we examined the FY 2013 LTCH claims data used to determine the FY 2015 MS–LTC–DRG relative weights and found that approximately 54 percent of LTCH cases would meet the criteria for exclusion from the site neutral payment rate (that is, those cases would be paid the LTCH PPS standard Federal payment rate) and approximately 46 percent of LTCH cases would be paid the site neutral payment rate. We then compared the MS–LTC–DRG relative payment weights computed using data from all LTCH PPS cases to the MS–LTC–DRG relative payment weights computed using only data from the LTCH PPS standard Federal payment rate cases. Specifically, using the FY 2013 LTCH claims data (the same LTCH claims data used in the FY 2015 IPPS/LTCH PPS final rule), we calculated FY 2015 MS–LTC–DRG relative payment weights using only data from the 54 percent of LTCH PPS cases that would be paid the LTCH PPS standard Federal payment rate, and compared them to the FY 2015 MS–LTC–DRG relative payment weights established in Table 11 of the FY 2015 IPPS/LTCH PPS final rule, which were calculated using data from all LTCH cases (that is, both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases). Similar to results found by industry stakeholders, we found that both approaches produced comparable MS–LTC–DRG payments for LTCH PPS standard Federal payment rate cases. For example, our analysis of the average MS–LTC–DRG relative payment weight (that is, the case-mix) of LTCH PPS cases that would be paid the LTCH PPS standard Federal payment rate showed that the average case-mix using relative payment weights determined from using only data from LTCH PPS standard Federal payment rate cases differed by only approximately 0.01 percentage point from the average case-mix of those same cases using relative weights determined from data from all LTCH PPS cases.

However, as discussed in more detail in section VII.B.7.b. of the preamble of this proposed rule, where we present our proposals regarding outlier payments for site neutral payment rate cases, we believe that the costs and resource use for cases paid at the site neutral payment rate in the future may be lower on average than the costs and resource use for LTCH cases in our historical data that would have been paid at the site neutral payment rate if the statutory changes were in place when the discharges occurred. We believe that this is likely, even if the proportion of site neutral payment rate cases in future data remains similar to the historical data (that is, 46 percent). Therefore, even though the above analysis shows that including or excluding what would have been site neutral payment rate cases if the new statutory requirements were applied to the historical discharges would not have much impact on the relative payment weight calculation for FY 2016, over time we believe that the relative payment weights could become distorted if future site neutral payment rate cases involve less intensive resource use and lower costs, which we believe is a plausible response to the lower site neutral payment rates under the statutory LTCH PPS changes. This also could lead to less stability in the

MS–LTC–DRG relative payment weights because these cases become incorporated into data used to calculate the relative payment weights.

Taking all of this information into account and given the comments we received on this issue in the FY 2015 rulemaking cycle, we believe that computing the MS–LTC–DRG relative payment weights using only data from LTCH PPS cases that would have been (or, in the future, are) paid the LTCH PPS standard Federal payment rate (that is, cases that meet the criteria for exclusion from the site neutral payment rate) would result in the most appropriate payments under the new statutory structure. Therefore, in this proposed rule, we are proposing that, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative payment weighting factors would be determined using only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases). Under our proposal, the MS–LTC–DRG relative payment weights would not be used to determine the LTCH PPS payment for cases paid the site neutral payment rate, and (in general) site neutral payment rate cases would be paid an IPPS comparable per diem amount (or 100 percent of the estimated cost of the case, if lower), which in most instances would be lower than the LTCH PPS standard Federal payment rate.

As discussed above, several commenters also stated that payments for LTCH PPS standard Federal payment rate cases should be held at the same payment level that they would have been in the absence of the statutory changes. That is, any proposed changes in methodology should not result in any change (increase or decrease) in aggregate payments for LTCH PPS standard Federal payment rate cases under the new statutory LTCH PPS structure. As discussed in section VII.C.3. of the preamble of this proposed rule, under the existing LTCH PPS regulations at § 412.517(b), we already have a budget neutrality requirement for the annual changes to the MS–LTC–DRG classifications and relative payment weights, which specifies that any such changes must be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected. We are proposing to continue to apply that provision because we believe that a budget neutrality requirement is appropriate for the MS–LTC–DRG relative payment weights that would be used to determine LTCH PPS payments for LTCH PPS standard Federal payment rate cases for the reasons discussed when the policy was originally adopted in the FY 2008 LTCH PPS final rule (72 FR 26880 through 26884). Therefore, we are not proposing any changes to the budget neutrality requirement at § 412.517(b). Furthermore, in light of our proposals regarding the MS–LTC–DRG relative payment weighting factors, we are proposing to add paragraph (c) to § 412.517 to specify that, beginning in FY 2016, the annual recalibration of the MS–LTC–DRG relative weighting factors are determined using data from LTCH discharges described under proposed new § 412.522(a)(2). As discussed above, we believe that computing the MS–LTC–DRG relative payment weights using only data from LTCH PPS standard Federal payment rate cases would result in the most appropriate payments under the new statutory structure required by section 1206(a) of Public Law 113–67, and would provide stability and predictability in MS LTC–DRG payments for LTCH PPS standard Federal payment rate cases compared to current LTCH PPS payments.

b. High-Cost Outliers

Under the LTCH PPS, the existing regulations at § 412.525(a) provide for an additional adjustment to LTCH PPS payments to account for outlier cases that have extraordinarily high costs relative to the costs of most discharges (referred to as high-cost outliers (HCOs).) Providing such adjustments for HCOs strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. In addition, HCO payments reduce the financial losses that would otherwise be incurred by hospitals when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. Currently, we set the HCO threshold before the beginning of the payment year so that total estimated HCO payments are projected to equal 8 percent of estimated total payments under the LTCH PPS. Under our current HCO policy, an LTCH would receive an additional payment if the estimated cost of a case exceeds the adjusted LTCH PPS payment plus a fixed-loss amount. In such cases, the additional HCO payment amount is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the adjusted Federal MS–LTC–DRG prospective payment amount for the case and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that an LTCH would incur under the HCO policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the HCO policy, the fixed-loss amount is the maximum loss that an LTCH can incur for a case with unusually high costs before receiving an additional payment amount. The additional payment amount under the LTCH PPS HCO policy is determined using a marginal cost factor, which is a fixed percentage of costs above the HCO threshold. The marginal cost factor under the LTCH PPS HCO policy is 80 percent.

Under the current HCO policy, we annually determine a fixed-loss amount, that is, the maximum loss that an LTCH can incur under the LTCH PPS for a case with unusually high costs before an adjustment is made to the payment for the case. We do so by using the best available data to estimate aggregate LTCH PPS payments with and without a HCO policy, and, based on those estimates, set the fixed-loss amount at an amount that results in estimated total HCO payments being equal to 8 percent of estimated total LTCH PPS payments. Additional information on the LTCH PPS HCO methodology can be found in the FY 2003 LTCH PPS final rule (67 FR 56022 through 56027) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50398 through 50400).

As discussed in the previous section, under the new statutory LTCH PPS structure, section 1206(a) of Public Law 113–67 establishes two distinct payment rates for LTCH discharges beginning in FY 2016. To implement this statutory change, under proposed new § 412.522(a)(2), we are proposing to pay for LTCH discharges that meet the criteria for exclusion from site neutral payment rate based on the LTCH PPS standard Federal payment rate, which includes HCO payments. Under proposed new § 412.522(c), consistent with the statute, we are proposing that the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under existing § 412.529(d)(4) (including any applicable adjustments, such as outlier payments), or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). Below we discuss our proposals for determining HCO payments under the new statutory LTCH PPS payment structure.

In response to our solicitation for stakeholder input included in the FY 2015 IPPS/LTCH PPS proposed rule, we received numerous comments that addressed the HCO policy under the new statutory LTCH PPS structure. In its comment, MedPAC recommended that both LTCH PPS standard Federal rate

cases and site neutral payment rate cases receive HCO payments, and that estimated total HCO payments under the LTCH PPS continue to be projected to be equal to 8 percent of estimated total LTCH PPS payments for all cases (that is, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases). In contrast, most of the other commenters recommended that separate HCO fixed-loss amounts and separate HCO payment ''targets'' (that is, the projected percentage that estimated HCO payments are of estimated total payments) be determined for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. Specifically, these commenters recommended that we calculate a fixed-loss amount under the current HCO policy for LTCH PPS standard Federal payment rate cases using only data (and estimated payments) from what would have been or are LTCH PPS standard Federal payment rate cases, without including data (and estimated payments) from cases that would have been or are paid the site neutral payment rate. In addition, some of the commenters recommended initially applying the existing HCO policy separately to both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases; that is, determining separate HCO fixed-loss amounts so that estimated HCO payments would be equal to 8 percent of estimated total payments for each of the two LTCH PPS payment types (the LTCH PPS standard Federal payment rate cases and site neutral payment rate cases), respectively, and then adjusting the HCO targets as more data under the statutory revisions to the LTCH PPS become available. In other words, commenters suggested that it may be more appropriate to have different HCO targets for the two LTCH PPS payment types rather than two HCO targets of 8 percent. When making recommendations regarding the HCO policy under the statutory LTCH PPS changes, several commenters urged CMS to focus on maintaining LTCH PPS payments for LTCH PPS standard Federal payment rate cases at the same payment level as they are currently under the LTCH PPS, including the level of HCO payments, and to mitigate any instability in the HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases.

Several commenters conducted independent analyses that looked at separate HCO fixed-loss amounts for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. Upon review of their analyses, these commenters specifically recommended that separate HCO fixed-loss amounts be used for the two LTCH PPS payment types. A few of the commenters' analyses included assumptions about LTCH behavioral response to statutory changes to the LTCH PPS (such as changes in patient volume and costs). A few commenters indicated that using historical data would not reflect the anticipated behavioral response as a result of the new statutory payment structure and, therefore, may lead to an overestimation of costs and HCO payments (particularly with regard to payments for site neutral payment rate cases), resulting in a fixed-loss amount that is set too high relative to the HCO target. If this were to occur, these commenters expressed concern that LTCHs would be ''underpaid'' because HCO payments are budget neutral and actual HCO payments would fall below the HCO payments target.

We appreciate the commenters' detailed feedback and have taken their concerns and recommendations into consideration while framing our proposed HCO policy under the new statutory LTCH PPS structure. As we always have for the LTCH PPS, we designed our proposed HCO policy under the new statutory structure to achieve a balance of the following goals: To reduce financial risk, reduce incentives to underserve costly beneficiaries, and improve the overall fairness of the PPS (67 FR 56023). With these goals in mind, we evaluated whether it would be appropriate to modify our current HCO policy to account for the establishment of the new LTCH PPS dual-rate payment structure. This included examining whether our current HCO target, under which we set a single fixed-loss amount so that estimated total HCO payments are projected to equal 8 percent of estimated total LTCH PPS payments, should continue to be used upon implementation of the statutory LTCH PPS payment changes, or whether it would be more appropriate to have two separate HCO targets (one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases).

In examining this issue, we considered how LTCH discharges based on historical claims data would have been classified under the new dual-rate LTCH PPS payment structure and the CMS' Office of the Actuary (OACT) projections regarding how LTCHs would likely respond to our proposed implementation of policies resulting from the statutory payment changes. For FY 2016, our actuaries currently project that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the new statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. (As previously noted, based on FY 2013 LTCH claims data, we found that approximately 54 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 46 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time.) While our actuaries do not project an immediate change in these proportions, they do project cost and resource changes to take into account the lower payment rates. Our actuaries also project that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. This actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. These assumptions are consistent with statements from several commenters who noted that the type of site neutral payment rate cases may change in cost and severity over time in response to the new statutory payment structure because the payment for those cases would generally be lower than the current payment made under the LTCH PPS for these types of cases.

In light of these projections and expectations, we believe that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. Currently, the FY 2015 LTCH PPS fixed-loss amount is $14,972, which was determined using FY 2013 LTCH claims data (79 FR 50400). The FY 2015 IPPS fixed-loss amount is $25,799 (79 FR 50374). A single fixed-loss amount and target under the LTCH PPS would allow LTCH cases paid at the site neutral payment rate to qualify for HCO payments much more easily than comparable IPPS cases assigned to the same MS–DRG. This would occur

because the HCO threshold (which is generally the sum of the adjusted Federal PPS payment for the case and the fixed-loss amount) under the IPPS would be higher than the HCO threshold under the LTCH PPS for a case assigned to the same MS–DRG (which would be expected to have a comparable adjusted Federal PPS payment, costs and resource use to a case paid as a LTCH PPS site neutral payment rate case). While we recognize that differing statutory requirements between the two payment systems result in comparable LTCH PPS site neutral payment rate cases and IPPS cases not being paid exactly the same amount, we do not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS. Based on the FY 2015 figures, an IPPS hospital would have to absorb approximately $11,000 more in additional estimated costs than the LTCH treating a comparable case based on the difference between the IPPS fixed-loss amount of $25,799 and the LTCH PPS fixed-loss amount of $14,792 before it would begin to receive HCO payments. We believe that the most appropriate fixed-loss amount for site neutral payment rate cases under the LTCH PPS for a given fiscal year beginning with FY 2016 would be the IPPS fixed-loss amount for that fiscal year. Therefore, for FY 2016, we are proposing a fixed-loss amount for site neutral payment rate cases of $24,485, which is the same proposed FY 2016 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this proposed rule. We believe that this proposed policy would reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. We also are proposing to make a payment adjustment for HCOs paid under the site neutral payment rate at a rate equal to 80 percent of the difference between the estimated cost of the case and the proposed IPPS HCO threshold, which is consistent with the current LTCH PPS HCO policy. The proposed IPPS HCO threshold for site neutral payment rate cases would be the sum of the LTCH PPS payment for such cases and the proposed IPPS fixed-loss amount of $24,485. In light of these proposals, we note that any site neutral payment rate case that is paid 100 percent of the estimated cost of the case because that amount is lower than the IPPS comparable per diem amount would never be eligible to receive a HCO payment because, by definition, the estimated costs of such cases would never exceed the IPPS comparable amount by any threshold.

Having established the IPPS fixed-loss amount as an appropriate threshold to propose for HCOs paid under the site neutral payment rate, we next examined how to establish an appropriate fixed-loss amount and HCO target for LTCH PPS standard Federal payment rate cases. With that said, we agree with the commenters who recommended that we establish a fixed-loss amount and target for LTCH PPS standard Federal payment rate cases using the current LTCH PPS HCO policy, but limiting the data used under that policy to what would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges. We agree with the commenters that believed that this policy would result in increased stability over time with respect to HCO payments for the LTCH PPS standard Federal payment rate cases. We also believe that this approach would meet the goals cited for our current HCO policy; that is, reducing financial risk, reducing incentives to underserve costly beneficiaries, and improving the overall fairness of the LTCH PPS (67 FR 56023). Therefore, we are not proposing any modifications to the HCO methodology as it applies to LTCH PPS standard Federal payment rate cases other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. Specifically, under our proposal, LTCH PPS standard Federal payment rate cases as described under proposed new § 412.522(a)(2) would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which would be the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount for such cases. The fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to be equal to 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In this proposed rule, to codify our proposed changes to the HCO policy to account for the new statutory dual-rate LTCH PPS payment structure, we are proposing to revise paragraphs (a)(1), (a)(2), and (a)(3), and add a new paragraph (a)(4) to existing § 412.525. In existing § 412.525 (a)(1), (a)(2), and (a)(3), we are proposing to make technical changes to the existing language to make it clear that the provisions in those paragraphs apply to LTCH discharges under both LTCH PPS payment rates (that is, site neutral payment rate cases as described at proposed new § 412.522(a)(1) and the standard Federal payment rate cases as described at proposed new § 412.522(a)(2)). Under the proposed added paragraph (a)(4) to § 412.524, we also are proposing to specify what the terms ''applicable LTCH PPS prospective payment'' and ''applicable fixed-loss amount'' mean for purposes of this paragraph. Specifically, we are proposing that, for purposes of § 412.525(a), ''applicable LTCH PPS prospective payment'' would mean either the site neutral payment rate under proposed new § 412.522(c) for LTCH discharges described under proposed new § 412.522(a)(1) or the standard Federal prospective payment rates under § 412.523 for LTCH discharges described under proposed new § 412.522(a)(2). Similarly, we are proposing that, for purposes of § 412.525(a), ''applicable fixed-loss amount'' would mean either, for LTCH described under proposed new § 412.522(a)(1), the fixed-loss amount established for such cases, or, for LTCH discharges described under proposed new § 412.522(a)(2), the fixed-loss amount established for such cases. In addition, we are proposing to add language to paragraph (a) of § 412.525 to clarify that the fixed-loss is the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs ''before receiving an additional payment,'' and is not the maximum loss an LTCH can incur. We are proposing to make this clarification to highlight that the additional payment under the HCO policy is 80 percent (not 100 percent) of the estimated costs above the outlier threshold (that is, the sum of the applicable LTCH PPS prospective payment and the applicable fixed-loss amount).

The current LTCH PPS HCO policy has a budget neutrality requirement in which the LTCH PPS standard Federal payment rate is reduced by an adjustment factor to account or the estimated proportion of HCO payments to total estimated LTCH PPS payments, that is, 8 percent. (We refer readers to § 412.523(d)(1) of the regulations.) This budget neutrality requirement is intended to ensure that the HCO policy would not result in any change in estimated aggregate LTCH PPS payments. Under our proposal to continue to apply the current HCO methodology as it relates to LTCH PPS

standard Federal payment rate cases (other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases), we also would continue to apply the current budget neutrality requirement (described above). In accordance with the current LTCH PPS HCO policy budget neutrality requirement, we believe that the HCO policy for site neutral payment rate cases should also be budget neutral, meaning that the proposed site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments. In order to achieve this, under proposed new § 412.522(c)(2)(i), we are proposing to apply a budget neutrality factor to the payment for all site neutral payment rate cases described under proposed new § 412.522(a)(1), which would also be established on an estimated basis. This approach is consistent with the HCO policy proposed for LTCH PPS standard Federal payment rate cases, which is budget neutral within the universe of LTCH PPS standard Federal payment rate cases. We are inviting public comments on this proposed approach and the alternative approach of applying a single budget neutrality factor to all LTCH PPS cases, irrespective of the site neutral payment rate.

In order to estimate the magnitude a proposed budget neutrality adjustment under our proposed HCO payment budget neutrality requirement for site neutral payment rate cases, we again relied on the assumption by our actuaries that site neutral payment rate cases would have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Under the IPPS, the fixed-loss amount is estimated based on a 5.1 percent target (79 FR 50378). In accordance with section 1886(d)(5)(A)(iv) of the Act, estimated operating IPPS HCO payments for any year are projected to be at least 5 percent, but no more than 6 percent of estimated total operating DRG payments, which does not include IME and DSH payments plus HCO payments. When setting the HCO threshold, we historically compute a 5.1 percent target by dividing the total operating IPPS HCO payments by the total operating IPPS DRG payments plus operating IPPS HCO payments (79 FR 50374). We believe that it would be reasonable to set the site neutral payment rate case HCO target at the IPPS HCO target because these cases are expected to have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Furthermore, using the IPPS fixed-loss threshold for the site neutral payment rate cases would be expected to result in HCO payments for site neutral payment rate cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. We recognize that, given the uncertainty surrounding the site neutral payment rate case population under the revised LTCH PPS and differences between the relative utilization of the MS–DRGs and MS–LTC–DRGs between the two systems, this prediction may not take effect. However, we must begin somewhere, and this proposed policy seems to be the best budget neutrality option at this time based on the information available to ensure LTCH PPS spending does not inappropriately increase under our proposal for site neutral payment rate HCO cases. As with all of our policies, we will continue to monitor HCOs payments under the LTCH PPS and, as necessary, propose modifications to this proposed method as needed based on what is observed during the implementation process.

Therefore, under proposed new § 412.522(c)(2)(i), we are proposing to adjust payments to site neutral payment rate cases (that is, LTCH PPS discharges described under proposed new § 412.522(a)(1)) by a budget neutrality factor so that the estimated HCO payments payable to site neutral payment rate cases do not result any increase in aggregate LTCH PPS payments. As discussed in greater detail in section V.D.4. of the Addendum to this proposed rule, in estimating total LTCH PPS payments in Federal FY 2016, we are proposing an adjustment to account for the varying effective dates of the statutory LTCH PPS payment changes required by section 1886(m)(6) of the Act, as amended by section 1206 of Public Law 113–67, which are effective for discharges occurring in cost reporting periods beginning on or after October 1, 2015.

In addition to the proposed changes to the existing HCO policy under § 412.525(a) and the budget neutrality adjustment to account for site neutral payment rate HCO payments under proposed § 412.522(c)(2)(i), we are proposing to make conforming changes to existing § 412.523 under paragraph (d)(1) to specify that the HCO target of 8 percent in that provision only applies to HCO payments under § 412.525(a) as they relate to LTCH PPS standard Federal payment rate cases; that is, HCO payments made for discharges described under proposed new § 412.522(a)(2) and not all HCO payments described under proposed new § 412.525(a).

In summary, in this proposed rule, we are proposing to have separate HCO fixed-loss amounts and HCO targets (and corresponding budget neutrality adjustments) for site neutral payment rate cases and LTCH PPS standard Federal payment rate cases, respectively, under the new LTCH PPS dual-rate payment structure. For the reasons discussed above, we believe that separate and independent HCO fixed-loss amounts for each of the two types of LTCH PPS cases would result in the most appropriate payments under the LTCH PPS and achieve the stated goals of our HCO policy. In accordance with our proposed HCO policy for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases, we are proposing that, beginning with FY 2016, our current HCO policy would apply to LTCH PPS standard Federal payment rate cases, such that LTCH PPS standard Federal payment rate cases would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the LTCH PPS standard Federal payment HCO threshold (which would be the sum of the LTCH PPS standard Federal payment rate for the case and the fixed-loss amount for such cases). The fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to equal 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. To maintain budget neutrality, the LTCH PPS standard Federal payment rate would continue to be adjusted by 8 percent to account for the estimated HCO payments to LTCH PPS standard Federal payment rate cases. Similarly, we are proposing that site neutral payment rate cases would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the site neutral payment rate HCO threshold, which would be the sum of site neutral payment rate for the case and the fixed-loss amount for such cases. For site neutral payment rate cases, we are proposing to use the fixed-loss amount determined annually under the IPPS HCO policy, and we estimate that this would result in an estimated proportion of HCO payments to total LTCH PPS payments for site neutral payment rate cases of 5.1 percent. We are proposing that HCO payments to site neutral payment rate cases would be budget neutral, consistent with the current LTCH PPS HCO policy. To maintain budget neutrality, we are proposing to apply a budget neutrality factor to the LTCH PPS payments for

site neutral payment rate cases. To codify the proposals discussed in this section, we are proposing to make changes to the existing HCO policy under § 412.525(a) and conforming changes to existing § 412.523(d)(1), as well as a budget neutrality requirement for HCO payments to site neutral payment rate cases under proposed new § 412.522(c)(2)(i).

c. Limitation on Charges to Beneficiaries

In accordance with existing regulations and for the consistency with other established hospital prospective payment systems polices, we are proposing to revise § 412.507 to establish allowable charges to Medicare beneficiaries whose discharge from the LTCH is paid under the site neutral payment rate (as described in section VII.B.4. of the preamble of this proposed rule). Section 1206(a)(1) of Public Law 113–67 requires that, beginning with cost reporting periods occurring on or after October 1, 2015, all LTCH discharges be paid at the applicable site neutral payment rate unless certain criteria are met. In general, the site neutral rate payment would be based on the lesser of 100 percent of the estimated cost of the case or the IPPS comparable per diem amount (as discussed more detail in section VII.B.4.a. of the preamble of this proposed rule). We believe that, in general, the LTCH PPS payment an LTCH receives at the site neutral payment rate represents a full payment for purposes of determining allowable beneficiary charges for covered services. As such, using the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to revise § 412.507 to limit allowable charges to beneficiaries. Specifically, we are proposing that, if Medicare has paid the full site neutral payment rate for a discharge, an LTCH may only charge the beneficiary applicable deductibles and copay amounts until the high-cost outlier threshold is met. In addition, we are proposing to revise the terminology used under § 412.507 to differentiate between cases paid under the site neutral payment rate and those paid under the LTCH PPS standard Federal payment rate. We note that under this proposed revision, for a case paid under the site neutral payment rate, that payment applies to the LTCH's costs for services furnished until the high-cost outlier threshold is met, and LTCHs may charge the beneficiary for noncovered services in the same manner as if the case were paid under the LTCH PPS standard Federal payment rate, as specified under existing § 412.507. We are not proposing additional changes to our current provisions limiting charges to beneficiaries for discharges paid as SSO cases because, as explained in section VII.B.5. of the preamble of this proposed rule, we are not proposing to adopt any SSO payment adjustment policies for discharges paid under the site neutral payment rate at this time. We believe that these proposals concerning the limitation on charges to beneficiaries are in accordance with existing regulations and consistent with other established hospital payment systems policies.

C. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2016

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of ''existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.''

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect ''the differences in patient resource use . . .'' of LTCH patients (section 123(a)(1) of the BBRA (Pub. L. 106–113)).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 753 MS–DRG groupings. For FY 2016, there would be 758 MS–DRG groupings if we finalize all of the proposed changed discussed in section II.G. of the preamble of this proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. Below we provide a general summary of our existing methodology for determining the proposed FY 2016 MS–LTC–DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2016, we are proposing to use the same methodology and steps to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.C.3. of the preamble of this proposed rule). However, under the dual-rate LTCH PPS payment structure required by statute, we are proposing that, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative weights would be determined (1) using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate were in effect when claims data from time periods before the new statutory dual-rate LTCH PPS payment structure applies were

used to calculate the relative weights, and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described in greater detail in section VII.C.3.c. of the preamble of this proposed rule). In addition, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.C.3.c. of the preamble of this proposed rule.

Under our proposal, the MS–LTC–DRG relative weights would not be used to determine the LTCH PPS payment for cases paid at the site neutral payment rate and data from cases paid at the site neutral payment rate or that would have been paid at the site neutral payment if the dual rate LTCH PPS payment structure had been in effect would not be used to develop the relative weights. (For details on our proposed application of the site neutral payment rate, we refer readers to section VII.B. of the preamble of this proposed rule. For additional information on our proposal to use data from applicable LTCH cases to determine the MS–LTC–DRG relative weights under the statutory dual-rate LTCH PPS payment structure, we refer readers to section VII.B.7.a. of the preamble of this proposed rule.)

Furthermore, for FY 2016, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we account for adjustments made to LTCH PPS standard Federal payment rate payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.C.3.g. of the preamble of this proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–9–CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS–LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted on the 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of part 162. Among other requirements, by January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the Internal Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). For additional information on the ICD–9–CM coding system, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples are published in the *Coding Clinic for ICD–9–CM,* a product of the American Hospital Association. (We refer readers to section II.G.13. of the preamble of this proposed rule for additional information on the annual revisions to the ICD–9–CM codes.)

Currently, providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. We have been discussing the conversion to the ICD–10 coding system for many years. Hospitals, including LTCHs, are

required to use the ICD–10 coding system effective October 1, 2015. Consequently, providers will begin using the code sets under the ICD–10 coding system to report diagnoses (ICD–10–CM codes) and procedures (ICD–10–PCS codes) for Medicare hospital inpatient services under the MS–DRG system (and by extension the MS–LTC–DRG system) beginning October 1, 2015. For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.G.1. of the preamble of this proposed rule.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2016

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2015, through September 30, 2016 (FY 2016) consistent with the proposed changes to specific MS–DRG classifications presented in section II.G. of the preamble of this proposed rule. Therefore, the proposed MS–LTC–DRGs for FY 2016 presented in this proposed rule are the same as the proposed MS–DRGs that are being proposed for use under the IPPS for FY 2016. Specifically, as discussed in section II.G.1.b. of this preamble of this proposed rule, we are proposing to use the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the proposed MS–DRG updates (and by extension the MS–LTC–DRG) updates for FY 2016. The proposed GROUPER Version 33 is based on ICD–10–CM/PCS diagnoses and procedure codes, consistent with the requirement to use ICD–10 beginning October 1, 2015, as noted above and discussed in greater detail section II.G.1. of the preamble of this proposed rule. We are inviting public comments on how well the ICD–10 MS–DRGs Version 33 (and by extension the ICD–10 MS–LTC–DRGs Version 33) replicates the logic of the ICD–9 MS–DRGs Version 32 (and by extension ICD–9 MS–LTC–DRGs Version 32). (We note that, when referencing MS–LTC–DRGs Version 33 in the remainder of this section, we are referring to the ICD–10-based MS–LTC–DRGs Version 33 unless otherwise stated. Similarly, when referencing MS–LTC–DRGs Version 32 for the remainder of this section, we are referring to the ICD–9-based MS–LTC–DRGs Version 32 unless otherwise stated.) In addition, because the proposed MS–LTC–DRGs for FY 2016 are the same as the proposed MS–DRGs for FY 2016, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 33, as discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10 coding system, would also be applicable under the LTCH PPS for FY 2016.

3. Development of the Proposed FY 2016 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the new dual-rate LTCH PPS payment structure required by the statute, as previously discussed in section VII.B.7.a. of the preamble of this proposed rule, we are proposing, beginning with FY 2016, to recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases. Under this proposal, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal rate when calculating the payment for standard payment rate cases. However, the MS–LTC–DRG relative weights would not be used to determine the LTCH PPS payment for cases paid under the site neutral payment rate. (For details on our proposed application of the site neutral payment rate, we refer readers to section VII.B. of the preamble of this proposed rule.)

The basic methodology used to develop the MS–LTC–DRG relative weights is generally consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991), with the exception of some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from

the adoption of the MS–LTC–DRGs. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2016

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50170 through 50176), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2015. The basic methodology we used to develop the FY 2015 MS–LTC–DRG relative weights was the same as the methodology we used to develop the FY 2014 MS–LTC–DRG relative weights in the FY 2014 IPPS/LTCH PPS final rule and was consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991).

In this proposed rule, we are proposing to continue to use the same general methodology to determine the proposed MS–LTC–DRG relative weights for FY 2016, including the proposed application of established policies related to, the hospital-specific relative value methodology, the treatment of severity levels in the proposed MS–LTC–DRGs, proposed low-volume and no-volume MS–LTC–DRGs, proposed adjustments for nonmonotonicity, and the steps for calculating the proposed MS–LTC–DRG relative weights with a proposed budget neutrality factor. However, as previously noted and discussed in greater detail in section VII.B.7.a. of the preamble of this proposed rule, under the dual-rate LTCH PPS payment structure required by statute, we are proposing that the FY 2016 MS–LTC DRG relative weights would be determined based only on data from applicable LTCH cases. We discuss the effects of our proposal concerning the data used to determine the FY 2016 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

Furthermore, as we have done since the FY 2008 update, we are proposing to apply a two-step budget neutrality adjustment to the annual update to the MS–LTC–DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the classification and relative weight changes (72 FR 26882 through 26884). For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296). Below we present our proposed methodology for determining the proposed MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments, which is generally consistent with the methodology presented in the FY 2015 IPPS/LTCH PPS final rule, except for the proposed use of applicable LTCH data.

c. Applicable LTCH Data

For this FY 2016 proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments, we obtained total charges from FY 2014 Medicare LTCH claims data from the December 2014 update of the FY 2014 MedPAR file, which are the best available data at this time, and the proposed Version 33 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if more recent data become available, we would use those data and the finalized Version 33 of the GROUPER in establishing the FY 2016 MS–LTC–DRG relative weights in the final rule. To calculate the proposed FY 2016 MS–LTC–DRG relative weights under the new statutory dual-rate LTCH PPS payment structure that will be effective beginning October 1, 2015, as previously discussed in section VII.B.7.a. of the preamble of this proposed rule, beginning with the annual recalibration of the MS–LTC–DRG relative weights for FY 2016, we are proposing to use applicable LTCH data. Accordingly, we began by first evaluating the LTCH claims data in the December 2014 update of the FY 2014 MedPAR file to determine which LTCH cases would have met the criteria for exclusion from the site neutral payment rate under proposed § 412.522(b) (as discussed in greater detail in section VII.B.3. of the preamble of this proposed rule) had the new dual-rate LTCH PPS payment structure been in effect at the time those claims were processed. We identified the FY 2014 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which, under our proposals, would identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation (as discussed in section VII.B.3.b. of the preamble of this proposed rule); and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the proposed ICU criterion (discussed in section VII.B.3.e. of the preamble of this proposed rule); or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the proposed ventilator criterion (discussed in section VII.B.3.f. of the preamble of this proposed rule). Claims data from December 2014 update of the FY 2014 MedPAR file that reported ICD–9–CM procedure code 96.72 were used to identify cases involving at least 96 hours of ventilator services in accordance with the proposed ventilator criterion. (We note that the corresponding ICD–10–PCS code for cases involving at least 94 hours of ventilation services is 5A1955Z, effective as of October 1, 2015.)

Then, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice, we excluded the Medicare Advantage (Part C) claims that were in the resulting data set based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the

proposed relative weights for the LTCH PPS standard Federal payment rate payments for FY 2016.

In summary, in identifying the claims data for the development of the proposed FY 2016 MS–LTC–DRG relative weights in this proposed rule, we are proposing to use claims data after we trim the claims data of 10 all-inclusive rate providers and the 1 LTCH that is paid in accordance with a demonstration project reported in the December 2014 update of the FY 2014 MedPAR file, as well as any Medicare Advantage claims data for cases that would have met the criteria for exclusion from the site neutral payment rate under proposed § 412.522(b) if the new dual-rate LTCH PPS payment structure were in effect at the time those claims were processed. We are proposing to use the remaining data (that is, the applicable LTCH data) to calculate the proposed relative weights for the LTCH PPS standard Federal payment rate payments for FY 2016.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2016 LTCH PPS standard Federal payment rate payments. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we are proposing to reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, we standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.C.3.g. (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described below) and assigned the relative weight of the quintile; and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). We are proposing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2016 relative weights for LLTCH PPS standard Federal payment rate payments. This approach is consistent with our policies regarding the continued use of our existing methodology related to the treatment of severity levels as presented in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50172).

We provide in-depth discussions of our proposed policy regarding weight-setting for proposed low-volume MS–LTC–DRGs in section VII.C.3.f. of the preamble of this proposed rule and for proposed no-volume MS–LTC–DRGs, under proposed Step 5 in section VII.C.3.g. of the preamble of this proposed rule.) Furthermore, in determining the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail below in proposed Step 6 of section VII.C.3.g. of the preamble of this proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs for LTCH PPS Standard Federal payment rate cases with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology for purposes

of determining the FY 2015 MS–LTC–DRG relative weights, we are proposing to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In cases where the initial assignment of a proposed low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.C.3.g. (Step 6) of the preamble of this proposed rule.

We identified 250 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into one of the proposed 5 low-volume quintiles, each containing 50 MS–LTC–DRGs (250/5 = 50). We assigned the proposed low-volume MS–LTC–DRGs to specific proposed low-volume quintiles by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases was evenly divisible by 5. Therefore, it was not necessary to employ our historical methodology for determining which of the low-volume quintiles contain an additional low-volume MS–LTC–DRG. If the number of MS–LTC–DRGs with less than 25 applicable LTCH cases from the most recent data available for the final rule does not divide evenly, we are proposing to use our historical methodology for determining which quintiles would contain the additional MS–LTC–DRGs. For this proposed rule, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 50th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into proposed Quintile 1. The 50 proposed MS–LTC–DRGs with the highest average charge cases were assigned into proposed Quintile 5. Table 13A, listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the proposed composition of the proposed low-volume quintiles for MS–LTC–DRGs for FY 2016.

Accordingly, in order to determine the proposed FY 2016 relative weights for the proposed MS–LTC–DRGs with low-volume, we are proposing to use the five low-volume quintiles described above. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the proposed methodology described in section VII.C.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we will continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments result in appropriate payment for LTCH cases that would be grouped to proposed low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2016 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to use the same steps from our existing methodology to determine the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments. (For additional information on the original development of the steps in this methodology, and modifications to it since the adoption of the MS–LTC–DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).) As stated previously in this section, this approach is consistent with our policies regarding the continued use of our existing methodology, which was used to determine the FY 2015 MS–LTC–DRG relative weights as presented in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50173 through 50176). However, in doing so, we are proposing to use only applicable LTCH (as discussed in section VII.B.7.a. of the preamble of this proposed rule).

In summary, to determine the proposed FY 2016 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described above) and cross-walking proposed no-volume MS–LTC–DRGs as described below. After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate the FY 2016 relative weights for LTCH PPS standard Federal payment rate payments by first removing statistical outliers and cases with a length of stay of 7 days or less (Steps 1 and 2 below). Next, we are proposing to adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3 below). After removing statistical outliers (Step 1 below) and applicable LTCH cases with a length of stay of 7 days or less (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges, we are proposing to calculate ''relative adjusted weights'' for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method. Below we discuss in detail the steps for calculating the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments.

Step 1—Remove statistical outliers.

The first step in our proposed calculation of the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments is to remove statistical outlier cases from applicable LTCH cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights for LTCH PPS standard Federal payment rate payments could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what would be removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove cases with a length of stay of 7 days or less.

The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH

because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2016 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our historical relative weight methodology, in determining the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, we are further proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what would be removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Adjust charges for the effects of SSOs.

After removing statistical outliers and cases with a length of stay of 7 days or less, we are left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.'' As the next step in the calculation of the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments would lower the proposed FY 2016 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2016 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to then calculate the FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments using the HSRV methodology, which is an iterative process. First, for each case, we calculate a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS–LTC–DRG, we calculated the proposed FY 2016 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from step 3 for each MS–LTC–DRG) for the proposed MS–LTC–DRG by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its applicable LTCH cases (that is, its case-mix) is calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from above) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process is continued until there is convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001. (We note that, although we are not proposing any changes to this step of our relative weight methodology in this proposed rule, we have made some minor changes to the description of this step to clarify the application of our existing policy.)

Step 5—Determine a proposed FY 2016 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, we identified the proposed MS–LTC–DRGs for which there were no claims in the December 2014 update of the FY 2014 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are generally proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs for LTCH PPS standard Federal payment rate cases based on clinical similarity and relative costliness (with the exception of ''transplant'' proposed MS–LTC–DRGs, ''error'' proposed MS–LTC–DRGs, and proposed MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each proposed no-volume MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' proposed MS–LTC–DRG would be assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 758 proposed MS–LTC–DRGs for FY 2016, we identified 368 MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes no trimmed applicable LTCH cases in the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15

''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). We are proposing to assign proposed relative weights to each of the 343 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to one of the remaining 390 (758 − 368 = 390) proposed MS–LTC–DRGs for which we are able to propose relative weights based on the trimmed applicable LTCH cases in the FY 2014 MedPAR file data using the steps described above. (For the remainder of this discussion, we refer to the ''cross-walked''proposed MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we cross-walked one of the 343 ''no volume'' proposed MS–LTC–DRGs.) Then, we are generally proposing to assign the 343 no-volume proposed MS–LTC–DRG the proposed relative weight of the proposed cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we make adjustments to account for nonmonotonicity.)

We are proposing to cross-walk the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we are able to propose relative weights based on the December 2014 update of the FY 2014 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2015, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We then assigned the proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2016. We note that, if the proposed cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology described in Steps 1 through 4 above) is assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, is designated to one of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2016. (As we noted above, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing proposed relative weights.)

For this proposed rule, a list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the proposed cross-walked MS–LTC–DRGs) for FY 2016 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the proposed FY 2016 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2016 provided in Table 13B.

Example: There were no trimmed applicable LTCH cases in the FY 2014 MedPAR file that we are proposing to use for this proposed rule for proposed MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.9045 for FY 2016 to proposed MS–LTC–DRG 61 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. We are proposing to use the most recent available claims data to identify the trimmed applicable LTCH cases from which we will determine the proposed relative weights in this proposed rule.

For FY 2016, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 5); Liver Transplant without MCC (MS–LTC–DRG 6); Lung Transplant (MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 8); Pancreas Transplant (MS–LTC–DRG 10); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Furthermore, for FY 2016, we are proposing to establish a proposed relative weight equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–

LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). Under our proposals to implement the new dual-rate LTCH PPS payment structure required by statute, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs would not meet the criteria for exclusion from the site neutral payment rate. Therefore, there are no applicable LTCH cases to use in calculating a proposed relative weight for these ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs. In other words, under our proposed implementation of the ''criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation'' (as discussed in section VII.B.3.b. of the preamble of this proposed rule), any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those proposed MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that will be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. As discussed in detail in section VII.B.4.b. of the preamble of this proposed rule, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015, and on or before September 30, 2017 (that is, discharges occurring in cost reporting periods beginning during FYs 2016 and 2017), the transitional payment amount for site neutral payment rate cases would be a blended payment rate, which would be calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the proposed transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' MS–LTC–DRGs in FY 2016, we must assign a relative weight to these MS–LTC–DRGs, which we are proposing would be the FY 2015 relative weight. We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs would result in appropriate payments for LTCH cases that would be paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar proposed MS–LTC–DRGs for which we were able to determine proposed relative weights based on applicable LTCH cases in the FY 2014 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs to be used for the sole purpose of determining half of the proposed transitional blended payment for site neutral payment rate cases during the transition period.

Step 6—Adjust the proposed FY 2016 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions could consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2016 MS–LTC–DRG relative weights for LTCH PPS standard Federal payment rate payments in this proposed rule, consistent with our historical methodology, we are proposing to combine proposed MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2016 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

Step 7—Calculate the proposed FY 2016 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be

unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). Under the budget neutrality requirement at § 412.517(b), for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the proposed FY 2016 MS–LTC–DRG classifications and relative weights for LTCH PPS standard payment rate payments based on the most recent available LTCH data for applicable LTCH cases, and to apply a budget neutrality adjustment in determining the FY 2016 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. As discussed previously in this section, this approach is consistent with our general policies regarding the continued use of our existing methodologies, as presented in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50175 through 50176)

In this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, for FY 2016, we are proposing to calculate and apply a normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not affected by changes in the composition of case types or the proposed changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2016 (the first step of our proposed budget neutrality methodology), we are proposing to use the following three steps: (1.a.) We use the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2014 MedPAR file) and group them using the proposed FY 2016 GROUPER (proposed Version 33) and the recalibrated proposed FY 2016 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) we group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2015 GROUPER (Version 32) and FY 2015 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) we compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2015 (determined in Step 1.b.) by the average case-mix index for FY 2016 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2016, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by 1.28176 (determined in Step 1.c.) in the first step of the proposed budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our proposed MS–LTC–DRG budget neutrality methodology, we calculate a second proposed budget neutrality factor consisting of the ratio of estimated aggregate FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. above) after reclassification and recalibration to estimated aggregate payments for FY 2015 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. above).

That is, for this proposed rule, for FY 2016, under the second step of the proposed budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) We simulate estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized proposed relative weights for FY 2016 and proposed GROUPER Version 33 (as described above); (2.b.) we simulate estimated total FY 2015 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2015 GROUPER (Version 32) and the FY 2015 MS–LTC–DRG relative weights in Table 11 of the Addendum to the FY 2015 IPPS/LTCH PPS final rule available on the Internet; and (2.c.) we calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2016 MS–LTC–DRG relative weights, each normalized proposed relative weight is then multiplied by a budget neutrality factor of 0.996599 (the value determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to determine the proposed budget neutral FY 2016 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2016 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.28176 and a budget neutrality factor of 0.996599 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2016 (and reflect both the proposed normalization factor of 1.28176 and the proposed budget neutrality factor of 0.996599).

D. Proposed Changes to the LTCH PPS Standard Federal Payment Rates for FY 2016

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2016, that is, effective for LTCH discharges occurring on or after October 1, 2015 through September 30, 2016. As previously discussed, under the dual-rate LTCH PPS payment structure required by statute, we are proposing that, beginning with FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate would be paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our proposals related to the dual-rate LTCH PPS payment structure required by statute, we refer readers to section VII.C. of the preamble of this proposed rule.)

For details on the development of the initial FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS standard Federal rate as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); and FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180).

In this FY 2016 proposed rule, we present our proposals related to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2016, which includes the proposed annual market basket update. Consistent with our historical practice of using the best data available, we also are proposing to use more recent data, if available, to determine the FY 2016 annual market basket update to the LTCH PPS standard Federal payment rate in the final rule.

The application of the proposed update to the LTCH PPS standard Federal payment rate for FY 2016 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal payment rate for FY 2016 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for fiscal year FY 2016 as required by the statute (as discussed in section VII.D.2.c. of the preamble of this proposed rule). In addition, as discussed in section V.A. of the Addendum of this proposed rule, we are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level adjustment for FY 2016 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4).

2. Proposed FY 2016 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53468 through 53476), we adopted the newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53468).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year'' (which are discussed in more detail in section VII.C.2.b. of the preamble of this final rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the LTCH PPS standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the ''other adjustment'' specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as ''the multifactor productivity (MFP) adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

Section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate FY update period. In addition, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal payment rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act as they are both based on a fiscal year. We refer readers to section IV.A.1. of the preamble of this proposed rule for more information on the proposed FY 2016 MFP adjustment.

c. Proposed Adjustment to the Annual Update to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under § 412.523(c)(4) of the regulations. (As previously noted, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for

purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) The LTCH QRP, as required for FY 2014 and beyond by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year (§ 412.523(c)(4)(iii)). Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year (§ 412.523(c)(4)(ii)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the annual market basket update to the LTCH PPS standard Federal payment rate for FY 2016 in section VII.D.2.e. of the preamble of this proposed rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

d. Proposed Market Basket Under the LTCH PPS for FY 2016

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The FY 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the FY 2009-based LTCH-specific market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

For FY 2016, we are proposing to continue to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS for FY 2016. We continue to believe that the FY 2009-based LTCH-specific market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted the FY 2009-based LTCH-specific market basket for use under the LTCH PPS in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

e. Proposed Annual Market Basket Update for LTCHs for FY 2016

Consistent with our historical practice, we estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's first quarter 2015 forecast, the proposed FY 2016 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.7 percent. The current estimate of the MFP adjustment for FY 2016 based on IGI's first quarter 2015 forecast is 0.6 percent, as discussed in section IV.A. of the preamble of this proposed rule. In addition, consistent with our historical practice, we are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 market basket update and the MFP adjustment in the final rule.

For FY 2016, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full proposed FY 2016 market basket update by the proposed FY 2016 MFP adjustment. To determine the proposed market basket update for LTCHs for FY 2016, as reduced by the MFP adjustment, consistent with our established methodology, we subtract the proposed FY 2016 MFP adjustment from the proposed FY 2016 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2016 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.2 percentage point for FY 2016. Therefore, following application of the productivity adjustment, we are further proposing to reduce the adjusted proposed market basket update (that is, the full proposed market basket increase less the proposed MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the ''other adjustment'' required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2016, section 1886(m)(5) of the Act requires that for LTCHs that do not submit quality reporting data as required under the LTCHQR Program, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH PPS standard Federal payment rate for FY 2016 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full proposed LTCH PPS market basket increase estimate, subject to an adjustment based on changes in economy-wide productivity (''the MFP adjustment'') as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, will also be further reduced by 2.0 percentage points.

In this proposed rule, in accordance with the statute, we are reducing the proposed FY 2016 full market basket estimate of 2.7 percent (based on IGI's first quarter 2015 forecast of the FY 2009-based LTCH-specific market basket) by the proposed FY 2016 MFP adjustment of 0.6 percentage point (based on IGI's first quarter 2015 forecast). Following application of the productivity adjustment, the adjusted proposed market basket update of 2.1 percent (2.7 percent minus 0.6 percentage point) is then reduced by 0.2 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act. Therefore, in this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish a proposed annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2016 of 1.9 percent (that is, the most recent estimate of the LTCH PPS market basket proposed update of 2.7 percent, less the proposed MFP adjustment of 0.6 percentage point, and less the 0.2 percentage point required under section 1886(m)(4)(E) of the Act). Accordingly, consistent with our proposal, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xii), which specifies that the LTCH PPS standard Federal payment rate for FY 2016 is the LTCH PPS standard Federal payment rate for the

previous LTCH PPS year updated by 1.9 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xi) in conjunction with § 412.523(c)(4), we are proposing to further reduce the proposed annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, consistent with our proposal, we are proposing to establish a proposed annual update to the LTCH PPS standard Federal payment rate of -0.1 percent (that is, 1.9 percent minus 2.0 percentage points) for FY 2016 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated above, consistent with our historical practice, we are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and the MFP adjustment) we would use such data, if appropriate, to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2016 under § 412.523(c)(3)(xii) in the final rule. (We note that we also are adjusting the proposed FY 2016 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum of this proposed rule).)

E. Moratoria on the Establishment of LTCHs and LTCH Satellite Facilities and on the Increase in the Number of Beds in Existing LTCHs and LTCH Satellite Facilities

Section 1206(b)(2) of Public Law 113–67, as amended by section 112(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), established ''new'' statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities and on the increase in the number of hospital beds in existing LTCHs and LTCH satellite facilities. For a discussion on our implementation of these moratoria, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193). Since the implementation of these LTCH PPS policy moratoria, we have been informed that some confusion may exist regarding the exceptions to the moratorium on the establishment of new LTCH and LTCH satellite facilities, as well as the application of the moratorium on an increase in the number of beds in existing LTCH and LTCH satellite facilities.

Under existing regulations at 42 CFR 412.23(e)(6), we specify that, to qualify for an exception under the moratorium to establish a new LTCH or LTCH satellite facility during the timeframe between April 1, 2014, and September 30, 2017, a hospital or entity must meet the following criteria:

- The hospital or entity must have begun its qualifying period for payment as an LTCH in accordance with § 412.23(e).
- The hospital or entity must have a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for an LTCH, and must have expended before April 1, 2014, at least 10 percent of the estimated cost of the project or, if less, $2,500,000.
- The hospital or entity must have obtained an approved certificate of need in a State where one is required.

We believe that the existing regulation text regarding the moratorium on the establishment and classification of new LTCHs and LTCH satellite facilities could be misread as requiring fulfillment of all three conditions in order to qualify for an exception to the moratorium on the establishment of new LTCH and LTCH satellite facilities. This was not our intent, and we acknowledge that implementing the moratorium in that manner would have been directly contradictory to the statutory requirement. Technically, while we did not explicitly specify in the regulations text under § 412.23(e)(6) that only one of the listed criteria had to be met in order to qualify for an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities (the language text states ''as applicable''), we clearly stated it in the preamble of the FY 2015 IPPS/LTCH PPS final rule. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193).) In addition, the requirement that one of the three exceptions had to be met in order to qualify for an exception to the moratorium was also indicated in our proposal to implement the initial application of the moratorium during the FY 2009 rulemaking cycle. (We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 29705).)

As we stated in the preamble of the FY 2015 IPPS/LTCH PPS final rule), the provisions in the new moratorium are nearly identical to the language in the prior ''expired'' moratorium under section 114(d) of MMSEA (Pub. L. 110–173). As also noted, the mechanics of exceptions to the new and expired moratoria on the establishment of new LTCHs and LTCH satellite facilities are analogous. Therefore, except as noted, to the extent that the new and expired moratoria were consistent, we proposed and adopted the identical implementation mechanisms. To minimize the confusion that may exist as a result of the existing regulations text, we are proposing to revise the regulations under § 412.23(e)(6)(ii) to more accurately convey the established policy that only one of the statutory conditions, as applicable, needs to be met in order to qualify for the exception to the new moratorium on the establishment of new LTCH and LTCH satellite facilities.

We have become aware of some confusion concerning what constitutes the ''estimated cost of the project'' with regard to the second exception. To alleviate confusion, we are clarifying our longstanding policy on what constitutes the ''estimated cost of the project.'' In discussing this exception in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50189 through 50193), we noted that the ''cost of the project'' included the activities (plural) that were enumerated in the first prong of the exception. Those enumerated activities included ''the actual construction, renovation, lease, or demolition for a long-term care hospital.'' That is, our policy is that the sum total of any costs associated with any of the enumerated activities that comprised the project as a whole (with the project being the establishment of a new LTCH or a new LTCH satellite facility) would be considered in determining whether the facility met the amount specified in the statute. In using an ''or'' in this list of activities, we intended to acknowledge that any one project may or may not include every element listed (for example, new construction may not include any demolition), but if it does include an element, our policy is that the cost of that element and the costs of any other of the listed elements in the project are to be summed to determine the total cost of the project. Therefore, under our longstanding policy, when determining whether 10 percent of the estimated cost of the project had been expended prior to the start of the moratorium, the ''project'' is the establishment of a new LTCH or LTCH satellite facility, not any one element that, when combined with other elements listed in the first prong, would lead to the establishment of the LTCH or LTCH satellite facility. For example, if an entity has expended 10 percent of the costs of demolition, but that amount is less than both 10 percent of the estimated cost of the project, and less than the $2,500,000.00 ceiling amount, the entity would not qualify for this exception to the moratorium.

In addition, we are taking this opportunity to provide additional clarification on our policy concerning

the moratorium on increases in the number of beds in existing LTCH and LTCH satellite facilities. As we noted in the FY 2015 IPPS/LTCH PPS final rule, while the expired moratorium specifically included an exception to the moratorium on the increase in the number of beds in existing LTCHs and LTCH satellite facilities, the new moratorium under section 1206(b)(2)(B) of Public Law 113–67 expressly noted that the exceptions to the expired moratoria would not apply under the ''new'' moratoria. Further amendments made by section 112(b) of Public Law 113–93, which create the exceptions to the current moratoria, did not change that express omission (79 FR 50189 through 50193). Given the lack of any exception to the new moratorium on increasing the number of beds in an existing LTCH or LTCH satellite facility, an LTCH may not increase the total number of Medicare certified beds beyond the number that existed prior to April 1, 2014, including when an existing LTCH meets one of the exceptions to the moratorium on the establishment of a new LTCH satellite facility. An LTCH satellite facility's beds historically have been, and continue to be, counted as the LTCH's beds. Therefore, under our existing regulation at § 412.23(e)(7)(iii), an existing LTCH cannot, through meeting the criteria for an exception to the new moratorium on the establishment of a new LTCH satellite facility, increase its total number of Medicare certified beds by establishing any number beds at the new LTCH satellite facility that would result in the total number of Medicare certified beds in that LTCH exceeding what existed prior to April 1, 2014. That is, if an existing LTCH meets one of the statutory exceptions and opens a new LTCH satellite facility during the moratorium, that new LTCH satellite facility's beds must come from the movement of beds in existence prior to April 1, 2014, from other locations of the existing LTCH to the new LTCH satellite facility. This requirement also applies to any remote locations that may be established by an existing LTCH during the moratorium on new beds.

F. Proposed Changes to Average Length of Stay Criterion Under Public Law 113–67 (§ 412.23)

We are proposing to revise § 412.23 to implement the statutory changes to the calculation of the average length of stay for an LTCH under section 1206(a)(3) of Public Law 113–67. As required by section 1861(ccc) of the Act, in order for a hospital to be classified as an LTCH, it must maintain an average length of stay of greater than 25 days as calculated by the Secretary (or meet the requirements of clause (II) of section 1886(d)(1)(B)(iv) of the Act). Currently, the Medicare average length of stay is calculated, in accordance with § 412.23(e)(3) of the regulations, by dividing the total number of covered and noncovered Medicare inpatient days by the total number of Medicare discharges. This calculation currently includes Medicare inpatient days and discharges that are paid under a Medicare Advantage (MA) plan. (For a full discussion of the inclusion of MA days in the average length of stay calculation, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51774).)

Section 1206(a)(3)(A) of Public Law 113–67 specifies that, in general, for discharges occurring in cost reporting periods beginning on or after October 1, 2015, applicable total Medicare inpatient days and discharges that are paid at the site neutral payment rate (discussed in section VII.B. of the preamble of this proposed rule), or for which payments are made under an MA plan, are to be excluded from the calculation of an LTCH's average length of stay. In addition, section 1206(a)(3)(B) of Public Law 113–67 further requires that the exclusion of these inpatient days and discharges from the average length of stay calculation shall not apply to an LTCH that was classified as a subsection (d) hospital (as defined in section 1886(d)(1)(B) the Act) as of December 10, 2013. Therefore, under the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA and in accordance with section 1206(a) of Public Law 113–67, we are proposing to revise § 412.23 of the regulations to incorporate the statutory changes to the average length of stay calculation required by section 1206(a) of Public Law 113–67. Specifically, we are proposing to revise § 412.23 by adding a new paragraph (e)(3)(vi) to specify that Medicare inpatient days and discharges paid at the site neutral payment rate or under an MA plan will not be included in the calculation of an LTCH's average length of stay. Furthermore, we proposing to add new paragraph (e)(3)(vii) to § 412.23 to specify that the provisions of the proposed new paragraph (vi) will not apply to an LTCH that was classified as a subsection (d) hospital (as defined in section 1886(d)(1)(B) the Act) as of December 10, 2013, consistent with the statute.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, care coordination, and improving patient outcomes.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and,
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program and Hospital VBP Program (described further below) that link payment to performance.

In implementing the Hospital IQR Program and other quality reporting

programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so that the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We most recently adopted additional policies for the Hospital VBP Program in section IV.I. of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087). Under the Hospital VBP Program, hospitals receive value-based incentive payments based on their performance with respect to performance standards for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Given that measures adopted for the Hospital VBP Program must first have been specified under the Hospital IQR Program, these two programs are linked and the reporting infrastructure for the programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for poorly performing hospitals based on their rates of HACs.

In the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program.
- In section VIII.B., the PCHQR Program.
- In section VIII.C., the LTCH QRP.

In addition, in section VIII.D. of the preamble of this proposed rule, we are proposing changes to the Medicare EHR Incentive Program for eligible hospitals and CAHs.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249) for the measures we have adopted for the Hospital IQR measure set through the FY 2017 payment determination and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Quality Measures (Specifications Manual). This Specifications Manual is posted on the QualityNet Web site at *http://www.qualitynet.org/*. We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual available at the HCAHPS Web site, *http://www.hcahpsonline.org*. We maintain the HCAHPS technical specifications by updating the HCAHPS *Quality Assurance Guidelines* manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every three years. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional detail on the measure maintenance process.

We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using the subregulatory process to make non-substantive updates to measures used for the Hospital IQR Program. We recognize that some changes made to NQF-endorsed measures undergoing

maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778) for a more detailed discussion about public display of quality measures. We are not proposing to change our current policy of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site *http://www.medicare.gov/hospitalcompare* and/or the interactive *https://data.medicare.gov* Web site, after a preview period.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. For more information on measures reported to *Hospital Compare,* we refer readers to the Web site at: *http://www.medicare.gov/hospitalcompare*. Other information not reported to *Hospital Compare* may be made available on other CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov*.

2. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), for our finalized measure retention policy. When we adopt measures for the Hospital IQR Program beginning with a particular payment determination, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures.

We are not proposing any changes to our policy for retaining previously adopted measures for subsequent payment determinations.

3. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We also take into account the views of the Measure Applications Partnership (MAP) when determining when a measure should be removed, and we strive to eliminate redundancy of similar measures (77 FR 53505 through 53506). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we also finalized our proposal to clarify the criteria for determining when a measure is ''topped out.'' We are not proposing any changes to the two criteria that we use to determine whether or not a measure is ''topped out.''

We use these previously adopted measure removal criteria to help evaluate when we should propose a measure for removal. However, we continue to believe that there are circumstances in which a measure that meets criteria for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. Therefore, because of the continued need to balance benefits and drawbacks as well as our desire to increase transparency, we are proposing additional factors to consider for measure removal and also include factors to consider in order to retain measures.

Specifically, we are proposing to take into consideration the following additional factors in determining whether a measure should be removed:

- Feasibility to implement the measure specifications.

In addition, we are proposing to remove one of the factors (''Availability of alternative measures with a stronger relationship to patient outcomes'') we take into consideration when determining whether to remove measures, because it is duplicates another factor (''The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic'').

We are also proposing to take into consideration the following factors in determining whether a measure should be retained:

- Measure aligns with National Quality Strategy or CMS Quality Strategy goals;
- Measure aligns with other CMS programs, including other quality reporting programs, or the EHR Incentive Program; and
- Measure supports efforts to move facilities towards reporting electronic measures

For example, we may consider retaining a measure that is statistically ''topped-out'' in order to align with the Medicare EHR Incentive Program. Below is a table of newly proposed and previously adopted factors that we would take into consideration in removing or retaining measures:

FACTORS CMS CONSIDERS IN REMOVING OR RETAINING MEASURES

Measure Removal Factors
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. A measure does not align with current clinical guidelines or practice.
3. The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic).
4. Performance or improvement on a measure does not result in better patient outcomes.
5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
7. It is not feasible to implement the measure specifications*.

FACTORS CMS CONSIDERS IN REMOVING OR RETAINING MEASURES—Continued

''Topped-Out'' Criteria
1.• Statistically indistinguishable performance at the 75th and 90th percentiles; and • Truncated coefficient of variation ≤0.10.
Measure Retention Factors
1. Measure aligns with other CMS and HHS policy goals.* 2. Measure aligns with other CMS programs, including other quality reporting programs, or the EHR Incentive Program. 3. Measure supports efforts to move facilities towards reporting electronic measures.

* Consideration proposed in this FY 2016 IPPS/LTCH PPS proposed rule.

We note that these removal/retention factors continue to be considerations taken into account when deciding whether or not to remove measures; but they are not firm requirements.

We are inviting public comments on our proposal.

b. Proposed Removal of Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

We are proposing to remove the following nine measures, either in their entirety or just the chart-abstracted form, from the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years: STK–01: Venous Thromboembolism (VTE) Prophylaxis (NQF #0434), STK–06: Discharged on Statin Medication (NQF #0439), STK–08: Stroke Education (NQF endorsement removed), VTE–1: Venous Thromboembolism Prophylaxis (NQF #0371), VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis (NQF #0372), VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373), IMM–1: Pneumococcal Immunization (NQF #1653), AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival (NQF #0164), and SCIP–Inf–4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).

(1) STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3

We are proposing to remove the chart-abstracted versions of STK–01, STK–06, STK–08, VTE–1, VTE–2, and VTE–3 because these measures are ''topped-out.'' However, we are proposing to retain STK–06, STK–08, VTE–1, VTE–2, and VTE–3 as electronic clinical quality measures for the FY 2018 payment determination and subsequent years. As we state above in section VIII.A.3.a. of the preamble of this proposed rule, in our discussion of factors we consider in removing or retaining a measure, ''topped-out'' status is only one of many factors which we consider.

In balancing the benefits and disadvantages of removing or retaining a measure, we believe that the benefits of retaining the electronic versions of these measures outweigh the possible disadvantages. Specifically, we believe that while these measures are statistically ''topped-out,'' retaining the electronic versions of the measures is beneficial because they align the Hospital IQR Program with the Medicare EHR Incentive Program. In addition, retaining the electronic version of the measures would allow us to monitor the effectiveness of measure reporting by EHRs and help to familiarize hospitals with reporting electronically specified measures to CMS under the Hospital IQR Program.

Our data show that the electronically specified versions of these measures are reported with non-zero values by as many as 2,864 hospitals attesting under 2014 Meaningful Use and that hospitals report on the full range of available electronic clinical quality measures, indicating the value of variety. Accordingly, we know that EHRs are certified to these measures, and that hospitals do indeed report them. The available data suggest that retaining STK–06, STK–08, VTE–1, VTE–2, and VTE–3 as electronic clinical quality measures furthers CMS' high priority goal to enable the electronic reporting of quality data and to align the Hospital IQR and EHR Incentive Programs.

We also believe that reporting electronic clinical quality measures presents minimal burden on hospitals as compared to their chart-abstracted equivalents and that retaining the electronically specified versions of these measures is appropriate until we fully understand the differences between the chart-abstracted and electronic versions of quality measures. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50808) we stated that we do not believe that the measures, in their electronically specified form, are substantively different than their chart-abstracted form, although we recognized that the EHR-based extraction methodology is different from the chart-abstraction data collection methodology.

However, CMS now recognizes that although the intent of a measure is the same whether it is reported via chart-abstraction or electronically, the submission modes are not the same and measure rates may be different.

As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have only heard anecdotal comments about actual performance level differences between the two modes of collection. We do not have sufficient data to be able to confirm these comments, but in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50273), we finalized a proposal to conduct a validation pilot test for electronically specified measures, which we intend to complete in 2015. Therefore, the results of this pilot are not yet available. As we have stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555), determining the equivalence of electronic clinical quality measures and chart-abstracted measures would require extensive testing given that the data for the Hospital IQR Program supports public reporting for both the Hospital IQR and Hospital VBP Programs. Due to the reasons described above, we believe it is appropriate to retain the electronically specified version of these 6 measures at this time.

We are inviting public comment on our proposals.

(2) IMM–2 Influenza Immunization (NQF #1659)

One additional measure, IMM–2, has been determined to be statistically ''topped-out;'' however, after considering the benefits and disadvantages of removing or retaining this measure, we are retaining this measure in the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years, because the benefits outweigh the disadvantages. One of the factors that we consider when determining whether to remove or retain a measure is whether a measure aligns with National Quality Strategy (NQS) or CMS Quality

Strategy goals. Currently, IMM–2 is the only Hospital IQR Program measure to address the Best Practices to Enable Healthy Living NQS Priority and CMS Quality Strategy goal. In addition, IMM–2 supports the NQS priorities and CMS Quality Strategy goals to promote effective interventions to prevent and reduce the leading causes of mortality.[79]

(3) Removal of Immunization 1 (IMM–1) Pneumococcal Immunization (NQF #1653)

We adopted the IMM–1 Pneumococcal Immunization measure (NQF #1653) for the FY 2014 payment determination and subsequent years with data collection beginning with January 1, 2012 discharges (75 FR 50211). In October 2012, subsequent to the beginning of IMM–1 data collection on January 1, 2012, the Advisory Committee on Immunization Practices (ACIP) published new guidelines on pneumococcal vaccination.[80] With the publication of the new ACIP guidelines, IMM–1, as specified in the Hospital IQR Program, was no longer compliant with current clinical guidelines.

As part of our efforts to re-specify IMM–1 to account for the many potential scenarios that must be considered when determining if pneumococcal vaccination is appropriate, we determined that it was not feasible to implement the measure specifications that incorporated the new guidelines given their complexity.

Specifically, the October 2012 ACIP guidelines recommended the routine use of 13-valent pneumococcal conjugate (PCV13) vaccine for adults aged ≥19 years with certain comorbid conditions, and that PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23) that was currently recommended for these groups of adults. The timing of vaccination with PCV13 and PPSV23 is dependent upon if and when an individual has received the other vaccine.

In order to implement the measure consistent with these new guidelines, providers would need reliable, detailed data on: (1) Whether or not a pneumococcal vaccine was previously administered, (2) which type of pneumococcal vaccine (PCV13 vs. PPSV23) was administered, and (3) when it was administered. When considering possible clinical scenarios of screening and vaccinating for pneumonia, current chart and electronic data do not consistently allow for successful abstraction of these varied and detailed historical facts, all of which are needed to appropriately administer a pneumococcal vaccine.

We believe that the measure, as updated by ACIP guidelines, would burden hospitals with data abstraction and yield results with only questionable meaningfulness and reliability. We outlined these pneumococcal vaccination implementation issues in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50780 through 50781), and suspended data collection for IMM–1 until further notice.

Since the suspension of IMM–1, ACIP again updated its 2012 guidelines in September 2014.[81] In reviewing the updated 2014 guidelines, we held discussions with other HHS agencies to identify implementation strategies for these updated guidelines. However, we were still unable to identify a consistent data source, such as a national immunization registry, that is available to hospitals which would provide sufficient patient-level clinical information to ensure that hospitals would be able to accurately and reliably determine whether they were following the guidelines. There continues to be a lack of detailed and reliable patient level data on prior pneumococcal vaccination that is readily available to all hospitals. Without detailed, reliable, and readily available data for hospitals, it will be difficult to determine if the pneumococcal vaccinations are appropriately administered.

In determining whether to remove the IMM–1 measure, we considered the factors stated above in section VIII.A.3.a. of the preamble of this proposed rule, in our discussion of considerations for the removal and retention of quality measures from the Hospital IQR Program. Based on the continued lack of ready access to comprehensive patient-level immunization data by hospital staff and the continued infeasibility to implement or align this measure with current clinical guidelines or practice, we are proposing to remove this measure from the Hospital IQR Program. We emphasize that, despite the proposed removal of the IMM–1 measure from the Hospital IQR Program, we understand and value the role pneumococcal vaccines play in preventing pneumococcal disease[82] and we expect hospitals to continue to provide pneumococcal vaccinations for their hospital populations as appropriate.

We are inviting public comments on this proposal to remove IMM–1 from the Hospital IQR Program beginning in CY 2016 for the FY 2018 payment determination and subsequent years.

(4) Removal of AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival Measure (NQF #0164)

Our evaluation of the most recently available data shows that AMI–7a is not widely reported by hospitals, and according to the most recent data available, hospitals reporting this measure have less than the required number of cases to be publicly reported. In determining whether to remove AMI–7a as a chart-abstracted measure, we considered the factors stated in section VIII.A.3.a. of the preamble of this proposed rule in our discussion of considerations for the removal and retention of quality measures from the Hospital IQR Program. We are proposing to remove AMI–7a as a chart-abstracted measure beginning in CY 2016 for the FY 2018 payment determination and subsequent years because performance on this measure does not result in better patient outcomes. Specifically, measure data are infrequently reported, as most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy. In addition, we believe that the burden of requiring all hospitals to report data on this measure, when only a minority of facilities report enough cases to be publicly reported, outweighs the benefits of retaining the chart-abstracted version of this measure.

However, we are proposing to retain AMI–7a as an electronic clinical quality measure. We believe that once electronic capture of the measure is possible, the time and resources for electronic reporting should be significantly less as compared to manual abstraction. In addition, as discussed in section VIII.A.3.a. of the preamble of this proposed rule, retaining the electronically specified version of a measure allows us to support the alignment of the Hospital IQR Program and the Medicare EHR Incentive Program. In addition, retaining this measure will both allow us to monitor the effectiveness of measure reporting by EHRs and help familiarize hospitals with reporting electronically specified

[79] The Centers for Disease Control and Prevention: Key Facts About Seasonal Flu Vaccine. Retrieved from: *http://www.cdc.gov/flu/protect/keyfacts.htm.*

[80] MMWR October 12, 2012. Available at *http://www.cdc.gov/mmwr/PDF/wk/mm6140.pdf.* Accessed on October 31, 2012.

[81] MMWR September 2014. Available at *http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf.*

[82] CDC: Pneumococcal Disease. Retrieved from: *http://www.cdc.gov/pneumococcal/about/prevention.html.*

measures under the Hospital IQR Program.

We are inviting public comments on our proposal to remove the chart-abstracted version of AMI–7a but retain the electronic version for the CY 2016/FY 2018 payment determination and subsequent years.

(5) Removal of SCIP-Inf-4 Cardiac Surgery Patients With Controlled Postoperative Blood Glucose (NQF #0300)

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66876), we finalized SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300) for the Hospital IQR Program for FY 2009 and subsequent years. We also stated that hospitals were required to begin submitting data for SCIP-Inf-4 beginning with January 1, 2008 discharges.

Since the finalization of SCIP-Inf-4 for the Hospital IQR Program, the measure underwent routine NQF maintenance endorsement proceedings in 2012. During the NQF maintenance proceedings, the NQF Steering Committee discussed and recommended that the measure assess a lower blood glucose level target and lengthen the timeframe for achieving the lower blood glucose level target. As part of the maintenance endorsement renewal process, SCIP-Inf-4 was modified with the goal of achieving post-operative blood glucose levels of 180 mg/dl at 18–24 hours after surgery (previously, the timeframe was to achieve 200 mg/dl by 6 a.m. on post-operative days 1 and 2). We finalized the adoption of these measure refinements (see revised measure specifications at *http://www.qualityforum.org/QPS/0300*), in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50788) with data collection beginning with January 1, 2014 discharges. We also stated then that we would consider whether additional refinements should be made to better define the 18–24 hour timeframe for the measure.

Since finalizing the refinements to SCIP-Inf-4, we have been contacted by stakeholders and experts in the field of endocrinology regarding the newly refined goal of 180 mg/dl within an 18–24 hour timeframe. Specifically, there are concerns about the following aspects of the measure: (1) Defining ''optimal glycemic control;'' (2) measuring the correlation between optimal glycemic goals and better outcomes; [83] and (3) using an arbitrary 18–24 hour timeframe that does not cover a physiologically meaningful period of time.

Experts in the endocrinology field have shared that providers' enthusiasm to meet the measure blood glucose goals in the specified timeframe may lead to the following unintended consequences: (1) Providers delaying patients' meals until the 24-hour timeframe has passed; (2) providers keeping diabetic patients in intensive care units on insulin drips until the 24-hour timeframe has passed; (3) providers ensuring patients' postprandial glucose levels are kept below 180 mg/dl by concurrent use of intravenous and subcutaneous insulin administration; and (4) undetected hypoglycemic events caused by using multiple forms of insulin administration since the measure does not assess blood glucose levels past 24 hours. Multiple stakeholders also indicate that the Society of Thoracic Surgeons' guidelines [84] on preoperative through postoperative cardiac surgery glucose control, which helped inform CMS in maintenance of this measure, are currently being reviewed. Newer guidelines will address methods to monitor glycemic control in the post-cardiac surgical patient population. However, these guidelines are not currently available to guide further refinements of SCIP-Inf-4.

In view of stakeholder concerns, the seriousness of the potential negative unintended consequences, and recent analysis that shows the refined measure is ''topped-out,'' on January 9, 2015 we formally suspended the collection of data for SCIP-Inf-4 beginning with July 1, 2014 discharges. We refer readers to *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890406532&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2015-02-IP.pdf&blobcol=urldata&blobtable=MungoBlobs* for more information about the suspension.

In this proposed rule, we are proposing to remove SCIP-Inf-4 from the Hospital IQR Program effective beginning with CY 2016 discharges for the FY 2018 payment determination and subsequent years. We believe removal of this measure, rather than continued suspension, is appropriate for several reasons. First, performance on this measure does not result in better patient outcomes. Recent literature has highlighted that not meeting optimal glycemic control for a narrow point in time does not result in poorer outcomes.[85] Second, the measure does not align with current clinical guidelines or practice.[86] As previously stated, stakeholders and experts in the field of endocrinology have voiced their concerns in these areas, especially with using an arbitrary 18–24 hour timeframe that does not cover a physiologically meaningful period of time, as current practice guidelines aim for overall glycemic control.[87] Third, public reporting of a measure leads to negative unintended consequences other than patient harm. As mentioned above, these negative unintended consequences include potentially delaying patient meals or transition from the intensive care unit while keeping patients on insulin drips. For more information on the factors we consider for removing or retaining quality measures, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) and section VIII.A.3.a. of the preamble of this proposed rule. The measure will remain suspended until CY 2016 discharges begin. Despite our proposed removal of SCIP-Inf-4, we continue to believe glycemic control is important, and we hope to include measures focusing on glycemic control in the Hospital IQR Program in the near future.

We are inviting public comments on our proposal to remove SCIP-Inf-4 from the Hospital IQR Program for the FY 2018 payment determination and subsequent years.

The table below lists the measures we are proposing for removal for the FY 2018 payment determination and subsequent years.

[83] Optimal glycemic research for 6 a.m. blood glucose control shows a weak correlation between optimal glycemic goals and better outcomes related to morbidity, mortality and length of stay, suggesting that this type of metric may not be valid. LaPar FJ, Isbell JM, Kern JA, Ailawadi G, Kron IL. Surgical Care Improvement Project measure for postoperative glucose control should not be used as a measure of quality after cardiac surgery. *J Thorac Cardiovasc Surg* 2014;147:1041–8.

[84] Lazar HL, McDonnell M, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR et al. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. *Ann Thorac Surg* 2009; 87: 663–9.

[85] LaPar FJ, Isbell JM, Kern JA, Ailawadi G, Kron IL. Surgical Care Improvement Project measure for postoperative glucose control should not be used as a measure of quality after cardiac surgery. J Thorac Cardiovasc Surg 2014;147:1041–8.

[86] Harold L. Lazar HL, McDonnell ME, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR, Bridges CR and Haan CK. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. Ann Thorac Surg 2009;87:663–9.

[87] Harold L. Lazar HL, McDonnell ME, Chipkin SR, Furnary AP, Engelman RM, Sadhu AR, Bridges CR and Haan CK. The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management During Adult Cardiac Surgery. Ann Thorac Surg 2009;87:663–9.

MEASURES PROPOSED FOR REMOVAL FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

''Topped-out'' Measures
• STK–01: Venous Thromboembolism (VTE) Prophylaxis (NQF #0434)
• STK–06: Discharged on Statin Medication * (NQF #0439)
• STK–08: Stroke Education * (NQF endorsement removed)
• VTE–1: Venous Thromboembolism Prophylaxis * (NQF #0371)
• VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis * (NQF #0372)
• VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy * (NQF #0373)
Other Measures Proposed for Removal
• IMM–1 Pneumococcal Immunization (NQF #1653)
• SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300)
• AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival * (NQF #0164)

* Proposed for retention as electronic clinical quality measures for the Hospital IQR Program FY 2018 payment determination and subsequent years.

We are inviting public comment on our proposals.

4. Previously Adopted Hospital IQR Program Measures for the FY 2017 Payment Determination and Subsequent Years

a. Background

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50246), we described that the Hospital IQR Program measure set for the FY 2017 payment determination and subsequent years includes a total of 63 measures:

- 6 NHSN measures
- 28 electronic clinical quality measures (voluntary; 11 of these have the option of being reported as chart-abstracted measures)
- 15 chart-abstracted measures (11 of these have the option of being reported as electronic clinical quality measures)
- 21 claims-based measures
- 1 survey measure
- 3 structural measures

In the FY 2015 IPPS/LTCH PPS final rule, we described that of the 63 measures making up the Hospital IQR Program measure set for the FY 2017 payment determination and subsequent years, 42 were previously finalized measures, 11 were measures newly adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49865) and 10 were measures that were determined to be ''topped-out'' but were retained in the Hospital IQR Program as voluntary electronic clinical quality measures (79 FR 50208).

The following table shows measures previously adopted for the Hospital IQR Program FY 2017 payment determination and subsequent years. For a detailed list of the Hospital IQR Program FY 2018 payment determination and subsequent years measure set, we refer readers to section VIII.A.7.f. of the preamble of this proposed rule.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF No.
	NHSN	
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
	Chart-abstracted	
AMI–7a *	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
ED–1 *	Median Time from ED Arrival to ED Departure for patients Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm-2	Influenza Immunization	1659
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
SCIP-Inf-4	Cardiac Surgery Patients with Controlled Postoperative Blood Glucose	0300
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–01	Venous Thromboembolism (VTE) Prophylaxis	0434
STK–04 *	Thrombolytic Therapy	0437
STK–06 *	Discharged on Statin Medication	0439
STK–08 *	Stroke Education	N/A
VTE–1 *	Venous Thromboembolism Prophylaxis	0371
VTE–2 *	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
VTE–5*	Venous Thromboembolism Discharge Instructions	N/A
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
	Claims	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
STK Mortality	Stroke 30-day Mortality Rate	N/A
CABG Mortality	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
COPD READMIT	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
STK READMIT	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
CABG READMIT	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
AMI payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 4 (PSI/NSI)	Death among Surgical Inpatients with Serious, Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
	Electronic Clinical Quality Measures	
AMI–2	Aspirin Prescribed at Discharge for AMI	0142
AMI–7a*	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	N/A
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	N/A
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HTN	Healthy Term Newborn	0716
PC–01*	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother´s Choice.	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP-Inf-1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP-Inf-2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 (POD 1) or Postoperative Day 2 (POD 2) with Day of Surgery Being Day Zero.	N/A
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04*	Thrombolytic Therapy	0437
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06*	Discharged on Statin Medication	0439
STK–08*	Stroke Education	N/A
STK–10	Assessed for Rehabilitation	0441
VTE–1*	Venous Thromboembolism Prophylaxis	0371

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
VTE–2*	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol or Nomogram.	N/A
VTE–5*	Venous Thromboembolism Discharge Instructions	N/A
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
	Patient Survey	
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM–3)	0166 0228
	Structural	
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for General Surgery	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

*Measure is listed twice, as both chart-abstracted and electronic clinical quality measure.

b. NHSN Measures Standard Population Data

The previously adopted NHSN measures include the CAUTI, CLABSI, MRSA Bacteremia, CDI, colon and abdominal hysterectomy SSI measures, and HCP for the FY 2017 payment determination and subsequent years. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51616 through 51618; 76 FR 51629 through 51633) for more information about these measures. These NHSN measures measure the incidence of HAIs in hospitals participating in the Hospital IQR Program. In order to calculate the NHSN measures for use in the Hospital IQR Program, CDC must go through several steps.

First, CDC determines each NHSN measure's number of predicted infections. CDC determines this number using both specific hospital characteristics (for example, number of central line days for CLABSI) and infection rates that occurred among a standard population (sometimes referred to by CDC as ''national baseline'' but referred to here as ''standard population data''). CDC currently uses data it collected in calendar year (CY) 2009 for the CAUTI measure's standard population data.

In addition, for each NHSN measure, CDC calculates the Standardized Infection Ratio (SIR) by comparing a hospital's reported number of HAIs with the standard population data. For more information about the way NHSN measures are calculated, please refer to the QualityNet Web page on HAI measures at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

We would like to notify the public that CDC will update the standard population data to ensure the NHSN measures' number of predicted infections reflect the current state of HAIs in the United States. The standard referent population that CDC uses to calculate the Standardized Infection Ratios (SIRs) is comprised of healthcare-associated infection data that CDC's NHSN collects from healthcare facilities throughout the United States for infection events that occurred in a specified baseline time period. Beginning in CY 2016, CDC will use data collected for infection events that occurred in 2015 as the new standard referent population. To do so, CDC will collect HAI data that healthcare facilities are reporting for events that have or will occur in CY 2015 to use in updating the standard population data for HAI measures. This new CY 2015 standard population data for HAI measures will hereinafter be referred to as ''new standard population data.''

While this is not a Hospital IQR Program proposal, we are still inviting public input on the CDC's plans to update the standard population data for HAI measures.

5. Expansion and Updating of Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. We are not proposing any changes to these considerations.

6. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing refinements to the measure cohorts for: (1) The Hospital 30-day, All-cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) measure; and (2) the Hospital 30-day, All-cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization (NQF #0506) measure. The proposed refined measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report.[88] These measure refinements are discussed in greater detail below.

a. Proposed Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) Measure Cohort

(1) Background

We are proposing a refinement to the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) measure (hereinafter referred to as the CMS 30-

[88] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' found at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*.

day Pneumonia Mortality Measure), which expands the measure cohort. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain whether the patient subsequently died within 30 days of the index admission. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria, and we are proposing an expansion to this set of hospitalizations.

The previously adopted CMS 30-day Pneumonia Mortality Measure (72 FR 47351) includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For more cohort details on the measure as currently implemented, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. We anticipate that this refined measure will first be publicly reported on *Hospital Compare* with the proposed cohort change in CY 2016.

This refinement to the CMS 30-Day Pneumonia Mortality Measure is being proposed for several reasons. First, recent evidence has shown an increase in the use of sepsis and respiratory failure as principal diagnosis codes among patients hospitalized with pneumonia.[89] Pneumonia patients with these principle diagnosis codes are not currently included in the measure cohort, and including them would better capture the complete patient population of a hospital with patients receiving clinical management and treatment for pneumonia.

Second, because patients with a principal diagnosis of sepsis and respiratory failure are not included in the current CMS 30-Day Pneumonia Mortality Measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change.

Finally, another published study[90] has also demonstrated wide variation in the use of sepsis and respiratory failure codes as principal discharge diagnoses for pneumonia patients across hospitals, potentially biasing efforts to compare hospital performance on 30-day mortality. These published studies and CMS analyses show that hospitals that use sepsis and respiratory failure codes for the principal diagnosis frequently have better performance on the CMS 30-Day Pneumonia Mortality Measure. This coding practice improves performance on the measure because patients with greatest severity of illness (for example, those with sepsis or respiratory failure) are systematically excluded from the measure under current measure specifications, leaving only patients with less severity of illness in the cohort.

In response to these emerging data, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of enhancing or broadening the measure cohort to include the complete patient population, at each hospital, who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study.[91] That is, our results suggested that there is: (1) An increasing use of respiratory failure and sepsis as principal discharge diagnoses for pneumonia patients, and (2) wide variation across hospitals in the use of these codes.

In addition to assessing the use of the principal diagnosis codes of sepsis and respiratory failure, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. These findings suggest that a measure with an enhanced or broader cohort for the current CMS 30-Day Pneumonia Mortality Measure will ensure that the measure includes more complete and comparable populations across hospitals. Use of comparable populations would reduce measurement bias resulting from different coding practices across hospitals. We believe that measure results derived from refinement of the measure cohort in the manner we are proposing, which will include additional pneumonia patients that are not being included under the current measure specifications, will improve the fidelity of the measure's assessment of quality and outcome for pneumonia.

The proposed 30-Day Pneumonia Mortality Measure with this expanded measure cohort was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' with identification number E0468 and has been reviewed by the MAP. The revised measure was conditionally supported pending NQF endorsement of the measure update, as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*. This refined pneumonia mortality measure will be submitted to NQF for re-endorsement when the appropriate measure endorsement project has a call for measures this year. We will work to minimize potential confusion when publicly reporting the updated measure.

(2) Overview of Measure Cohort Change

The proposed measure refinement would expand the cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, assessment of the outcome of mortality, and 3 year data evaluation period all remain unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remain unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, we included additional risk variables to account for the discharge diagnoses added as part of the expanded cohort. For the full measure specifications of the proposed change to the measure, we refer readers to the AMI, HF, PN, COPD,

[89] Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. *Journal of the American Medical Association.* Apr 4 2012;307(13):1405–1413.

[90] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

[91] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

and Stroke Readmission Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(4) Effect of Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization Measure Cohort

Using administrative claims data for FY 2015 (that is, discharges between July 2010–June 2013), we analyzed and simulated the effect of the proposed cohort refinements on the CMS 30-day Pneumonia Mortality Measure as if these changes had been applied for FY 2015. We note that these statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for the FY 2015 payment determination.

Expanding the measure cohort to include a broader population of patients adds a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 cases), to the CMS 30-day Pneumonia Mortality Measure. In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's mortality rates and interval estimates are not publicly reported for the measure. For more information about this minimum case threshold for public reporting, we refer readers to section VIII.A.13. of the preamble of this proposed rule. The increase in the size of the measure cohort proposed in this rule would change results for many hospitals and would change the number of hospitals that have greater than 25 cases.

The previously adopted pneumonia mortality measure cohort includes 976,590 patients and 4,418 hospitals for the FY 2015 payment determination. We noted the following effects for the CMS 30-Day Pneumonia Mortality Measure if the expanded cohort had been applied for FY 2015: (1) The expansion of the cohort would include an additional 686,605 patients (creating a total measure cohort size of 1,663,195 patients); (2) an additional 86 hospitals would meet the minimum 25 patient cases volume threshold over the 3-year measure period and would be publicly reported for the measure; (3) 41 percent of the refined measure cohort would consist of patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission; and (4) there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification, for example from ''better than the national rate'' to ''no different than the national rate'' or from ''worse than the national rate'' to ''no different than the national rate.''

A detailed description of the refinements to the CMS 30-Day Pneumonia Mortality Measure and the effects of the change are available in the AMI, HF, PN, COPD, and Stroke Readmission Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* We note that this file contains information for both Mortality and Readmission.

We are inviting public comment on our proposal to refine the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) measure, expanding the measure cohort.

b. Proposed Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) Measure Cohort

(1) Background

In this proposed rule, we are proposing a refinement of the previously adopted measure, Hospital 30-day all-cause, risk-standardized readmission rate following pneumonia hospitalization (NQF #0506) (hereinafter referred to as the CMS 30-Day Pneumonia Readmission Measure) which expands the measure cohort. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain whether the patient was subsequently readmitted to the hospital within 30 days of the index admission. This cohort is the set of hospitalizations that meets all of the inclusion and exclusion criteria and we are proposing an expansion to this set of hospitalizations.

The previously adopted CMS 30-Day Pneumonia Readmission Measure, as specified in the FY 2009 IPPS PPS proposed rule (73 FR 23648) and adopted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780 through 68781), includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. For measure cohort details of the currently implemented measure, we refer readers to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Readmissions Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. The determination to refine the measure cohort was based on our evaluation of both the frequency and variation in utilization of these diagnosis codes, as such coding practices have been described in recently published studies. We anticipate that this measure will first be publicly reported with the proposed cohort change in CY 2016.

This refinement to the CMS 30-Day Pneumonia Readmission Measure is being proposed in response to recent evidence showing increasing use of the principal diagnosis codes of sepsis and respiratory failure among patients hospitalized with pneumonia. Including such patients will better represent the complete population of a hospital's patients who are receiving clinical management and treatment for pneumonia. In addition, because patients with a principal diagnosis of sepsis and respiratory failure are not included in the current CMS 30-Day Pneumonia Readmission Measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change.

Wide variation exists in the use of sepsis and respiratory failure codes across hospitals, potentially biasing efforts to compare hospital performance on 30-day readmission rates.[92] While

[92] Rothberg MB, Pekow PS, Priya A, Lindenauer PK.: Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

the referenced study [93] evaluated the effect of coding practices on mortality measure performance, the rationale is applicable to readmission measure performance as well. The increased use of sepsis and respiratory failure diagnosis codes improves performance because the patients with greatest severity of illness (for example, those with sepsis or respiratory failure) are currently systematically excluded from the measure, leaving only patients with lesser severity of illness in the measure cohort.

In response to this emerging data, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of broadening the measure cohort to include the complete population of patients at each hospital who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study [94] for mortality; that is, our results suggested that there is an increasing use of respiratory failure and sepsis as principal discharge diagnoses for pneumonia patients, as well as showed wide variation across hospitals in the use of these codes. In addition to assessing the use of the principal diagnosis codes of sepsis and respiratory failure, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. These findings suggest that expanding the measure cohort for the current CMS 30-Day Pneumonia Readmission Measure will ensure the measure includes more complete and comparable populations across hospitals. Use of comparable populations would reduce measurement bias resulting from different coding practices seen across hospitals. We believe that measure results derived from refinement of the measure cohort in the manner we are proposing, which will include additional pneumonia patients that are not being included under the current measure specifications, will improve the fidelity of the measure's assessment of quality and outcome for pneumonia.

The proposed refined measure was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' with identification number E0506, has been reviewed by the MAP, and was conditionally supported pending NQF review of the measure update. In particular, MAP members noted that the measure should be considered for socio-demographic status (SDS) adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized readmission rates, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. We refer readers to the ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/* for more information. When the appropriate measure endorsement project has a call for measures in 2015, this measure will be submitted to the NQF for reendorsement with special consideration of the potential impact of SDS adjustment on the measure.

(2) Overview of Measure Cohort Change

The proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission. The data sources, exclusion criteria, assessment of the outcome of readmission, and previous 3 years data evaluation period remain unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remain unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, we included additional risk variables to account for the discharge diagnoses added as part of the expanded cohort. For the full measure specifications of the proposed changes to the measure, we refer readers to the AMI, HF, PN, COPD, and Stroke Readmissions Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(4) Effect of Refinement of Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure Cohort

Using administrative claims data for FY 2015 (that is, discharges between July 2010–June 2013); we analyzed and simulated the effect of the proposed measure cohort refinements on the CMS 30-Day Pneumonia Readmission Measure as if these changes had been applied for FY 2015. We note that these statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for the FY 2015 payment determination. We anticipate that this measure will first be publicly reported with the proposed cohort change in CY 2016.

Based on our analysis, we anticipate that expanding the measure cohort to include a broader population of patients would add a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 cases), to the CMS 30-Day Pneumonia Readmission Measure. In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), CMS established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably tell how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's readmission rates and interval estimates are not publicly reported for the measure. For more information about this minimum case threshold for public reporting, we refer readers to section VIII.A.13. of the preamble of this proposed rule. The increase in the size of the measure cohort proposed in this measure cohort would change results for many hospitals and would change the number of hospitals that have greater than 25 cases.

The previously adopted pneumonia readmission measure cohort includes 1,094,959 patients and 4,451 hospitals for FY 2015 payment determination. We noted the following effects for the CMS 30-Day Pneumonia Readmission Measure if the expanded cohort had been applied for FY 2015: (1) The expansion of the CMS 30-Day Pneumonia Readmission Measure cohort would include an additional 670,491 patients (creating a total measure cohort of 1,765,450 patients); (2) there would be an additional 67

[93] Rothberg MB, Pekow PS, Priya A, Lindenauer PK.: Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

[94] Rothberg MB, Pekow PS, Priya A, Lindenauer PK.: Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine.* Mar 18 2014;160(6):380–388.

hospitals that meet the minimum 25 patient cases volume threshold over the 3-year applicable period and would be publicly reported for the measure; (3) patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission would represent 38 percent of the total expanded measure cohort; and (4) there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification, for example from ''better than the national rate'' to ''no different than the national rate'' or from ''worse than the national rate'' to ''no different than the national rate.''

A detailed description of the refinements to the CMS 30-Day Pneumonia Readmission Measure and the effects of the change are available in the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We are inviting public comment on our proposal to refine the previously adopted Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) measure, which expands the measure cohort.

7. Proposed Additional Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

We are proposing to add eight new measures to the Hospital IQR Program for the FY 2018 payment determination and subsequent years. We are proposing to adopt seven new claims-based measures and one new structural measure: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment Measure (claims-based); (3) Cellulitis Clinical Episode-Based Payment Measure (claims-based); (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based); (5) Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment Measure (claims-based); (6) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (7) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (8) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2014'' [95] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2015 Final Recommendations.[96]

For purposes of the Hospital IQR Program, section 1886(b)(3)(B)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. However, section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, 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.

a. Hospital Survey on Patient Safety Culture

(1) Background

For the FY 2018 payment determination and subsequent years, we are proposing to adopt the Hospital Survey on Patient Safety Culture. This proposed structural measure assesses whether a hospital administers a patient safety culture survey. Improving the safety of patient care is a priority and a quality improvement goal for CMS. We believe this structural measure will allow us to gain an understanding of whether hospitals are using a survey of patient safety culture in their hospitals. Because the number of questions in this measure is limited to five and can be completed using a Web-based tool, we believe this structural measure will not add undue reporting burden to hospitals.

We note that patient safety culture surveys are useful tools for measuring organizational conditions that can lead to adverse events and other incidences that can cause harm to patients in health care organizations.[97] Patient safety culture surveys can be used to: (1) Raise staff awareness about patient safety; (2) assess the current status of patient safety culture; (3) identify strengths and areas for improvement; and (4) examine trends in patient safety culture over time.[98]

There are multiple surveys that are currently used by the healthcare industry to assess patient safety culture including: the Pascal Metrics' Safety Attitudes Questionnaire (SAQ),[99] the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC),[100] the Patient Safety Climate in Healthcare Organizations (PSCHO),[101] and the Manchester Patient Safety Framework.[102] However, it is not clear which patient safety culture survey is used most frequently, or how many hospitals consistently assess their performance on these surveys. One example of use of a patient safety culture survey is the HSOPSC, which is nonproprietary and available to hospitals at no cost. AHRQ developed the survey, with CMS input, released it in 2004, and subsequently displayed results from 653 hospitals in 2014.[103] Use of the HSOPSC, as well as reporting results to AHRQ, was and continues to be voluntary. Among the reporting hospitals, there was variation in frequency of survey use, format of administration (Web versus paper) and staff sampling scheme.[104]

[95] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Retrieved from *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[96] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' found at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/map/*.

[97] Nieva VF, Sorra J.: *Safety culture assessment: a tool for improving patient safety in healthcare organizations.* Qual Saf Health Care 2003; 12:ii17–23.

[98] Frequently Asked Questions: Surveys on Patient Safety Culture. October 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/pscfaq.html*.

[99] Survey. (n.d.). Available at: *http://www.pascalmetrics.com/solutions/survey/*.

[100] Hospital Survey on Patient Safety Culture. (n.d.). Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html*.

[101] Measurement Instrument Database for the Social Sciences. (n.d.). Available at: *http://www.midss.org/content/patient-safety-climate-healthcare-organizations-pscho*.

[102] Dianne, P. (n.d.). Manchester Patient Safety Framework (MaPSaF). National Patient Safety Agency. Available at: *http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796*.

[103] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html*.

[104] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive

Through the proposed Hospital Survey on Patient Safety Culture Measure, we will begin to understand how hospitals are using surveys, like the examples cited above, in improving their patient safety culture. This proposed measure will allow CMS to collect data on whether a hospital conducts a patient safety culture survey, and if so, which tool they use, how frequently the tool is administered, and the response rate. This structural measure will help inform CMS of whether a measure targeting the culture of patient safety using a specific survey is feasible.

Finally, we note that the MAP supports this measure and specifically highlighted that a patient safety culture survey is an important tool for hospitals to use to build a system of quality improvement within health care facilities.[105] While this measure is not currently NQF-endorsed, we are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to patient safety that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess a patient safety culture, and found no other feasible and practical measures on this topic. We also are not aware of any other measures that assess whether a hospital administers a survey on patient safety.

(2) Overview of Measure

Reporting on a patient safety culture survey involves providing answers to the following questions listed below. Hospitals would submit answers via a Web-based tool on the QualityNet Web site:

(A) Does your facility administer a detailed assessment of patient safety culture using a standardized collection protocol and structured instrument?

(B) What is the name of the survey that is administered?

(C) How frequently is the survey administered?

(D) Does your facility report survey results to a centralized location? (Optional response options include the following: National data repository; State-based data repository; health system repository; other; and do not report the data outside the facility.)

(E) During the most recent assessment:

(a) How many staff members were requested to complete the survey?

(b) How many completed surveys were received?

(These questions can allow calculation of a response rate.)

(3) Data Sources

For FY 2018 payment determination and subsequent years, we are proposing that data collection for this structural measure for hospitals occur from January 1 through December 31 of each calendar year, with data submission occurring the following year. For the first year, data collection would be from January 1, 2016 through December 31, 2016. These data will be collected via a Web-based tool available on the QualityNet Web site.

We are inviting public comment on our proposal to adopt the Hospital Survey on Patient Safety Culture measure for the FY 2018 payment determination and subsequent years.

b. Clinical Episode-Based Payment Measures

(1) Background

Clinical episode-based payment measures are clinically coherent groupings of healthcare services that can be used to assess providers' resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers' clinical effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the ''Episode Grouper Evaluation Criteria'' project available at: *http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers__A_Report_from_the_National_Quality_Forum.aspx*) and in various peer-reviewed articles.[106] Episode-based measurement further supports CMS' efforts in response to the mandate in section 3003 of the Affordable Care Act that the Secretary develop an episode grouper to improve care efficiency and quality.

We are proposing four clinical episode-based payment measures for inclusion in the Hospital IQR Program beginning with the FY 2018 payment determination: The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure, the Cellulitis Clinical Episode-Based Payment measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure, and the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure. The proposed measures evaluate the difference between observed and expected episode cost at the episode level before comparing at the provider level.

The MAP conditionally supported these measures pending NQF endorsement.[107] Once the call for measures for the Cost and Resource Use project at NQF is announced, these measures will be submitted for endorsement.

The measures we are proposing are described below, and detailed specifications can be found in the ''Measure Methodology'' report for proposed episodic payment measures, available at: *http://www.qualitynet.org > Hospital-Inpatient > Claims-BasedMeasures > Proposed episodic payment measures > Measure Methodology*. The measures follow the general construction of the previously adopted, NQF-endorsed, Hospital IQR Program measure, Payment-Standardized Medicare Spending per Beneficiary (MSPB), described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and include standardized payments for Medicare Part A and Part B services.[108] Similar to the MSPB measure, the episodes are risk adjusted for individual patient characteristics and other factors (for example, attributes of inpatient stays). Unlike the MSPB measure however, these clinical episode-based measures include only Medicare Part A and B services that are clinically related to the triggering diagnosis or procedure.

Mathematically, the methodology described below first computes the provider's Episode Amount (calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost) and then divides the provider's Episode Amount by the

Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html*.

[105] National Quality Forum Measure Application Partnership. ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/map/*.

[106] For example: Hussey, P. S., Sorbero, M. E., Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. *Health Affairs, 28*(5), 1406–1417. doi:10.1377/hlthaff.28.5.1406.

[107] National Quality Forum. The report is available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx and the ''Spreadsheet of MAP 2015 Final Recommendations'' is available at: http://www.qualityforum.org/map/*.

[108] Detailed measure specifications can be found in the ''Medicare Spending Per Beneficiary (MSPB) Measure Overview,'' available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

episode-weighted median of all providers' Episode Amounts (as shown in equation (A) below).

$$\text{(A) } Episode\ Measure_j = \frac{Episode\ Amount_j}{\substack{Episode-Weighted \\ Median\ of\ All\ Providers' \\ Episode\ Amounts}} = \frac{\frac{\Sigma_{i \in j}(\frac{O_{ij}}{E_{ij}})}{n_j} * \bar{O}_{i \in I}}{\substack{Episode-Weighted \\ Median\ of\ All\ Providers' \\ Episode\ Amounts}}$$

where
O_{ij} = observed episode cost for episode *i* in provider *j,*
E_{ij} = expected episode cost for episode *i* in provider *j,*
$\bar{O}_{i \in I}$ = average observed episode cost across all episodes *i* nationally, and
n_j = total number of episodes for provider *j.*

This methodology builds on that which was submitted to the MAP, in response to MAP feedback, and in order to yield a national episode-weighted measure. We are proposing these clinical episode-based payment measures because they meet the following episode selection criteria we established for the purpose of selecting the best conditions and procedures to begin with, for clinical episode-based payment measures: (1) The condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2) there was a high degree of agreement among clinical experts consulted for this project that standardized Medicare payments for services provided during this episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for postacute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners.

(2) Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced over 234,000 kidney/urinary tract infection episodes triggered by related inpatient stays.[109] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.5 billion in 2012, with an average episode cost of over $10,000. There is substantial variation in kidney/urinary tract infection episode costs—ranging from approximately $4,800 at the 5th percentile to approximately $27,000 at the 95th—that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically-related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for common conditions, but other members expressed caution that the most efficient providers may reduce overall hospitalizations and that the remaining hospitalizations may be a biased sample for measuring performance across providers. In response to this concern, we note that this measure is limited by design to the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. To address the concern that providers involved in the hospitalization of only the most complex cases might be disadvantaged under the measure, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, such that expected costs for more complex patients will be higher and expected costs for less complex patients will be lower. Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess kidney/urinary tract infection. We also are not aware of any other measures that assess kidney/urinary tract infection treatment efficiency and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a kidney/urinary tract infection-related hospital admission. This measure, like the NQF-endorsed MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies a kidney/urinary tract infection.

[109] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.*

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described later in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. The period of performance for the measure is one year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A kidney/urinary tract infection episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates a kidney/urinary tract infection. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(3) Cellulitis Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Cellulitis Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced more than 143,000 cellulitis episodes triggered by related inpatient stays.[110] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $1.4 billion in 2012, with an average episode cost of approximately $10,000. There is substantial variation in cellulitis episode costs—ranging from about $5,000 at the 5th percentile to about $24,000 at the 95th—that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for an important condition. Other members expressed caution on the use of this measure noting that cellulitis is a highly variable condition that may be challenging to measure using an episode-based framework. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that there is substantial variation in cellulitis episode costs that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. This variation suggests that there may be opportunity to improve the efficiency of care for cellulitis treatment.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess cellulitis. We also are not aware of any other measures that assess cellulitis treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Cellulitis Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including post-acute care) a cellulitis-related hospital admission. The Cellulitis Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Cellulitis Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Cellulitis Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies cellulitis.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during this episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. The period of performance is one year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A cellulitis episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates cellulitis. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Cellulitis Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the GI Hemorrhage Clinical Episode-Based Payment measure have high costs with

[110] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.*

substantial variation. In calendar year 2012, Medicare FFS beneficiaries experienced 181,646 GI hemorrhage episodes triggered by related inpatient stays.[111] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled nearly $2 billion in 2012, with an average episode cost of about $11,000. There is substantial variation in GI hemorrhage episode costs—ranging from approximately $6,500 at the 5th percentile to approximately $23,000 at the 95th—that is driven by variation in post-discharge costs clinically related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization. For the purposes of reporting, and as suggested by the MAP, the GI hemorrhage episodes may be split into those treating an upper GI bleed and those treating a lower GI bleed due to clinical differences in patterns of care for those treatments. More information can be found in the supplemental documentation for the FY 2016 IPPS and LTCH Prospective Payment System Proposed Rule available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

The MAP conditionally supported this measure pending NQF review and endorsement. MAP members noted that this measure addresses the cost of care for GI bleeding. Several members expressed caution that the most efficient providers may reduce overall hospitalizations thus those inpatient hospitalizations that remain are a biased sample for measuring performance across providers. In response to these concerns, we note that this measure is limited by design to GI hemorrhage episodes treated in the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. With regard to the concern that efficient providers may reduce hospitalizations, leaving a biased sample of less efficient providers, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, thus to the extent that variation in treatment prior to hospitalization results in patterns of sicker (or healthier) GI hemorrhage patients admitted to certain hospitals, risk adjustment addresses these differences. For example, for providers who admit comparatively less complex patients to the inpatient hospital for treatment of GI bleeds, risk adjustment would cause their expected costs to be lower. Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess GI hemorrhage. We also are not aware of any other measures that assess GI hemorrhage treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a gastrointestinal hemorrhage-related hospital admission. This measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG that identifies a gastrointestinal hemorrhage.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7) of the preamble of this proposed rule. The period of performance is 1 year, beginning with CY 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A gastrointestinal hemorrhage episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG that indicates gastrointestinal hemorrhage. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(5) Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Spinal Fusion/Refusion Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced about 69,000 spinal fusion/refusion episodes triggered by related inpatient stays.[112] Payment-

[111] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

[112] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.6 billion in 2012, with an average episode cost of approximately $38,000. There is substantial variation in spinal fusion/refusion episode costs—ranging from approximately $28,000 at the 5th percentile to approximately $60,000 at the 95th—that is driven by variation in post-discharge costs clinically related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Some members raised concerns that patients with cancer should be excluded from this measure. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that this measure is titled ''Spine Fusion/Refusion Clinical Episode-Based Payment Measure'' in the MAP spreadsheet. Also, the episode is risk-adjusted to account for differences in patient characteristics, including the presence of cancer in the patient's history, which may affect costs but are outside of providers' control. Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess spinal fusion/refusion. We also are not aware of any other measures that assess spinal fusion/refusion treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a lumbar spine fusion/refusion-related hospital admission. The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window''). In contrast to the MSPB measure, the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS–DRG and ICD–9–CM procedure code that identify a lumbar spine fusion/refusion.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7) of the preamble of this proposed rule. The period of performance is 1 year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A lumbar spine fusion/refusion episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS–DRG and ICD–9 Procedure code that indicate lumbar spine fusion/refusion. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(6) Inclusion and Exclusion Criteria

A full list of the MS–DRG codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures can be found in the ''FY 2016 IPPS NPRM Episode Supplemental Documentation'' report in the ''Downloads'' section at: ''NPRM Episode Supplemental Documentation'' report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

The exclusion methodology applied to each of these measures is the same as the one used to calculate the previously adopted MSPB measure described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and available in the ''MSPB Measure Information Form'' at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. Episodes for beneficiaries that meet any of the following criteria are excluded from the measure:

- Lack of continuous enrollment in Medicare Parts A and B from 90 days prior to index admission through the end of the episode with Medicare as the primary payer.
- Death date during episode window.
- Enrollment in Medicare Advantage during the episode window.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode:

- Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event.
- Claims with payment ≤0.
- Acute inpatient stays that involved a transfer.
- Claims from a non-IPPS or non-subsection (d) hospital.

Claims that meet the following criterion will not be included in an episode:

- Claims with payment ≤0.

(7) Standardization and Risk-Adjustment

(A) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the Hospital IQR Program MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and used for all

of the payment measures included in the Value-Based Payment Modifier Program. The methodology removes geographic payment differences, such as wage index and geographic practice cost index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients (DSH).

(B) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). Specifications for the risk-adjustment employed in the proposed episode-based payment measures are included in the ''FY 2015 IPPS NPRM Episode Supplemental Documentation'' report, Section 4, titled ''Calculating the Hospital-Based Episode Measure,'' which can be found in the ''FY 2016 IPPS NPRM Episode Supplemental Documentation'' report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html*.

We are inviting public comment on our proposals.

c. Hospital-Level, Risk-Standardized Payment Associated With a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

(1) Background

Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[113] More than one-third of the U.S. population 65 years and older suffers from osteoarthritis,[114] a disabling condition for which elective THA/TKAs are most commonly performed. Estimates place the annual insurer cost of osteoarthritis in the United States at $149 billion, with Medicare payments to hospitals for THA/TKA exceeding $15 billion annually.[115]

There is evidence of variation in payments at hospitals for patients undergoing THA and/or TKA. The mean 90-day risk-standardized payment among Medicare FFS patients aged 65 or older with a qualifying elective primary THA/TKA procedure in 2010–2012 was $23,248, and ranged from $16,421 to $35,123 across 2,614 hospitals.[116] However, high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may have better clinical outcomes when compared with low payment hospitals while other high payment hospitals may not have better outcomes. Thus, CMS believes that payment measures provide complementary information to quality measures.

Quality measures for THA/TKA, such as: (1) Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (77 FR 53515 through 53518), and (2) Hospital-level risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (77 FR 53519 through 53521), are already adopted in the Hospital IQR Program and publicly reported, making THA/TKA an ideal procedure for which to assess payments for Medicare patients and relative hospital value. Including this proposed measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* would provide stakeholders with additional information about a hospital's cost of care for THA/TKA that will complement information about a hospital's quality of care. By including payments for 90 days after admission, this hospital-level resource use measure can capture the full spectrum of care and encourage collaboration and shared responsibility for patients' health after their procedures.

We are proposing to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed by the NQF, and were unable to identify any measures that assess hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA. We also are not aware of any other 90-day episode-of-care THA/TKA measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on December 10, 2014 pending a timely review by the NQF Cost and Resource Use Standing Committee. The MAP recommended harmonizing and determining the most parsimonious approach to measures the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.[117] Once the call for measures for the Cost and Resource Use project at NQF is announced, we will submit this measure for endorsement. In the meantime, we will consider ways to take these MAP recommendations into account.

(2) Overview of Measure and Rationale for Examining Payments for a 90-Day Episode-of-Care

The THA/TKA payment measure assesses hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA for any hospital participating in the Hospital IQR Program.

When considering payments for Medicare patients, we focused on a 90-day episode-of-care triggered by admission for several key reasons. First, THA and TKA procedures require ongoing post-discharge care. Second, the 90-day preset window encourages hospitals to optimize post-discharge care. Third, mechanical complications and wound or joint infections may present after 30 days and rates of these complications remain elevated for at least 90 days. Fourth, the 90-day post-admission timeframe is consistent with CMS' THA/TKA complication measure, which captures specific complications up to 90 days after admission. Furthermore, we obtained input from a national Technical Expert Panel (TEP) on the most appropriate window for the

[113] Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[114] Osteoarthritis. 2011; *http://www.cdc.gov/arthritis/basics/osteoarthritis.html*.

[115] Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, Birkmeyer JD.: Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. *Health Aff (Millwood)*. Nov 2011;30(11):2107–2115.

[116] Kim N, Ott LS, Lin Z et al.: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0). 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[117] National Quality Forum. The report is available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx* and the ''Spreadsheet of MAP 2015 Final Recommendations'' is available at: *http://www.qualityforum.org/map/*.

episode-of-care. Based on TEP feedback, we chose a measure follow-up period of 90 days that includes all payments for the initial 30 days of the episode, and all payments in a predefined set of care settings and services for days 31 through 90.

We refer readers to the measure methodology report and measure risk adjustment statistical model on our Measure Methodology page, under the ''Downloads'' section of the Web page. We refer readers to the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(3) Data Sources

The proposed Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure uses Part A and Part B Medicare administrative claims data that contain payments for Medicare FFS beneficiaries who were hospitalized and underwent an elective THA/TKA. This measure will use 3 years of data.

(4) Outcome

The primary outcome of this measure is the hospital-level risk-standardized payment for an elective primary THA/TKA episode-of-care. This measure captures payments for Medicare patients across multiple care settings, services, and supplies (inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). This measure includes patient copayments as well as payments from coinsurance. While the approach to standardization in calculating payments over the episode is very similar to the previously adopted Hospital IQR measure, Payment-Standardized Medicare Spending Per Beneficiary (MSPB) as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626), the THA/TKA measure has a different cohort and risk-model. For more information on how MSPB is calculated, we refer readers to the measure development reports found on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*.

To isolate payment variation that reflects practice patterns rather than CMS payment adjustments, this measure excludes policy and geography payment adjustments unrelated to clinical care decisions. We achieve this by ''stripping'' or ''standardizing'' payments for each care setting. Stripping refers to removing geographic differences and policy adjustments in payment rates for individual services from the total payment for that service. Standardizing refers to averaging payments across geographic areas for those services where geographic differences in payment cannot be stripped. Stripping and standardizing the payment amounts allows for a fair comparison across hospitals based solely on payments for decisions related to clinical care of THA/TKA.

By risk standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's risk-standardized payment (RSP) to an average hospital with a similar case-mix. We define our analytic timeframe as beginning with the index admission for an elective primary THA/TKA to 90 days post-admission. The measurement includes all payments for the first 30 days after admission and only certain payments based on a pre-defined set of care settings and services for days 31–90.

(5) Cohort

The measure includes Medicare FFS patients aged 65 or older admitted for elective primary THA and/or TKA, and calculates payments made on behalf of these patients (including payments made by CMS, patients, and other insurers) over a 90-day episode-of-care beginning with the index admission. The measure cohort aligns with another previously adopted Hospital IQR Program measure—90-day hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA (NQF #1550) (77 FR 53516 through 53518). Consistent with this previously adopted measure, the proposed measure includes hospitalizations identified by a procedure code of either THA or TKA, as classified by the ICD–9–CM codes 81.51 and 81.54, respectively. The measure includes only those hospitalizations from short-stay acute care hospitals in the index cohort and restricts the cohort to patients enrolled in FFS Medicare Parts A and B (with no Medicare Advantage coverage).

(6) Inclusion and Exclusion Criteria

This proposed measure includes hospitalizations for patients 65 years and older at the time of index admission. An index admission/hospitalization is the initial admission for a qualifying elective primary THA/TKA that triggers the 90-day episode-of-care for this payment measure. An index admission is the hospitalization to which the RSP outcome is attributed and includes index admissions for patients having a qualifying elective primary THA/TKA procedure. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients without at least 90 days of post-admission enrollment in FFS Medicare Parts A and B because this is necessary to identify the outcome (payments) in the dataset over the analytic period; (2) admissions for patients discharged against medical advice (AMA) because hospitals had limited opportunity to implement high quality care; (3) admissions for patients transferred to federal hospitals because we do not have claims data for these hospitals, so including these patients would cause payments to be underestimated; (4) admissions for patients with more than two THA/TKA procedure codes during the index hospitalization because, although clinically possible, it is highly unlikely that patients would receive more than two elective THA/TKA procedures in one hospitalization, and this may reflect a coding error; (5) admissions that could not be matched to admissions in the THA/TKA complication measure because, as part of our data processing, we matched our index THA/TKA admissions to the THA/TKA complication measure cohort to obtain the risk-adjustment variables; and (6) admissions without a DRG weight and the provider received no payment because, without either DRG weight or payment data, we cannot calculate a payment for the patient's index admission.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how payments are affected by patient comorbidities relative to patients cared for by other hospitals. We refer readers to the measure risk adjustment statistical model on our Measure Methodology Web page, under the ''Downloads'' section of the Web page. Please see the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(8) Calculating the Risk-Standardized Payment (RSP)

The measure is calculated using a hierarchical generalized linear model with a log link and an inverse Gaussian distribution, which is a widely accepted statistical method that enables fair evaluation of relative hospital performance by taking into account patient risk factors as well as the

number of patients that a hospital treats. This statistical model accounts for the structure of the data (patients clustered within hospitals) and calculates: (1) How much variation in hospital payment overall is accounted for by patients' individual risk factors (such as age and other medical conditions) and (2) how much variation is accounted for by hospital-specific performance. This approach appropriately models a positive, continuous, right-skewed outcome like payment and also accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. This hierarchical generalized linear model is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals and sample sizes vary across hospitals. Clustered patients are within the same hospital, and the quality of care of the hospital affects all patients, so the outcomes for each hospital's patients are not fully independent (that is, completely unrelated) as is assumed by many statistical models. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the THA/TKA hospitalization as well as select conditions indicated by secondary diagnosis codes on index admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications of care rather than patient comorbidities.

The RSP is calculated as the ratio of predicted payments to expected payments and then the ratio is multiplied by the national unadjusted average payment for an episode-of-care. The ratio is greater than one for hospitals that have higher payments than would be expected for an average hospital with similar cases and less than one if the hospital has lower payments than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or ''risk-adjusted'' rate used in other similar types of statistical analyses. The RSP is a point estimate—the best estimate of a hospital's payment based on the hospital's case mix.

To calculate the measure result for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate. We use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). The interval estimate indicates that the true value of the payment ratio lies between the lower limit and the upper limit of the interval. For more detailed information on the calculation methodology, we refer readers to our Measure Methodology Web page, under the ''Downloads'' section. We refer readers to the ''Hip and Knee Arthroplasty Payment'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We are inviting public comment on our proposal to adopt the Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure for the FY 2018 payment determination and subsequent years.

d. Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction

(1) Background

Acute myocardial infarction (AMI) is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. We note that AMI was the tenth most common principal discharge diagnosis among patients with Medicare in 2012.[118] AMI also accounts for a large fraction of hospitalization costs, and it was the sixth most expensive condition billed to Medicare in 2011.[119]

Some of the costs for AMI can be attributed to high acute care utilization for post-discharge AMI patients in the form of readmissions, observation stays, and ED visits. We note that patients admitted for AMI have disproportionately high readmission rates, and that readmission rates following discharge for AMI are highly variable across hospitals in the United States.[120] [121] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (CY 2009 OPPS/ASC final rule with comment period; 73 FR 68780 through 68781) (hereinafter referred to as READM–30–AMI), publicly reported 30-day risk-standardized readmission rates for AMI ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[122] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM–30–AMI measure.[123] [124]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[125] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[126] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients, providers, and policymakers.[127] For example, a report from OIG noted that in 2012, Medicare

[118] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP) http://hcupnet.ahrq.gov/.*

[119] Torio CM, Andrews RM.: National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.*

[120] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407–413.

[121] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459–467.

[122] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.*

[123] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[124] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: the journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[125] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[126] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52–63.

[127] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251–1259.

beneficiaries had 1.5 million observation stays.[128] Many of these observation stays lasted longer than the intended one day. This OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.[129]

Thus, in the context of the previously adopted and publicly reported READM–30–AMI measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–AMI measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[130]

In response to these concerns, CMS improved on a previously existing non-Hospital IQR Program measure entitled ''30-Day Post-Hospital AMI Discharge Care Transition Composite'' (NQF #0698). The improved measure (now called Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction) is a risk-adjusted outcome measure for AMI that incorporates the full range of acute care use that patients may experience post-discharge: Hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge AMI patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

We are proposing to include this improved measure under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered existing measures related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for AMI that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that this measure is reviewed by NQF and endorsed. We refer readers to the Spreadsheet of MAP 2015 Final Recommendations available at: *http://www.qualityforum.org/map/*, and note that in the document, this measure is entitled ''Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following acute myocardial infarction (AMI) hospitalization.'' In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for AMI measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for AMI, compared to the days expected based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for AMI.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED, (2) admitted to observation status, or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index AMI hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

''Planned'' readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM–30–AMI measure. A more detailed discussion of exclusions follows below.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the existing Hospital IQR Program measure, READM–30–AMI, except that this proposed measure does not include patients admitted to Veterans Administration hospitals. That

[128] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[129] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[130] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

is, the cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of AMI; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) were alive at discharge. We defined the cohorts using the following ICD–9–CM diagnosis codes identified in inpatient claims data:

- 410.00 (Acute myocardial infarction of anterolateral wall, episode of care unspecified);
- 410.01 (Acute myocardial infarction of anterolateral wall, initial episode of care);
- 410.10 (Acute myocardial infarction of other anterior wall, episode of care unspecified);
- 410.11 (Acute myocardial infarction of other anterior wall, initial episode of care);
- 410.20 (Acute myocardial infarction of inferolateral wall, episode of care unspecified);
- 410.21 (Acute myocardial infarction of inferolateral wall, initial episode of care);
- 410.30 (Acute myocardial infarction of inferoposterior wall, episode of care unspecified);
- 410.31 (Acute myocardial infarction of inferoposterior wall, initial episode of care);
- 410.40 (Acute myocardial infarction of other inferior wall, episode of care unspecified);
- 410.41 (Acute myocardial infarction of other inferior wall, initial episode of care);
- 410.50 (Acute myocardial infarction of other lateral wall, episode of care unspecified);
- 410.51 (Acute myocardial infarction of other lateral wall, initial episode of care);
- 410.60 (True posterior wall infarction, episode of care unspecified);
- 410.61 (True posterior wall infarction, initial episode of care);
- 410.70 (Subendocardial infarction, episode of care unspecified);
- 410.71 (Subendocardial infarction, initial episode of care);
- 410.80 (Acute myocardial infarction of other specified sites, episode of care unspecified);
- 410.81 (Acute myocardial infarction of other specified sites, initial episode of care);
- 410.90 (Acute myocardial infarction of unspecified site, episode of care unspecified);
- 410.91 (Acute myocardial infarction of unspecified site, initial episode of care).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (3) hospitalizations for patients admitted and discharged on the same day (and not transferred or deceased) because these patients likely did not suffer clinically significant AMI; and (4) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional AMI admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a ''hurdle'' model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) A probability that they have a non-zero number of days; and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACDs)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM–30–AMI measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We are inviting public comment on our proposal to adopt the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure for the FY 2018 payment determination and subsequent years.

e. Excess Days in Acute Care After Hospitalization for Heart Failure

(1) Background

Heart failure is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Heart failure was the second most common principal discharge diagnosis among patients with Medicare in 2012.[131] Heart failure also accounts for a large fraction of hospitalization costs, and it was the

[131] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP) http://hcupnet.ahrq.gov/.*

third most expensive condition billed to Medicare in 2011.[132]

Some of the costs for heart failure can be attributed to high acute care utilization for post-discharge heart failure patients in the form of readmissions, observation stays, and ED visits. Patients admitted for heart failure have disproportionately high readmission rates. Readmission rates following discharge for heart failure are highly variable across hospitals in the United States.[133] [134] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Heart Failure Hospitalization (NQF #0330) (READM–30–HF) (73 FR 46806 through 48610), publicly reported 30-day risk-standardized readmission rates for heart failure ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[135] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM–30–HF measure.[136] [137] Patients returning to the ED after heart failure hospitalization most commonly return for heart failure recurrence and chest pain.[138]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[139] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[140] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients, providers, and policymakers.[141] [142] [143] For example, a report from the OIG noted that in 2012, Medicare beneficiaries had 1.5 million observation stays.[144] Many of these observation stays lasted longer than the intended one day. The OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.

Thus, in the context of the currently adopted and publicly reported Hospital IQR Program READM–30–HF measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–HF measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[145]

In response to these concerns, we improved on an existing non-Hospital IQR Program measure entitled ''30-Day Post-Hospital HF Discharge Care Transition Composite'' (NQF #0699). The improved measure (now called Excess Days in Acute Care after Hospitalization for Heart Failure) is a risk-adjusted outcome measure for heart failure that incorporates the full range of acute care use that patients may experience post-discharge: hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge heart failure patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

We are proposing this improved measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays and ED visits) following hospitalization for heart failure that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that it is reviewed by NQF and endorsed. We note that this measure was entitled

[132] Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; Available at: *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp*.

[133] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407–413.

[134] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459–467.

[135] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf*.

[136] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[137] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: the journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[138] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA:The journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[139] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[140] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52–63.

[141] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[142] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: The Journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[143] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251–1259.

[144] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI–02–12–00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

[145] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

''Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following heart failure hospitalization,'' in the MAP Spreadsheet. In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for Heart Failure measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for heart failure, compared to the days expected at an average hospital, based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for heart failure.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED, (2) admitted to observation status, or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index heart failure hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

''Planned'' readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm (78 FR 50786 through 50787), a set of criteria for classifying readmissions that are likely to be planned among the general Medicare population using Medicare claims data, previously developed for Hospital IQR Program 30-day readmission measures, including the previously adopted READM–30–HF measure.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program READM–30–HF measure (73 FR 46806 through 48610). The READM–30–HF cohort criteria are included in a report posted on our Measure Methodology Web page, under the ''Downloads'' section in the ''AMI, HF, PN, COPD, and Stroke Readmission Updates'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. This measure differs from the READM–30–HF measure cohort in that this measure does not include patients admitted to Veterans Administration hospitals. That is, the cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of heart failure; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) were alive at discharge. We defined the cohorts using the following ICD–9–CM diagnosis codes identified in inpatient claims data:

- 402.01 (Malignant hypertensive heart disease with heart failure);
- 402.11 (Benign hypertensive heart disease with heart failure);
- 402.91 (Unspecified hypertensive heart disease with heart failure);
- 404.01 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.03 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease);
- 04.11 (Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.13 (Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 404.91 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.93 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 428.0 (Congestive heart failure, unspecified);
- 428.1 (Left heart failure);
- 428.20 (Systolic heart failure, unspecified);
- 428.21 (Acute systolic heart failure);
- 428.22 (Chronic systolic heart failure);
- 428.23 (Acute on chronic systolic heart failure);
- 428.30 (Diastolic heart failure, unspecified);
- 428.31 (Acute diastolic heart failure);
- 428.32 (Chronic diastolic heart failure);
- 428.33 (Acute on chronic diastolic heart failure)
- 428.40 (Combined systolic and diastolic heart failure, unspecified);
- 428.41 (Acute combined systolic and diastolic heart failure);
- 428.42 (Chronic combined systolic and diastolic heart failure);
- 428.43 (Acute on chronic combined systolic and diastolic heart failure);
- 428.9 (Heart failure, unspecified).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the

30-day outcome cannot be assessed in this group because claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because providers did not have the opportunity to deliver full care and prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional heart failure admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the health care system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a ''hurdle'' model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) A probability that they have a non-zero number of days and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACDs)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM–30–HF measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We are inviting public comment on our proposal to adopt the Excess Days in Acute Care after Hospitalization for Heart Failure measure for the FY 2018 payment determination and subsequent years.

f. Summary of Previously Adopted and Proposed Hospital IQR Program Measure Set for the FY 2018 Payment Determination and Subsequent Years

The table below outlines the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years and includes both previously adopted and proposed measures.

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	NHSN	
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure • Colon Procedures • Hysterectomy Procedures.	0753
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
	Chart-abstracted	
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm–2	Influenza Immunization	1659
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–04 *	Thrombolytic Therapy	0437
VTE–5 *	Venous Thromboembolism Discharge Instructions	N/A
VTE–6 *	Incidence of Potentially Preventable Venous Thromboembolism	N/A

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
	Claims	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
STK Mortality	Stroke 30-day Mortality Rate	N/A
CABG Mortality	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
COPD READMIT	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
STK READMIT	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
CABG READMIT	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 4 (PSI/NSI)	Death among Surgical Inpatients with Serious, Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
THA/TKA Payment **	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Kidney/UTI Payment **	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A
Spine Fusion/Refusion Payment **.	Spine Fusion/Refusion Clinical Episode-Based Payment Measure	N/A
Cellulitis Payment **	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment **	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
AMI Excess Days **	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days **	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
	Electronic Clinical Quality Measure	
AMI–2	Aspirin Prescribed at Discharge for AMI	0142
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0164
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	N/A
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	N/A
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
HTN	Healthy Term Newborn	0716
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice.	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP–Inf–1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP–Inf–2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP–Inf–9	Urinary catheter Removed on Postoperative Day 1 (POD 1) or Postoperative Day 2 (POD 2) with Day of Surgery Being Day Zero.	N/A
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04 *	Thrombolytic Therapy	0437

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	N/A
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol or Nomogram.	N/A
VTE–5*	Venous Thromboembolism Discharge Instructions	N/A
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	N/A
	Patient Survey	
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM-3)	0166 0228
	Structural	
Patient Safety Culture**	Hospital Survey on Patient Safety Culture	N/A
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for Registry for General Surgery	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

*Measure is listed twice, as both chart-abstracted and electronic clinical quality measure.
**Measures we are proposing beginning with FY 2018 and for subsequent years.

8. Electronic Clinical Quality Measures

In this proposed rule, we are clarifying our policy for one previously adopted voluntarily reported electronic clinical quality measure for the FY 2017 payment determination. Specifically, we are clarifying our requirements for the submission of STK–01 for CY 2015/FY 2017 payment determination. In addition, we are proposing to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures required for the FY 2018 payment determination and subsequent years.

a. Previously Adopted Voluntarily Reported Electronic Clinical Quality Measures for the FY 2017 Payment Determination

For a discussion of our previously finalized electronic clinical quality measures and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811 through 50819), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276).

b. Clarification for the Venous Thromboembolism (VTE) Prophylaxis (STK–01) Measure (NQF #0434)

In this proposed rule, we are proposing to clarify reporting requirements for the Venous Thromboembolism (VTE) Prophylaxis (STK–01) Measure (NQF #0434). In the FY 2016 IPPS/LTCH PPS final rule (78 FR 50808), we stated that hospitals need not report the STK–01 measure as part of the STK measure set if reporting electronically, because no electronic specification existed for STK–01. In other words, hospitals that successfully submit STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures are not required to also chart-abstract and submit STK–01 in order to meet Hospital IQR Program requirements for the FY 2016 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK–01 as previously required. To review the details in the 2014 IPPS/LTCH PPS final rule, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Regulations.html*.

We are clarifying that this policy continues for the CY 2015/FY 2017 payment determination. Hospitals that chose to submit the STK–02, STK–03, STK–04, STK–05, STK–06, STK–08, and STK–10 as electronic clinical quality measures are not required to also chart-abstract and submit STK–01 in order to meet Hospital IQR Program requirements for the FY 2017 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK–01 as previously required. We note that STK–01 is proposed for removal for CY 2016/FY 2018 payment determination and refer readers to section VIII.A.3.b. of the preamble of this proposed rule for more details.

We are inviting public comment on this proposal.

c. Proposed Requirements for Hospitals To Report Electronic Clinical Quality Measures for the FY 2018 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to expand our electronic clinical quality measure policy in order to make reporting of electronic clinical quality measures required, rather than voluntary, under the Hospital IQR Program. Specifically, we are proposing that, beginning in CY 2016/FY 2018 payment determination and subsequent years, we will require hospitals to select and submit 16 electronic clinical quality measures covering three NQS domains from the 28 available electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, we are proposing that hospitals must submit Q3 and Q4 data for 16 measures chosen by a hospital and reported as electronic clinical quality measures. For example, for the FY 2018 payment determination, hospitals would be required to submit Q3 and Q4 CY 2016 data for 16 measures of their choice. This proposal is in alignment with the Medicare EHR Incentive

Program, as discussed in section VIII.D.2.b. of the preamble of this proposed rule.

Hospitals would not fail validation based on these data for CY 2016/FY 2018 payment determination reporting because validation for electronic measures is currently under development. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a proposal to conduct a validation pilot test for electronically specified measures in FY 2015. The pilot is currently underway and therefore, the results are not yet available.

We will delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measure will be marked with a footnote on *Hospital Compare* noting that: (1) The hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) CMS will eventually publicly report this data once CMS determines the data to be reliable and accurate.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50815 through 50818), we adopted a policy under which we would only publicly report electronic clinical quality measure data under the Hospital IQR Program if we determined that the data are accurate enough to be reported. We believe that our current proposal to delay public reporting of electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination is also in line with our existing policies. In future rulemaking, we will continue to address our intent to ensure that measures meet the reliability and validity requirements set for public reporting and that the measures are accurate and understandable before measures are publicly reported on *Hospital Compare.*

As shown in the table above entitled ''Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years,'' 6 measures (ED–1, ED–2, STK–04, VTE–5, VTE–6, and PC–01) may be reported either via chart-abstraction or as electronic clinical quality measures. For the FY 2018 payment determination and subsequent years, hospitals may either report a full year of data (Q1 through Q4) in accordance with the submission requirements for chart-abstracted data, or electronically submit two quarters of data (Q3 and Q4) for each of these 6 measures. If hospitals choose to report these 6 measures electronically, the measures can be used to count toward the Hospital IQR Program's 16 required electronic clinical quality measures. Hospitals choosing to report these 6 measures via chart-abstraction must select other electronic measures to meet the requirement to report 16 electronic clinical quality measures. Additional detail on submitting electronic data for measures can be found in section VIII.A.10.d.(3) of the preamble of this proposed rule.

We recognize that measure rates may not be comparable between measures reported via chart-abstraction and measures that are electronically specified. Collecting electronic measure data according to our proposal that hospitals must select and submit 16 electronic clinical quality measures will help us evaluate variations in data capture modes (chart-abstracted versus electronic clinical quality measures) in order to determine whether and what adjustments are necessary for the two different modes of collection. We refer readers to section VIII.A.3.b. of the preamble of this proposed rule, where we discuss CMS' belief that, although the intent of a measure is the same whether it is reported via chart-abstraction or electronically, the submission modes and measure rates are not the same.

We also considered two alternative required electronic clinical quality measure reporting options. Alternative A would require hospitals to submit 10 of 28 quality measures: (1) VTE–1; (2) STK–02; (3) ED–1; (4) STK–05; (5) STK–06; (6) STK–10; (7) VTE–2; (8) STK–08; (9) ED–2; and (10) STK–03. Our data show that these measures are most frequently reported with non-zero values among hospitals attesting under 2014 Meaningful Use. In addition, all 10 of these measures have been included in the Hospital IQR Program measure set as voluntary electronic clinical quality measures since CY 2014/FY 2016 payment determination (79 FR 50209 through 50211). Alternative B would require hospitals to submit 10 of 28 quality measures of each hospital's choice. Both alternatives differ from our proposal only in the number and/or composition of the electronic clinical quality measures to be reported; that is, for both of these alternatives, the reporting periods and submission requirements would be the same as those proposed in this proposed rule.

However, we determined not to pursue these alternative reporting options as we believe that requiring hospitals to report more measures electronically is in line with our goals to move towards electronic clinical quality measure reporting and to align with the EHR Incentive Program, which requires reporting on 16 clinical quality measures covering at least 3 domains.

We believe that our proposals will ultimately decrease reporting burden to hospitals. Once capture is possible within EHR, the time and resources needed to submit quality measures data are significantly less compared to manual abstraction. Electronic clinical quality measure collection does not require hospital staff time to find and pull paper medical records and manually review them to abstract data elements used in measure calculation. We acknowledge that there are initial costs, but believe that long-term benefits associated with electronic data capture outweigh those costs.

We welcome public comment on our proposal to require hospitals to select and submit 16 electronic clinical quality measures covering three NQS domains from the 28 available electronic clinical quality measures for eligible hospitals and CAHs for the FY 2018 payment determination and subsequent years. We refer readers to section VIII.A.10.d.(3) of the preamble of this proposed rule for detail on reporting periods and submission deadlines for electronic clinical quality measures.

9. Future Considerations for Electronically Specified Measures: Consideration To Implement a New Type of Measure That Utilizes Core Clinical Data Elements

a. Background

We have implemented several claims-based measures comparing hospital performance on 30-day mortality, 30-day readmission, and complications following hospitalization for several conditions and procedures in the Hospital IQR, Hospital Readmissions Reductions, and Hospital VBP Programs. Although these measures have been shown to provide valid information about hospital performance, the clinical community continues to express the opinion that data gathered directly from patients and used by clinicians to guide diagnostic decisions and treatment are preferable for risk adjustment of hospital outcome measures. In response to clinicians and providers' feedback in public comment periods during measure development, and keeping with our goal to move toward the use of electronic health records (EHRs) for electronic quality measure reporting throughout CMS programs, where feasible, we are considering: (1) The use of core clinical data elements derived from EHRs for use in future quality measures (for example, risk adjustment of outcome

measures); (2) the collection of additional administrative linkage variables to link a patient's episode of care from EHR data with his administrative claim data, and (3) use of content exchange standards.

During a July 2014 public comment period on the CMS Call for Public Comment Web site [146] for the hybrid hospital-wide readmission measure with administrative claims and electronic health record data, we received supportive feedback on the importance of the use of clinical data in hospital outcome measures. Commenters supported our efforts in examining new approaches to provide a more accurate assessment and portrayal of services provided by clinicians and hospitals, and the feedback also indicated their belief that it is very important that enriched clinical data from an EHR be used to supplement the clinically limited datasets available from administrative claims data. We note that reviewers can find the public comment summary report within the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1), in the ''Downloads'' section of our Measure Methodology Web page. We refer readers to the Core Clinical Data Elements and Hybrid Measures zip file found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

In response to this public feedback, as well as CMS policy goals, we have identified a set of 21 clinical variables, or core clinical data elements, which we note are routinely collected on hospitalized adults and feasibly extracted from hospital EHRs. We believe that these core clinical data elements can be adapted for future use as part of specific quality measures. During our testing, we found that these 21 core clinical data elements can be used to risk adjust 30-day mortality and 30-day readmission outcome measures. Although we have thus far only tested the core clinical data elements for use in the risk adjustment models of hospital-level outcome measures, they could be utilized in other ways in the future. We anticipate that EHRs will continue to improve capturing of relevant clinical data and we also anticipate future expansion of the list of core clinical data elements.

In the future, one way in which we envision using core clinical data elements in conjunction with other sources of data, such as administrative claims, is to calculate ''hybrid'' outcome measures, which are quality measures that utilize more than one source of data. We believe that these types of hybrid measures could enhance the current CMS administrative claims-based outcome measures by utilizing patient clinical data captured in the EHR. We have shown that core clinical data elements captured in EHRs and used to risk adjust hospital outcome measures improve the discrimination of the measures, or the ability to distinguish good and poor performers, as assessed by the c-statistic, which evaluates the measure's ability to discriminate or differentiate among high and low performing hospitals.[147] [148] [149] Finally, hybrid measure results would need to be calculated by CMS to determine hospitals' risk-adjusted rates relative to national rates used in public reporting. With hybrid measures, hospitals would forward data extracted from the EHR, and CMS would perform the measure calculations.

To illustrate one way in which the 21 core clinical data elements can be used, we developed two hybrid measures: (1) Hospital 30-Day Risk-Standardized Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473); and (2) a hybrid hospital-wide 30-day readmission measure, which has not yet undergone NQF endorsement proceedings. However, the latter measure's development was encouraged by the MAP.[150] We note that the 2013 Core Clinical Data Elements Technical Report Version 1.1 (a methodology report) provides a more detailed review of the clinical core data elements. This document is posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, available on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

b. Overview of Core Clinical Data Elements

Core clinical data elements are a set of clinical variables derived from EHRs that can be used to risk adjust hospital outcome measures. We have currently identified a set of 21 core clinical data elements that: (1) Can be feasibly extracted from current EHR systems; (2) are available on most adult patients; and (3) are relevant to patient outcomes following hospitalization. These core clinical data elements are listed in the table below.

CURRENTLY IDENTIFIED CORE CLINICAL DATA ELEMENTS CONSIDERED FOR RISK-ADJUSTMENT OF HYBRID OUTCOME MEASURES USED IN THE HOSPITAL SETTING

Data elements	Units of measurement	Time window for first captured values (hours)
Patient Characteristics		
Age at admission	Years	—
Gender	Male or female	—
First-Captured Vital Signs		
Heart Rate	Beats per minute	0–2
Systolic Blood Pressure	mmHg	0–2

[146] CMS.gov. Measure Management System, Public Comment. Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*.

[147] Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1).

[148] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1).

[149] 2013 Core Clinical Data Elements Technical Report (Version 1.1).

[150] National Quality Forum. Measure Application Partnership. Available at: *https://share.cms.gov/center/CCSQ/QMHAG/DHMM/Measures%20Development%20and%20Maintenance/map/MAP%202014/MAP%202015/map_pre-rulemaking_final_report_2015.pdf*. Accessed on February 5, 2015.

CURRENTLY IDENTIFIED CORE CLINICAL DATA ELEMENTS CONSIDERED FOR RISK-ADJUSTMENT OF HYBRID OUTCOME MEASURES USED IN THE HOSPITAL SETTING—Continued

Data elements	Units of measurement	Time window for first captured values (hours)
Diastolic Blood Pressure	mmHg	0–2
Respiratory Rate	Breath per minute	0–2
Temperature	Degrees Fahrenheit	0–2
Oxygen Saturation	Percent	0–2
Weight	Pounds	0–24
First-Captured Laboratory Results		
Hemoglobin	g/dL	0–24
Hematocrit	% red blood cells	0–24
Platelet	Count	0–24
WBC Count	Cells/mL	0–24
Potassium	mEq/L	0–24
Sodium	mEq/L	0–24
Chloride	mEq/L	0–24
Bicarbonate	mmol/L	0–24
BUN	mg/dL	0–24
Creatinine	mg/dL	0–24
Glucose	mg/dL	0–24
Troponin	ng/mL	0–24

This set of core clinical data elements consists of the first captured vital signs, and the results of a complete blood count and basic chemistry panel. These core clinical data elements were selected because they were empirically shown to be captured during routine clinical practice on most adult hospitalized patients.[151] Among other ways, one way in which we envision using these core clinical data elements is to risk adjust outcomes measures, since the elements improve the discrimination of hospital outcome measures as assessed by c-statistic and enhances the face validity of measures for the clinical community, which continue to express a preference for these types of data to account for patients' severity of illness.[152]

In the context of risk-adjustment, future hybrid measures would utilize some or all of the 21 core clinical data elements listed above, as well as any future feasible core clinical data elements. For example, the Hospital 30-day Risk-Standardized Acute Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473) uses five core clinical data elements: Age; heart rate; systolic blood pressure; troponin; and creatinine.[153] In contrast, the hybrid hospital-wide measure uses 14 of the 21 core clinical data elements (age, heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation, weight, hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine and glucose).[154] These two hybrid measures illustrate how specific core clinical data elements used in a given hybrid measure will vary depending on the core clinical data elements identified as relevant for and predictive of that measure outcome in the target cohort.

We note that the 21 core clinical data elements included are already routinely recorded in the EHR by clinical staff at the beginning of an inpatient encounter to diagnose and treat patients. Collection of these core clinical data elements are in response to stakeholder preference, and in particular, for the use of clinical information in risk models, but is not meant to guide or alter the care patients receive. We believe clinical staff should continue to only perform measurements or tests that are appropriate for diagnostic assessment or treatment of patients.

We assessed the feasibility of extraction of the 21 core clinical data elements in models of readmission and mortality outcome measures (Core Clinical Data Elements Development is discussed below). For additional detail on testing and the measure methodologies, we refer readers to the 2013 Core Clinical Data Elements Technical Report Version 1.1 methodology report posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

c. Core Clinical Data Elements Development

To identify this set of core clinical data elements, we first focused on those data elements that can be used to risk adjust hospital outcome measures. We developed a systematic five-step approach in which we: (1) Established a set of criteria to assess the feasibility of consistently identifying and extracting EHR data elements, and convened a diverse group of health information technology experts and end users to apply these criteria to EHR data; (2) conducted a systematic review of the literature to identify clinical data that has been shown to predict patient outcomes following acute care hospital admissions; (3) assessed the frequency and timing of capture of candidate data

[151] 2013 Core Clinical Data Elements Technical Report (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[152] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1) and Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[153] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[154] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

elements using a dataset from an active EHR data warehouse of a large healthcare system serving over 3.3 million beneficiaries; [155] (4) tested the utility of feasible data elements in risk-adjusted hierarchical models of 30-day mortality following hospitalization for a variety of common and costly medical conditions (for example, heart failure, pneumonia, and stroke); and (5) tested the core clinical data elements as risk-adjustment variables in the previously adopted Hospital IQR Program measure, CMS 30-Day Hospital-Wide All-Cause Unplanned Readmission Outcome measure (NQF #1789) finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528), creating the hybrid hospital-wide readmission measure. These steps are discussed in more detail below.

To identify and test the core clinical data elements, a TEP was convened. TEP members applied feasibility criteria to each data type in the Quality Data Model (QDM) considering the context of adult hospitalized patients only. The QDM is an information model that provides a standardized description of the clinical information captured in EHRs, and provides a uniform framework to support quality measurement that utilizes EHR data. TEP members were asked to indicate whether at least one data element within each data type was: (1) Consistently obtained in the target population (patients 18 years and older) based on current clinical practice; (2) captured with a standard definition and recorded in a standard format within the EHR; and (3) entered in structured fields that are feasibly retrieved from current EHR systems.

Next, we conducted a systematic review of the literature to identify clinical data shown to be predictive of mortality and readmission in statistical models. A thorough review of studies revealed that several categories of clinical information from patient medical records captured during diagnostic assessment and treatment were commonly used to predict mortality and readmission. These included, but were not limited to, basic demographic information, laboratory test results, and vital sign findings. The results are described in the 2013 Core Clinical Data Elements Technical Report (Version 1.1) and is available on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

In order to empirically establish the feasibility of potential clinical data elements identified by the TEP, we used a large multi-site database from a healthcare system serving over 3.3 million beneficiaries. We examined the format of the clinical data elements, the consistency and timing of capture, and the distribution of these extracted clinical data values across conditions, hospitals, and point of hospital entry. From the results of that analysis, we identified a list of clinical data elements that were consistently captured for more than 90 percent of adults admitted for common medical conditions. In addition, only the first clinical data elements captured close to the time a patient arrived at the facility were considered in order to reflect patients' clinical status when they presented, and not the results of treatment received at the facility. Analyses showed that vital signs (heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, temperature, and oxygen saturation) were captured within 2 hours of arrival to the hospital for most patients who were subsequently admitted to the same facility. In addition, analyses showed that weight and laboratory tests (hemoglobin, hematocrit, platelet, white blood cell (WBC) count, potassium, sodium, chloride, bicarbonate, blood urea nitrogen (BUN), creatinine, glucose, and troponin) were captured within 24 hours of arrival to the hospital for most patients who were subsequently admitted to the same facility. This was true whether patients were first assessed in the emergency department, or an inpatient unit. From these analyses, we specified the units of measurement and time window for first captured values for each of the 21 feasible and relevant core clinical data elements.

d. Core Clinical Data Elements Feasibility Testing Using Readmission and Mortality Models

In order to demonstrate that the core clinical data elements improved hospital outcome measures, we tested them in models of 30-day mortality and 30-day readmission following hospitalization from a variety of conditions. The 21 core clinical data elements shown in the table above were statistically significant predictors in at least one measure of 30-day mortality after admission for eight common medical conditions: AMI; congestive heart failure; pneumonia; acute cerebrovascular disease; septicemia (except during labor); diabetes mellitus with complications; coronary atherosclerosis; and cardiac dysrhythmias.[156] All of the core clinical data elements listed above were also statistically significant predictors of readmission in the risk-adjusted models of 30-day readmission in a hospital-wide cohort.[157] The testing results demonstrate that the core clinical data elements enhanced the discrimination (assessed using the c-statistic) when used either in combination with or in place of administrative claims data for risk adjustment of currently reported CMS 30-day mortality and readmission outcome measures. For more detailed information on testing, we refer readers to the methodology reports posted on our Measure Methodology Web page, under the ''Downloads'' section in Core Clinical Data Elements and Hybrid Measures zip file, found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

e. Use of Core Clinical Data Elements in Hospital Quality Measures for the Hospital IQR Program

In the future, we are considering requiring hospitals to electronically submit core clinical data elements in several contexts. One use considered would be to risk-adjust claims-based hybrid quality measures similar to what is described in our discussion above. In addition, we are also considering using core clinical data elements for quality measures that apply more generally to an all-payer population (that is, a population greater than or equal to 18 years of age). As we learn more about this method of data collection, we will be able to give more information. As it stands, we envision that use of core clinical data elements for an all payer population would not be limited to merely risk-adjustment or in claims-based hybrid measures. However, should we require reporting of core clinical data elements, it would be in the context of specific measures proposed through rulemaking for the Hospital IQR Program and potentially

[155] 2013 Core Clinical Data Elements Technical Report Version 1.1. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[156] Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[157] Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1). Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

other CMS quality programs. Specific electronically submitted core clinical data elements required would depend on the individual measure adopted.

For claims-based hybrid measures, linking variables would be required to ensure that the datasets containing administrative claims data are correctly linked with EHR datasets containing the core clinical data elements for proper risk adjustment. The linkage variables would come from an additional requirement for hospitals to submit these variables. Such linkage variables, for example, might include admission and discharge dates, CMS certification number, and date of birth. Some of these linkage variables are already routinely collected by EHRs; however, actual linkage variables required for a specific hybrid measure would depend on empirical testing of approaches to linkage for individual measure cohorts.

f. Content Exchange Standard Considerations for Core Clinical Data Elements

Data can be collected in EHRs and health information technology (IT) systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. These standards are referred to as content exchange standards, because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. Commonly used content exchange standards include the Consolidated Clinical Data Architecture (C–CDA) and the Quality Reporting Data Architecture (QRDA). The C–CDA standard is frequently used for the representation of summary care records and provides a format for electronically representing data within document templates and sections.[158] The QRDA standard provides a document format and standard structure to electronically report quality measure data.[159] QRDA allows for the use of CDA templates (the same underlying standard used in C–CDA) to represent quality measures using the QDM information model described above. Thus, QRDA could be considered a related standard to C–CDA for the specific quality reporting use case.

The core clinical data elements we are considering could be electronically reported to CMS formatted according to either the C–CDA or QRDA standard to promote consistent representation and more efficient calculation of hybrid measure results. These standards are also currently required for participation in the Medicare and Medicaid EHR Incentive Programs. Sections 1886(n) and 1814(l) of the Act, as added by the HITECH Act, authorize incentive payments under Medicare for eligible hospitals and critical access hospitals that successfully demonstrate the meaningful use of Certified EHR Technology (CEHRT). Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive incentives. We refer readers to the CEHRT definition adopted by the Office of the National Coordinator for Health IT (ONC) in its 2014 Edition standards and certification criteria final rule (77 FR 53972). ONC's CEHRT definition is adopted in § 170.102 and includes the capabilities defined for the Base EHR, including certification to create transitions of care documents using the C–CDA standard and to successfully report clinical quality measures using the QRDA standard (we refer readers to Table 6 of the ONC 2014 Edition standards and certification criteria final rule at 77 FR 54265).

We are specifically considering the use of QRDA Category I (QRDA–I) as the transmission standard for core clinical data elements to CMS, because the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter, to be certain the data has been appropriately connected to the encounter. The QRDA–I standard enables an individual patient-level quality report that contains quality data for one patient for one or more quality measures. For further detail on QRDA–I, the most recently available QRDA–I specifications can be found at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

Regardless of whether C–CDA or QRDA–I was used for the reporting of core clinical data elements, we note that these data exchange standards would enhance alignment across CMS programs, as well as reduce EHR developer and provider burden by adopting standards that are already in place for the exchange of electronically specified clinical and quality data.

As part of this comment solicitation, we are inviting comment on whether EHR technology should be required to be certified under the ONC Health IT Certification Program[160] for the submission of the core clinical data elements for participation in the Hospital IQR Program using the most appropriate content exchange standard (such as, and not limited to, QRDA–1 or C–CDA). We believe that certification could test and certify that EHR technology can properly collect the core clinical data elements formatted to the appropriate content exchange standard (such as, and not limited to QRDA–1 or C–CDA), promoting more standardized and consistently represented data that can be submitted to CMS to risk-adjust hybrid measures.

In summary, we are seeking public comment on the concept of collecting core clinical data elements, and in particular, we are interested in feedback specifically regarding: (1) The use of the core clinical data elements derived from EHRs for use in risk adjustment of outcome measures as well as other types of measures; (2) the collection of additional administrative linkage variables to link a patient's episode of care from EHR data with his/her administrative claim data; and (3) the use of content exchange standards for reporting these data elements. Regarding the use of content exchange standards, we welcome input on the benefits and implementation considerations if CMS were to require QRDA–I, as well as the tradeoffs to requiring QRDA–I instead of C–CDA or other content exchange standards.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. We note that, in accordance with the statute, the FY 2015 payment determination begins the

[158] Health Level 7 International. Product Brief. Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379*.

[159] Health Level 7 International. Product Brief. Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

[160] Health IT.gov. Certification Programs and Policy. Available at: *http://healthit.gov/policy-researchers-implementers/about-onc-hit-certification-program*.

first year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program year, we require that hospitals submit data on each measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. Hospitals must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2018 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to the codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811). We are not proposing any changes to the procedural requirements.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

d. Alignment of the Medicare EHR Incentive Program Reporting for Eligible Hospitals and CAHs With the Hospital IQR Program

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) for our policies to align electronic clinical quality measures data reporting and submission periods on a calendar year basis for the FY 2017 payment determination for both the Medicare EHR Incentive Program for eligible hospitals and CAHs, and the Hospital IQR Program. In this proposed rule, we are proposing to: (1) Continue to require Certified Electronic Health Record Technology (CEHRT) 2014 Edition and (2) update reporting periods and submission deadlines, for the FY 2018 payment determination for the Hospital IQR Program.

(2) Proposed Electronic Clinical Quality Measure Certification for the FY 2018 Payment Determination

As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50251), for the Hospital IQR Program, hospitals that submit electronic clinical quality measures data for the FY 2017 payment determination are required to submit data using CEHRT 2014 Edition, which is an Electronic Health Record certification. Although we required CEHRT, eligible hospitals were not required to ensure that their CEHRT products were recertified to the most recent version of the electronic specifications for the clinical quality measures. We also stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50251), that for the FY 2017 payment determination, a hospital could submit electronic clinical quality measures for the Hospital IQR Program during CY 2015 even if they attest their aggregate measure numerators and denominators through the Medicare EHR Incentive Program. The hospital could submit as test data or production data. Test data submissions are submissions that do not count as submissions; they are practice submissions. Production data submissions are considered final submissions meant to fulfill Hospital IQR Program submission requirements.

We are proposing to continue the requirement for hospitals to use CEHRT 2014 Edition [161] when submitting electronic clinical quality measures for the CY 2016/FY 2018 payment determination. We note that the Office of the National Coordinator for Health Information Technology (ONC) has proposed a new Edition of EHR technology which may be available for some providers as early as 2016 in its ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (hereafter known as the ''2015 Edition proposed rule'') (80 FR 16804 through 16921). However, we will require hospitals to continue to submit data for Hospital IQR Program purposes using the 2014 Edition for the FY 2018 payment determination. Any changes for the Hospital IQR Program because of ONC's update will be proposed in future rule making.

We are inviting public comments on this proposal.

(3) Proposed Reporting Periods and Electronic Submission Deadlines for the FY 2018 Payment Determination

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), we finalized our policy that hospitals could voluntarily submit electronic clinical quality measure data for one calendar year (CY) quarter's data for either CY Q1 (January 1–March 31, 2015), CY Q2 (April 1–June 30, 2015), or CY Q3 (July 1–September 30) by November 30, 2015.

In this proposed rule, for the FY 2018 payment determination, we are proposing changes to both the reporting periods and the submission deadlines.

For the FY 2018 payment determination, we are proposing that hospitals must submit both Q3 and Q4 of 2016 data for 16 measures reported as electronic clinical quality measures. We also are proposing that for the FY 2018 payment determination, hospitals must submit the electronic clinical quality measure data for these two quarters (Q3 and Q4 of 2016) within 2 months after the end of the applicable calendar year quarter. For CY 2016, these deadlines would be November 30, 2016 for Q3 and February 28, 2017 for Q4. We refer readers to the table entitled ''Proposed CY 2016/FY 2018 Payment Determination Hospital IQR Program Electronic Reporting Periods and Submission Deadlines for Eligible Hospitals,'' below.

As part of our measure maintenance process, each year we make updates to the electronic specifications of the Clinical Quality Measures approved for submission in CMS programs. These annual updates are found on our Web site at: *http://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. In developing these reporting periods and submission timelines, we considered hospitals' and vendors' ability to report electronic clinical quality measures and the burden associated with implementing the 2015 annual update. The May 2015 annual update of electronic clinical quality measure specifications will include changes to the Quality Data Model (QDM) and the Health Quality Measure Format (HQMF),[162] and we recognize that hospitals may require additional time to implement the associated software changes. Because of

[161] Meaningful Use in 2014. Retrieved from: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/EducationalMaterials.html*.

[162] eCQI Resource Center: Advance Notice of Proposed Changes for the 2015 eCQM Annual Update; Pre-release 2015 Annual Update specifications available in HQMF R2.1 format. Available at: *http://www.healthit.gov/ecqi-resource-center/*.

this, we are proposing that hospitals must adopt the most recent annual update prior to data submission. For example, for the CY 2016/FY 2018 payment determination, hospitals would need to submit electronic clinical quality measure using the 2015 Annual Update. As a result and as stated above, we are proposing to delay the required reporting of electronic clinical quality measures to begin with Q3 of 2016, with a reporting deadline of November 30, 2016. The table below shows the required electronic clinical quality measure reporting periods and submission deadlines for CY 2016.

PROPOSED CY 2016/FY 2018 PAYMENT DETERMINATION HOSPITAL IQR PROGRAM ELECTRONIC REPORTING PERIODS AND SUBMISSION DEADLINES FOR ELIGIBLE HOSPITALS

Discharge reporting periods	Submission deadline
January 1, 2016–March 31, 2016.	N/A.
April 1, 2016–June 30, 2016.	N/A.
July 1, 2016–September 30, 2016.	November 30, 2016.
October 1, 2016–December 31, 2016.	February 28, 2017.

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321) for a detailed discussion of the final policy in the Medicare EHR Incentive Program for eligible hospitals and CAHs as well as section VIII.D. of the preamble of this proposed rule where the EHR Incentive Program discusses its proposals to further align with the Hospital IQR Program.

We are inviting public comments on our proposals to continue the CEHRT 2014 Edition requirement and update our electronic clinical quality measure data reporting and submission periods for the FY 2018 payment determination.

e. Sampling and Case Thresholds for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We are making one proposal regarding our population and sampling policy. However, we are not proposing any changes to case thresholds.

Currently, hospitals must submit to CMS quarterly aggregate population and sample size counts for Medicare and nonMedicare discharges for all measures in the topic areas for which chart-abstracted data must be submitted. Hospitals are required to submit their aggregate population and sample size count for each topic area. In accordance with the policy we first adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), hospitals that have not treated patients in a specific topic area must still submit quarterly population and sample size counts for all Hospital IQR Program chart-abstracted data topics. For example, if a hospital has not treated AMI patients, the hospital is still required to submit a zero for its quarterly aggregate population and sample count for that topic in order to meet the requirement.

In this proposed rule, we are proposing to revise this policy so that, beginning with the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program. This differs from the current policy in that there may be instances where a hospital chooses to electronically submit a measure that can be submitted either via chart-abstraction or as an electronic clinical quality measure and under the proposed policy, we would not require population and sample size data in this case. Under the proposed policy, if a hospital submits a measure as an electronic clinical quality measure, or if a measure becomes voluntary or suspended, the population and sample data would not be required.

We are inviting public comments on this proposal.

f. HCAHPS Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on HCAHPS requirements. We are not proposing any changes to HCAHPS requirements.

Hospitals and HCAHPS survey vendors should check the official HCAHPS Web site at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight and data adjustments.

g. Data Submission Requirements for Structural Measures for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. We are not proposing any changes to data submission requirements for structural measures.

h. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

For details on the data submission and reporting requirements for healthcare-associated infection (HAI) measures reported via the CDC's National Healthcare Safety Network (NHSN) Web site, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822). Clarifications to the HAI data reporting and submission requirements policy can also be found in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In this proposed rule, we are not proposing any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

11. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; the FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years and still in effect. Several modifications to these processes were finalized for the FY 2016 and FY 2017 payment determinations in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273) for the FY 2017 payment determination and subsequent years, we finalized additional modifications to these processes. These changes fall into the

following categories: (a) Eligibility criteria for hospitals selected for validation; (b) number of charts to be submitted per hospital for validation; (c) combining scores for HAI and clinical process of care measures; (d) processes to submit patient medical records for chart-abstracted measures; and (e) plans to validate electronic clinical quality measure data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a policy to conduct a validation pilot test for electronic clinical quality measures. We stated that we intended to complete pilot activities in CY 2015 (79 FR 50271) and that continues to be our intention. We are not proposing any changes to our validation pilot test.

However, in this proposed rule, we are proposing modifications to existing processes for validation of chart-abstracted measures, specifically for the Influenza Immunization (NQF #1659) measure.

b. Proposed Modifications to the Existing Processes for Validation of Chart-Abstracted Hospital IQR Program Data

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50265 through 50273), we finalized a validation process, which included a separate validation stratum for the Influenza Immunization (NQF #1659) measure (the immunization measure validation stratum) because that measure overlapped with the Hospital VBP Program. The finalized validation process for chart-abstracted measures included three separate validation strata: HAI, Immunization, and Other/Clinical Process of Care (79 FR 50265 through 50273). The Immunization stratum includes only one measure, Immunization for Influenza (NQF #1659). This Immunization measure was included in its own stratum because it is used in the Hospital VBP Program and we wanted to ensure that every hospital selected for validation would be validated in this topic area.

As discussed in section IV.F.2.b.(1) of the preamble of this proposed rule, we are proposing to remove the IMM–2 Influenza Immunization measure from the Hospital VBP Program. Given this proposed removal of the Influenza Immunization measure from the Hospital VBP Program, it is no longer necessary to ensure validation of this topic area by including a separate stratum for the Influenza measure. As a result, in this proposed rule, for the Hospital IQR Program beginning with the FY 2018 payment determination and for subsequent years, we are proposing to remove the separate immunization validation stratum and include the Influenza Immunization measure in the clinical process of care measure validation stratum. Under this proposal, we would continue to apply our chart-abstracted measure validation processes only to those chart-abstracted measures that are required under the Hospital IQR Program in a chart-abstracted form (as opposed to those measures that a hospital reports as electronic clinical quality measures, for example). This proposal is consistent with our proposed policy to require population and sample size data only for those measures that are required under the Hospital IQR Program. We refer readers to section VIII.A.10.e. of the preamble of this proposed rule for more detail on that proposal.

We note that although this proposal includes an adjustment to the composition of the clinical process of care validation stratum, we are not proposing any changes to the overall validation sample size. Under the existing validation process, a total of eight charts are drawn for validation—five of which are drawn from the clinical process of care measures stratum and three of which are drawn from the immunization measure stratum. Under this proposal, however, while the total number of charts drawn is the same (eight), all eight measures will be drawn from the clinical process of care measure stratum, which would then include the Influenza Immunization measure. Accordingly, one sample of charts will be drawn from the clinical process of care measures.

The proposed removal of the immunization validation stratum and inclusion of the Influenza Immunization measure in the clinical process of care validation stratum would result in an expanded pool of clinical process of care topic areas sampled for validation to include STK, VTE, ED, Sepsis, and Immunization. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50266), all chart-abstracted measure topic areas included in the Hospital IQR Program, with the exception of the Perinatal Care topic area, are automatically included in the validation process. We do not include this topic area because the Elective Delivery PC–01 (NQF #0469) measure is reported in aggregate form, which is not consistent with our patient-level validation process (79 FR 50266).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50268 through 50269), we outlined the weighting of each of three validation topic areas: Healthcare-associated infection (66.7 percent); Immunization (22.2 percent); and Other/Clinical Process of Care (11.1 percent). The table below shows the proposed effect on topic area weighting of our proposal to remove the immunization measure validation stratum and to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation stratum.

PROPOSED TOPIC AREA WEIGHTING FOR VALIDATION FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Topic area	Weight (percent)
Healthcare-associated infection (HAI)	66.7
Other/Clinical Process of Care	33.3
Total	100.0

We are inviting public comments on our proposal to remove the immunization measure validation stratum, to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation stratum, and to reweight the topic areas for validation beginning with the FY 2018 payment determination and for subsequent years.

12. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for details on Data Accuracy and Completeness Acknowledgement (DACA) requirements. We are not proposing any changes to the DACA requirements.

13. Public Display Requirements for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as *http://www.cms.gov* and/or *https://data.medicare.gov*.

We note that for the Mortality, Readmission, Complication, Payment and AHRQ measures, we will continue to replace publically reported data with

a footnote for hospitals that do not have data for at least 25 cases combined during the reporting period. If there are fewer than 25 eligible cases, the measures are assigned to a separate category described as ''The number of cases is too small (fewer than 25) to reliably tell how well the hospital is performing.'' The measures are included in the calculation but are not publicly reported on *Hospital Compare.* For chart-abstracted or Web-based measures, if either the numerator or the denominator is greater than 0 and less than 11, the data are not reported on *Hospital Compare,* but rather data is displayed as ''Not Available''. This guidance does not apply to calculated measures, only to those in which cases/patients could be identified. We also provide footnote explanations on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare/Data/Footnotes.html*.

We refer readers to section VIII.A.8.b. of the preamble of this proposed rule, where we are proposing to delay publicly reporting electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow time for us to evaluate the effectiveness of electronically reported clinical quality measure data. In the meantime, measures reported via electronic clinical quality measures will be marked with a footnote on *Hospital Compare* noting that: (1) The hospital submitted data via EHR; (2) data are being processed and analyzed; and (3) we will eventually publicly report this data once we determine the data to be reliable and accurate.

We are inviting public comments on our proposal.

14. Reconsideration and Appeal Procedures for the FY 2018 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and at 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to the reconsideration and appeals procedures.

15. Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program extraordinary circumstances extensions or exemptions policy.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), we noted that we will refer to the process as the Extraordinary Circumstances Extensions or Exemptions process and, accordingly, finalized changes reflecting this updated language in the corresponding regulation text. We are not proposing any changes to the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year. For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561).

2. Proposed Removal of Six Surgical Care Improvement Project (SCIP) Measures From the PCHQR Program Beginning With Fourth Quarter (Q4) 2015 Discharges and for Subsequent Years

We are proposing to remove six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years. Under this proposal, PCHs will meet reporting requirements for the FY 2016 and FY 2017 programs by submitting first quarter (Q1) through third quarter (Q3) 2015 data for these measures:

- Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis within 24 Hours Prior to Surgery to 24 Hours After Surgery (NQF #0218)
- Urinary Catheter Removed on Post-Operative Day One (POD1) or Post-Operative Day Two (POD2) with Day of Surgery Being Day Zero (NQF #0453)
- Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527)
- Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)
- Prophylactic Antibiotic Discontinued Within 24 Hours After Surgery End Time (NQF #0529)
- Surgery Patients on Beta-Blocker Therapy Prior to Admission who Received a Beta-Blocker During the Perioperative Period (NQF #0284)

We first adopted the six SCIP measures in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50840 through 50841) and refer readers to that rule for a detailed discussion of the measures. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50205), these measures have been determined to be topped-out in the Hospital IQR Program and were removed from that program. To meet FY 2016 and FY 2017 program requirements, we are proposing that PCHs would continue to submit these six measures for first quarter (Q1) 2015 through third quarter (Q3) 2015 discharges in accordance with the submission timeline we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285). We are proposing to remove these measures from the PCHQR Program because we have removed them from the Hospital IQR Program and, because they have been removed from that program, it is no longer operationally feasible to collect these measures under the PCHQR Program. By removing these measures, we also would alleviate the maintenance costs and administrative burden for PCHs associated with reporting them (79 FR 50205).

We are inviting public comments on these proposals.

3. Proposed New Quality Measures Beginning With the FY 2018 Program

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we have taken a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In this proposed rule, we are not proposing any changes to the principles we consider when

developing and selecting measures for the PCHQR Program.

b. Summary of Proposed New Measures

For the FY 2018 PCHQR Program, we are proposing to adopt three new quality measures. These measures meet the requirement under section 1866(k)(3)(A) of the Act that measures specified for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act (currently the NQF).

The proposed measures are as follows:

- Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDC NHSN CDI Measure)
- CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (CDC NHSN MRSA Measure)
- CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431) (CDC NHSN HCP Measure)

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration (MUC) for December 1, 2014,'' [163] which is a list of quality and efficiency measures being considered for use in various Medicare programs. The proposed measures were also submitted to the Measure Applications Partnership (MAP), a public-private partnership convened by the NQF for the purpose of providing input to the Secretary on the selection of certain quality and efficiency measures. For the PCHQR Program, the MAP supported the inclusion of all three measures. The MAP's recommendations can be found in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [164]

In addition, all three of the proposed measures are currently reported under the Hospital IQR Program as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631). We refer readers to CDC's Web site for detailed measure information for the three measures we are proposing.[165] [166] The sections below outline our rationale for proposing to adopt these measures.

c. CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

Healthcare-associated infections (HAIs), such as CDI and MRSA, are a significant cause of morbidity and mortality. At any given time, approximately one in every 25 inpatients has an infection related to hospital care.[167] These infections cost the U.S. healthcare system billions of dollars each year and lead to the loss of tens of thousands of lives. In addition, HAIs can have devastating emotional, financial and medical consequences.[168] As a result of these adverse outcomes, we are committed to increasing patient safety by partnering with hospitals (for example, the CMS Partnership for Patients) [169] to make hospital care safer, more reliable, and less costly by preventing injury and increased morbidity in patients, as well as allowing them to heal without complications.[170]

CDC reports that prolonged antibiotic exposure, a long length of stay in a healthcare setting, and the existence of a serious underlying illness or immunocompromised condition (for example, cancer) increase the risk of CDI.[171] As a result, we believe it is important to collect data on CDIs in the PCH setting, where cancer patients face increased exposure to these risk factors. Additionally, in recent years, CDIs have become more frequent, more severe, and more difficult to treat.[172] Each year, CDI is linked to 14,000 American deaths.[173] Infection is especially common in older adults, but also affects some otherwise healthy people who are not hospitalized and/or taking antibiotics.[174]

This proposed measure addresses the National Quality Strategy (NQS) Patient Safety domain. The measure reports the standardized infection ratio (SIR) of hospital-onset CDI Laboratory-identified events (LabID events) among all patients in the facility. The numerator includes the total number of observed hospital-onset CDI LabID events among all inpatients in the facility, excluding well baby-nurseries and Neonatal Intensive Care Units.[175] The denominator includes the total number of predicted hospital-onset CDI LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset CDI LabID event rate for similar types of facilities (obtained from a standard population).[176] [177]

Beginning with a 2010–2011 baseline SIR of 1.0, we set a national goal to reduce the incidence of facility-onset CDI overall by 30 percent (to a SIR of 0.70) by no later than 2013. However, we were not able to meet that goal, and the rate of facility-onset CDI decreased by only 2 percent as of 2012 (to a SIR of 0.98). Therefore, we believe it is critical to continue collecting data on CDI in the hospital setting, and to adopt this measure for the PCH setting, in order to ensure the highest quality of care for cancer patients and continue our effort to support HHS' National Action Plan to Prevent Healthcare Associated Infections (HAIs) and our proposed 2020 goal to reduce facility-onset of CDI by 30 percent from the 2015 baseline.[178] The collection and evaluation of CDI data will allow PCH staff to evaluate whether their infection control efforts need improvement. We recognize the severe impact of CDI,[179] and aim to continue efforts to increase patient protection and safety, and at the same time prevent adverse infections in the PCH setting.

[163] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[164] National Quality Forum ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' Available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*; and ''Spreadsheet of MAP 2015 Final Recommendations'' Available at: *http://www.qualityforum.org/map/*.

[165] CDC. Surveillance for C. difficile, MRSA, and other Drug-resistant Infections. Available at: *http://www.cdc.gov/nhsn/acute-care-hospital/cdiff-mrsa/index.html*.

[166] CDC. Surveillance for Healthcare Personnel Vaccination. Available at: *http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/index.html*.

[167] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[168] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[169] CMS Innovation Center Partnership for Patients. Available at: *http://innovation.cms.gov/initiatives/partnership-for-patients/*.

[170] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Available at: *http://www.health.gov/hai/prevent_hai.asp#hai*.

[171] CDC *C. difficile* FAQ. Available at: *http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_infect.html*.

[172] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[173] CDC Vital Signs. Available at: *http://www.cdc.gov/vitalsigns/pdf/2012-03-vitalsigns.pdf*.

[174] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[175] NQF QPS. Available at: *http://www.qualityforum.org/Qps/MeasureDetails.aspx?standardID=1717&print=0&entityTypeID=1*.

[176] NQF QPS. Available at: *http://www.qualityforum.org/Publications/2013/02/Patient_Safety_Measures_Complications_-_Phase_2.aspx*.

[177] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631).

[178] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Available at: *http://www.health.gov/hai/pdfs/HAI-Targets.pdf*.

[179] *Ibid*.

By proposing this measure in the PCHQR Program, we aim to continue to provide a common mechanism (that is, reporting to CDC's NHSN) that all hospitals, including PCHs, can use to uniformly submit and report measure data and inform their clinicians of the impact of targeted prevention efforts.

We are inviting public comments on our proposal to add the CDC NHSN CDI Outcome Measure to the PCHQR Program beginning with the FY 2018 program.

d. CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

Invasive MRSA infections may cause approximately 18,000 deaths per year during a hospital stay.[180] Cancer patients are at increased risk for MRSA infections, specifically older adults with weakened immune systems who are receiving hospital inpatient care.[181] As a result, we believe it is important to collect data on MRSA in the PCH setting.

This proposed measure addresses the NQS Patient Safety domain. This measure reports the SIR of hospital-onset unique blood source MRSA LabID events among all inpatients in a facility. The numerator includes the total number of observed hospital-onset unique blood source MRSA LabID events among all inpatients in the facility.[182] The denominator includes the total number of predicted hospital-onset unique blood source MRSA LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset MRSA bacteremia LabID event rate for similar types of facilities (obtained from a standard population). [183] [184]

Beginning with a 2009 baseline SIR of 1.0, we set a national goal to reduce the incidence of facility-onset MRSA infections by 50 percent by 2020. However, by 2012 the rate of facility-onset MRSA infections decreased by only 3 percent (to a SIR of 0.97). Therefore, we believe it is critical to continue collecting data on CDI in the hospital setting, and to adopt this measure for the PCH setting, to ensure the highest quality of care for cancer patients and continue our effort to support the HHS' National Action Plan and the proposed 2020 goal to reduce facility-onset MRSA infections by 50 percent from the 2015 baseline.[185]

The collection and evaluation of MRSA data will allow PCH staff to evaluate whether their infection control efforts need improvement. By proposing this measure in the PCHQR Program, we aim to continue to provide a common mechanism (CDC NHSN) for all hospitals, including PCHs, to uniformly report measure data and inform their clinicians of the impact of targeted prevention efforts. Furthermore, we recognize the severe impact of MRSA and aim to continue our efforts to increase patient protection and safety, while at the same time preventing adverse infections in the PCH setting.

We are inviting public comments on our proposal to add the CDC NHSN MRSA Measure to the PCHQR Program beginning with the FY 2018 program.

e. CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel [HCP] Measure (NQF #0431) (CDC NHSN HCP Measure)

CDC estimates that in the United States, each year, on average 5 percent to 20 percent of the population gets influenza and more than 200,000 people are hospitalized from seasonal influenza-related complications.[186] Influenza seasons are unpredictable and can be severe. Over a period of 30 years, between 1976 and 2006, estimates of influenza-associated deaths per year in the United States ranged from a low of approximately 3,000 to a high of approximately 49,000 people.[187] Because influenza can become widespread and have serious consequences, the Advisory Committee on Immunization Practices (ACIP) recommends that all health care personnel (HCP) and persons in training for health care professions be vaccinated annually against influenza.[188] Persons who are infected with the influenza virus, including those with subclinical infection, can transmit the influenza virus to persons at higher risk for complications, such as immunocompromised cancer patients. Additionally, vaccination of HCP has been associated with reduced work absenteeism and fewer deaths among patients. Results of several studies also indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[189] [190] [191] Such findings have led researchers to call for mandatory influenza vaccination of HCP.[192]

This proposed measure addresses the NQS Patient Safety domain. The measure reports the percent of HCP who receive the influenza vaccination.[193] The numerator includes HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year, either: (a) Received an influenza vaccination administered at the facility, or reported in writing (paper or electronic) or provided documentation that the influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; (c) declined the influenza vaccination; or (d) had an unknown vaccination status.[194] The denominator includes the number of HCP who are working in the health care facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact, and includes: (a) Employees; (b) licensed independent practitioners; and (c) adult students/trainees and volunteers.[195] [196]

[180] Catherine Liu, Arnold Bayer, et al.: Clinical Practice Guidelines by the Infectious Disease Society of America for the Treatment of Methicillin-Resistant *Staphylococcus Aureus* Infections in Adults and Children Infectious Disease Society of America 2011; 52:e18.

[181] CDC. General Information about MRSA in Healthcare Settings: Available at: *http://www.cdc.gov/mrsa/healthcare/index.html.*

[182] NQF QPS. Available at: *http://www.qualityforum.org/Qps/MeasureDetails.aspx?standardID=1716&print=0&entityTypeID=1.*

[183] Ibid.

[184] FY 2012 IPPS/LTCH PPS final rule (76 FR 51630).

[185] HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Available at: *http://www.health.gov/hai/pdfs/HAI-Targets.pdf.*

[186] CDC. Seasonal Influenza Q&A. Available at: *http://www.cdc.gov/flu/about/qa/disease.html.*

[187] CDC. Estimating Seasonal Influenza-Associated Deaths in the United States: CDC Study Confirms Variability of Flu. Available at: *http://www.cdc.gov/flu/about/disease/us_flu-related_deaths.html.*

[188] CDC. ''Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009.'' MMWR 58, no. Early Release (2009):1–52.

[189] Salgado CD, Giannetta ET, Hayden FG, Farr BM.: Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923–928.

[190] Potter J, Stott DJ, Roberts MA, et al.: Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

[191] Hayward AC, Harling R, Wetten S, et al.: Effectiveness of an influenza vaccine program for care home staff to prevent death, morbidity, and health service use among residents: cluster randomized controlled trial. British Medical Journal 2006; 333:1241–1246.

[192] Talbot TR, Bradley SF, Cosgrove SE., et al.: SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890.

[193] NQF QPS. Available at: *http://www.qualityforum.org/Qps/0431.*

[194] Ibid.

[195] Ibid.

[196] FY 2012 IPPS/LTCH PPS final rule (76 FR 51631).

Numerators and denominators are collected separately for each of the specified groups.

We believe it is important to collect data on this measure in order to ensure the highest quality of care for cancer patients in our effort to support one of the Healthy People 2020 goals of immunizing 90 percent of healthcare personnel nationally by 2020.[197] Overall, final 2013–14 influenza vaccination coverage among HCP was 75.2 percent, similar to coverage of 72.0 percent in the 2012–13 season.[198] We aim to increase patient protection and safety and at the same time prevent adverse outcomes (for example, transmitting influenza to patients, specifically high risk cancer patients, and premature death due to influenza) in the PCH setting.

We believe that this measure is applicable to the PCH setting based on CDC guidelines that patients who currently have cancer or who have had certain types of cancer in the past (such as lymphoma or leukemia), are at high risk for complications from influenza, including hospitalization and death.[199] The involvement of HCP in influenza transmission has been a longstanding concern.[200] [201] Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[202]

By proposing this measure in the PCHQR Program, we aim to not only provide a common mechanism (CDC NHSN) for all hospitals, including PCHs, to uniformly report the measure data, but also to inform their clinicians of the impact of targeted prevention efforts. In addition, and most importantly, we believe that collecting this measure data in the PCH setting is necessary to support our effort to prevent unnecessary additional or prolonged hospitalizations (and associated costs), and to decrease premature death among cancer patients.

We are inviting public comments on our proposal to add the CDC NHSN HCP Measure to the PCHQR Program beginning with the FY 2018 program.

In summary, we are proposing three new measures for reporting beginning with the FY 2018 program. In conjunction with our proposal to remove the six SCIP measures from the PCHQR Program beginning with Q4 2015 discharges, the PCHQR measure set would consist of 16 measures beginning with the FY 2018 program. Our proposed policies regarding the form, manner, and timing of data collection for these measures are discussed in section VIII.B.7. of the preamble to this proposed rule.

The table below lists all previously adopted measures as well as the proposed new measures for the PCHQR Program beginning with the FY 2018 program. It does not include the measures we are proposing to remove.

Topic	Summary of finalized and proposed PCHQR Program measures beginning with the FY 2018 program
Safety and Healthcare-Associated Infection—HAI.	• CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).*
	• CDC NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138).*
	• Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure* [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753).*
	• CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).**
	• CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).**
	• CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel [HCP] (NQF #0431).**
Clinical Process/Cancer-Specific Treatments.	• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).*
	• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).*
	• Adjuvant Hormonal Therapy (NQF #0220).*
Clinical Process/Oncology Care Measures.	• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382).*
	• Oncology: Plan of Care for Pain (NQF #0383).*
	• Oncology: Pain Intensity Quantified (NQF #0384).*
	• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (NQF #0390).*
	• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (NQF #0389).*
Patient Engagement/Experience of Care.	• HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems Survey] (NQF #0166).*
Clinical Effectiveness Measure.	• External Beam Radiotherapy for Bone Metastases (NQF #1822).*

* Previously finalized measures.
** Proposed for the FY 2018 program and subsequent years in this proposed rule.

4. Possible New Quality Measure Topics for Future Years

Future quality measure topics and quality measure domain areas are discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280). In addition, we welcome public comment and specific suggestions for measure topics addressing the following CMS Quality Strategy domains: Making care affordable; communication and coordination; and working with communities to promote best practices of healthy living.

[197] Healthy People 2020. Immunization and Infectious Diseases. Available at: *http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives.*

[198] CDC. Influenza Vaccination Information for Health Care Workers. Available at: *http://www.cdc.gov/flu/healthcareworkers.html.*

[199] CDC Preventing Infections in Cancer Patients. Available at: *http://www.cdc.gov/cancer/flu/*

[200] Maltezou HC, Drancourt M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[201] Salgado CD, Farr BM, Hall KK, Hayden FG.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[202] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC.: Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

5. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet Web site at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to this policy in this proposed rule.

6. Public Display Requirements

a. Background

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site.

In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562 through 53563), we finalized our policy to publicly display PCHQR Program data on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and established a preview period of 30 days prior to making such data public.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50847 through 50848), we finalized our proposal to display publicly in 2014 and subsequent years the data for two measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282), we finalized our proposal to display publicly in 2015 and subsequent years the data for one measure and our proposal to display publicly no later than 2017 the data for two additional measures. In summary, we have finalized proposals to publicly display five PCHQR measures on *Hospital Compare,* including three Cancer Specific Treatment measures and two CDC NHSN HAI measures.

SUMMARY OF FINALIZED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223). • Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).	2014 and subsequent years
• Adjuvant Hormonal Therapy (NQF #0220)	2015 and subsequent years.
• CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) • CDC NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138).	2017 and subsequent years.

b. Proposed Additional Public Display Requirements

We are proposing to publicly display six additional PCHQR measures beginning in 2016 and for subsequent years:

- Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)
- Oncology: Plan of Care for Pain (NQF #0383)
- Oncology: Pain Intensity Quantified (NQF #0384)
- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (NQF #0390)
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (NQF #0389)
- HCAHPS (NQF #0166)

We are inviting public comment on these proposals.

7. Form, Manner, and Timing of Data Submission

a. Background

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR Program, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

b. Proposed Reporting Requirements for Proposed New Measures: CDC NHSN CDI (NQF #1717), CDC NHSN MRSA (NQF #1716), and CDC NHSN HCP (NQF #0431) Measures

We are proposing that PCHs submit CDC NHSN CDI, MRSA, and HCP measure data for all patients to the CDC through the NHSN database. This is the same procedural/reporting mechanism used for the CDC NHSN CLABSI and CAUTI measures that we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564) and for the CDC SSI measure that we finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848 through 50850). The data submission and reporting procedures have been set forth by the CDC for NHSN participation in general and for submission of the CDC NHSN CDI, MRSA, and HCP measures to NHSN. We refer readers to the CDC's Web site (*http://www.cdc.gov/nhsn/cms/index.html*) for detailed data submission and reporting procedures.

We are proposing to adopt a quarterly submission process for the CDC NHSN CDI and MRSA measures as shown in the table below. We have successfully implemented this reporting mechanism in the Hospital IQR Program (77 FR 53539), and we strongly believe that this type of data submission is the most feasible option because PCHs are currently reporting the CDC NHSN CAUTI, CLABSI, and CDC SSI measures to the CDC NHSN this way.

PROPOSED CDC NHSN CDI (NQF #1717) AND CDC NHSN MRSA (NQF #1716) MEASURES REPORTING PERIODS AND SUBMISSION TIMEFRAMES BEGINNING WITH THE FY 2018 PROGRAM

Program year (FY)	Reporting periods (CY)	Data submission deadlines (CY)
2018	Q1 2016 events (January 1, 2016–March 31, 2016).	August 15, 2016.
	Q2 2016 events (April 1, 2016–June 30, 2016)	November 15, 2016.
	Q3 2016 events (July 1, 2016–September 30, 2016).	February 15, 2017.
	Q4 2016 events (October 1, 2016–December 31, 2016).	May 15, 2017.
Subsequent Years	Q1 events (January 1–March 31 of year 2 years before the program year).	August 15 of year two years before the program year.
	Q2 events (April 1–June 30 of year 2 years before the program year).	November 15 of year 2 years before the program year.
	Q3 events (July 1–September 30 of year 2 years before the program year).	February 15 of year 1 year before the program year.
	Q4 events (October 1–December 31 of year 2 years before the program year).	May 15 of year 1 year before the program year.

For the CDC NHSN HCP measure, we are proposing that data be submitted annually by May 15 of the applicable year as shown in the table below. The vaccination period runs from October through March. The proposed reporting period for FY 2018 will include Q4 2016 and Q1 2017 counts submitted by May 15, 2017.

PROPOSED CDC NHSN HCP (NQF #0431) MEASURE REPORTING PERIODS AND SUBMISSION TIMEFRAMES BEGINNING WITH THE FY 2018 PROGRAM

Program year (FY)	Reporting periods (CY)	Data submission deadlines (CY)
2018	Q4 2016 counts (October 1, 2016—December 31, 2016).	May 15, 2017.
	Q1 2017 counts (January 1, 2017—March 31, 2017).	
Subsequent Years	Q4 counts (October 1—December 31 of year 2 years before the program year).	May 15 of year 1 year before the program year.
	Q1 counts (January 1—March 31 of year 1 year before the program year).	

We are inviting public comments on these proposals.

As specified by CDC, the CDC NHSN CDI, MRSA, and HCP measures are reported on a facility-wide basis.[203] [204] Accordingly, we are not proposing a sampling methodology for these measures because CDC requirements are to collect data on all patients or HCP in the facility. However, measures specifications could be technically updated by the measure steward (CDC). We refer readers to the CDC Web site for technical changes and/or updates (*http://www.cdc.gov/nhsn/acute-care-hospital/index.html*).

We also intend to issue guidance to PCHs that will provide additional clarity regarding the specific data submission deadlines that we previously finalized for certain PCHQR measures. This guidance will be issued through the QualityNet Web site.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act, requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. The Secretary is required to specify quality measures that are endorsed by the entity with a contract under section 1890(a) of the Act. This entity is currently the NQF. Information regarding the NQF is available at: *http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx*. The Act authorizes an exception under which the Secretary may specify non-NQF-endorsed quality measures in the case of specified areas or medical topics determined appropriate by the Secretary for which a feasible or practical measure has not been endorsed by the NQF, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR

[203] CDC Multidrug—Resistant Organism & *Clostridium difficile* Infection (MDRO/CDI) Module. Available at: *http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf*.

[204] CDC HCP Vaccination Module. Available at: *http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf*.

50286) for a detailed discussion of the history of the LTCH QRP.

In addition, section 1206(c) of the Pathway for SGR Reform Act of 2013 added section 1886(m)(5)(D)(iv) of the Act, which requires the Secretary to establish, not later than October 1, 2015, a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298) for a detailed discussion of the Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support, which we adopted in the LTCH QRP for the FY 2018 payment determination and subsequent years to meet the requirements of section 1886(m)(5)(D)(iv) of the Act.

Finally, the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (the IMPACT Act of 2014) amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act of 2014 added section 1899B of the Act, and section 2(c)(3) of the IMPACT Act of 2014 amended section 1886(m)(5) of the Act.

New section 1899B of the Act is titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment and Discharge Planning. Under section 1899B(a)(1) of the Act, the Secretary must require post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act to include HHAs, SNFs, IRFs, and LTCHs) to submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use and other measures required under section 1899B(d)(1) of the Act. The Act also sets out specified application dates for each of the measures. The Secretary must specify the quality, resource use, and other measures not later than the applicable specified application date defined in section 1899B(a)(2)(E) of the Act.

Section 1899B(b) of the Act describes the standardized patient assessment data that PAC providers are required to submit in accordance with section 1899B(b)(1) of the Act; requires the Secretary, to the extent practicable, to match claims data with standardized patient assessment data in accordance with section 1899B(b)(2) of the Act; and requires the Secretary, as soon as practicable, to revise or replace existing patient assessment data to the extent that such data duplicate or overlap with standardized patient assessment data, in accordance with section 1899B(b)(3) of the Act.

Sections 1899B(c)(1) and (d)(1) of the Act direct the Secretary to specify measures that relate to at least five stated quality domains and three stated resource use and other measure domains. Section 1899B(c)(1) of the Act provides that the quality measures on which PAC providers, including LTCHs, are required to submit standardized patient assessment data and other necessary data specified by the Secretary must be with respect to at least the following domains:

- Functional status, cognitive function, and changes in function and cognitive function;
- Skin integrity and changes in skin integrity;
- Medication reconciliation;
- Incidence of major falls; and
- Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions (1) from a hospital or CAH to another applicable setting, including a PAC provider or the home of the individual, or (2) from a PAC provider to another applicable setting, including a different PAC provider, hospital, CAH, or the home of the individual.

Section 1899B(c)(2)(A) of the Act provides that, to the extent possible, the Secretary must require such reporting through the use of a PAC assessment instrument and modify the instrument as necessary to enable such use.

Section 1899B(d)(1) of the Act provides that the resource use and other measures on which PAC providers, including LTCHs, are required to submit any necessary data specified by the Secretary, which may include standardized assessment data in addition to claims data, must be with respect to at least the following domains:

- Resource use measures, including total estimated Medicare spending per beneficiary;
- Discharge to community; and
- Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates.

Sections 1899B(c) and (d) of the Act indicate that data satisfying the eight measure domains in the IMPACT Act of 2014 is the minimum data reporting requirement. Therefore, the Secretary may specify additional measures and additional domains.

Section 1899B(e)(1) of the Act requires that the Secretary implement the quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act in phases consisting of measure specification, data collection, and data analysis; the provision of feedback reports to PAC providers in accordance with section 1899B(f) of the Act; and public reporting of PAC providers' performance on such measures in accordance with section 1899B(g) of the Act. Section 1899B(e)(2) of the Act generally requires that each measure specified by the Secretary under section 1899B of the Act be NQF-endorsed, but authorizes an exception under which the Secretary may select non-NQF-endorsed quality measures in the case of specified areas or medical topics determined appropriate by the Secretary for which a feasible or practical measure has not been endorsed by the NQF, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(3) of the Act provides that the pre-rulemaking process required by section 1890A of the Act applies to quality, resource use, and other measures specified under sections 1899B(c)(1) and (d)(1) of the Act, but authorizes exceptions under which the Secretary may (1) use expedited procedures, such as ad hoc reviews, as necessary in the case of a measure required with respect to data submissions during the 1-year period before the applicable specified application date, or (2) alternatively, waive section 1890A of the Act in the case of such a measure if applying section 1890A of the Act (including through the use of expedited procedures) would result in the inability of the Secretary to satisfy any deadline specified under section 1899B of the Act with respect to the measure.

Section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers with respect to quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date.

Section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers with respect to quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the

process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public with respect to the PAC provider prior to such data being made public.

Section 1899B(h) of the Act sets out requirements for removing, suspending, or adding quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act.

Section 1899B(i) of the Act requires that not later than January 1, 2016, and periodically thereafter (but not less frequently than once every 5 years), the Secretary must promulgate regulations to modify the Medicare conditions of participation (CoPs) and subsequent interpretative guidance applicable to PAC providers, hospitals, and CAHs to, among other things, take into account quality, resource use, and other measures in the discharge planning process.

Section 1899B(j) of the Act requires the Secretary to allow for stakeholder input, such as through town halls, open door forums, and mailbox submissions, before the initial rulemaking process to implement section 1899B of the Act.

Section 2(c)(3) of the IMPACT Act of 2014 amended section 1886(m)(5) of the Act to address the payment consequences for LTCHs with respect to the additional data which LTCHs are required to submit under section 1899B of the Act. This section added new sections 1886(m)(5)(F) and (G) to the Act and made conforming changes. New section 1886(m)(5)(F) of the Act requires LTCHs (other than a hospital classified under section 1886(d)(1)(B)(iv)(II)) of the Act to submit the following additional data: (1) For the fiscal year beginning on the applicable specified application date and subsequent years, data on the quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act; and (2) for FY 2019 and subsequent years, the standardized patient assessment data required under section 1899B(b)(1) of the Act. Such data must be submitted in the form and manner, and at the time, specified by the Secretary. Finally, new section 1886(m)(5)(G) of the Act generally provides that to the extent that the additional data required under section 1886(m)(5)(F) of the Act duplicates other data required under section 1886(m)(5)(C) of the Act, submission of the former must be in lieu of submission of the latter.

As stated above, the IMPACT Act of 2014 adds a new section 1899B to the Act that imposes new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. Sections 1899B(c)(1) and 1899B(d)(1) of the Act collectively require that the Secretary specify quality measures and resource use and other measures with respect to certain domains not later than the specified application date that applies to each measure domain and PAC provider setting. Section 1899B(a)(2)(E) of the Act delineates the specified application dates for each measure domain and PAC provider. The IMPACT Act of 2014 also amends various other sections of the Act, including section 1886(m)(5) of the Act, to require the Secretary to reduce the otherwise applicable PPS payment to a PAC provider that does not report the new data in a form and manner, and at a time, specified by the Secretary. For LTCHs, amended section 1886(m)(5)(A)(i) of the Act would require the Secretary to reduce the payment update for any LTCH that does not satisfactorily submit the new required data.

Under the current LTCH QRP, the general timeline and sequencing of measure implementation occurs as follows: Specification of measures; proposal and finalization of measures through notice-and-comment rulemaking; LTCH submission of data on the adopted measures; analysis and processing of the submitted data; notification to LTCHs regarding their quality reporting compliance with respect to a particular rate year; consideration of any reconsideration requests; and imposition of a payment reduction in a particular rate year for failure to satisfactorily submit data with respect to that rate year. Any payment reductions that are taken with respect to a rate year begin approximately one year after the end of the data submission period for that rate year and approximately two years after we first adopt the measure.

To the extent that the IMPACT Act of 2014 could be interpreted to shorten this timeline so as to require us to reduce an LTCH's PPS payment for failure to satisfactorily submit data on a measure specified under section 1899B(c)(1) or (d)(1) of the Act beginning with the same rate year as the specified application date for that measure, such a timeline would not be feasible. The current timeline discussed above reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether an LTCH has complied with our quality reporting requirements. It also takes into consideration our desire to give LTCHs enough notice of new data reporting obligations so that they are prepared to timely start reporting the data. Therefore, we intend to follow the same timing and sequence of events for measures specified under sections 1899B(c)(1) and (d)(1) of the Act that we currently follow for other measures specified under the LTCH QRP. We intend to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and are proposing to adopt them consistent with the requirements in the Act and Administrative Procedure Act. To the extent that we finalize a proposal to adopt a measure for the LTCH QRP that satisfies an IMPACT Act of 2014 measure domain, we intend to require LTCHs to report data on the measure for the rate year that begins two years after the specified application date for that measure. Likewise, we intend to require LTCHs to begin reporting any other data specifically required under the IMPACT Act of 2014 for the rate year that begins two years after we adopt requirements that would govern the submission of that data.

2. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) for a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures. In this proposed rule, we apply the same considerations to the selection of quality, resource use, and other measures required under section 1899B of the Act for the LTCH QRP, in addition to the considerations discussed below.

The quality measures we are proposing address some of the measure domains that the Secretary is required to specify under sections 1899B(c)(1) and (d)(1) of the Act. The totality of the measures considered to meet the requirements of the IMPACT Act of 2014 will evolve, and additional measures will be proposed over time as they become available.

To meet the first specified application date applicable to LTCHs under section 1899B(a)(2)(E) of the Act, which is October 1, 2016, we have focused on measures that:

- Correspond to a measure domain in section 1899B(c)(1) or (d)(1) of the Act and are setting-agnostic: For example, falls with major injury and the incidence of pressure ulcers;
- Are currently adopted for one or more of our PAC quality reporting programs that are already either NQF-endorsed and in place or finalized for

use, or already previewed by the MAP with support;

- Minimize added burden on LTCHs;
- Minimize or avoid, to the extent feasible, revisions to the existing items in assessment tools currently in use (for example, the LTCH CARE Data Set);
- Avoid, where possible, duplication of existing assessment items.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership, and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the public by December 1 of each year a list of such measures that the Secretary is considering under title XVIII of the Act.

As discussed in section VIII.C.1. of the preamble of this proposed rule, section 1899B(e)(3) of the Act provides that the pre-rulemaking process required by section 1890A of the Act applies to the measures required under section 1899B, subject to certain exceptions for expedited procedures or, alternatively, waiver of section 1890A of the Act.

We initiated an Ad Hoc MAP process for the review of the quality measures under consideration for proposal in preparation for adoption of those quality measures into the LTCH QRP that are required by the IMPACT Act of 2014, and which must be specified by October 1, 2016. The List of Measures under Consideration (MUC List) under the IMPACT Act of 2014 was made available to the public for comment during the MAP Meeting on February 9, 2015 (*http://www.meeting-support.com/downloads/703163/4524/PACLTC%20Ad%20Hoc%20Slides.pdf*). Under the IMPACT Act of 2014, these measures must be standardized so they can be applied across PAC settings and must correspond to measure domains specified in sections 1899B(c)(1) and (d)(1) of the IMPACT Act of 2014. The specific cross-setting application of the measures under consideration for each such measure is discussed in the MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. The MAP reviewed each IMPACT Act of 2014-related quality measure proposed in this proposed rule for the LTCH QRP, in light of its intended cross-setting use. We refer readers to section VIII.C.6. of the preamble of this proposed rule for more information on the MAP's recommendations.

As discussed in section VIII.C.1. of the preamble of this proposed rule, above, section 1899B(j) of the Act requires that we allow for stakeholder input as part of the pre-rulemaking process. To meet this requirement, we provided the following opportunities for stakeholder input: (1) Our measure development contractor convened a technical expert panel (TEP) that included stakeholder experts and patient representatives on February 3, 2015; (2) we provided two separate listening sessions on February 10, 2015 and March 5, 2015; (3) we sought public input during the February 2015 Ad Hoc MAP process provided for the sole purpose of reviewing the measures we are proposing in reaction to the IMPACT Act of 2014; and (4) we sought public comment as part of our NQF measure maintenance submissions. In addition, we implemented a public mail box for the submission of comments in January 2015, *PACQualityInitiative@cms.hhs.gov*, which is accessible from our post-acute care quality initiatives Web site: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*, and held a National Stakeholder Special Open Door Forum to seek input on the measures on February 25, 2015.

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for the LTCH QRP, we are proposing measures that most closely align with the national priorities discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287), and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these measures in the LTCH setting is included under each quality measure proposal in the preamble of this proposed rule. In addition, for measures not endorsed by the NQF, we have sought, to the extent practicable, to adopt measures that have been endorsed or adopted by a national consensus organization, recommended by multi-stakeholder organizations, and/or developed with the input of providers, purchasers/payers, and other stakeholders.

3. Policy for Retention of LTCH QRP Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the LTCH QRP, we adopted a policy that once a quality measure is adopted, it will be retained for use in subsequent years, unless otherwise stated. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the LTCH QRP for a payment determination, this measure will be automatically adopted for all subsequent years or until we propose to remove, suspend, or replace the measure. For further information on how measures are considered for removal, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615).

In this proposed rule, we are not proposing any changes to this policy for retaining LTCH QRP measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCH QRP Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we finalized a policy that if the NQF updates an endorsed measure that we have adopted for the LTCH QRP in a manner that we consider to not substantively change the nature of the measure, we will use a subregulatory process to incorporate those updates to the measure specifications that apply to the LTCH QRP. Substantive changes will be proposed and finalized through rulemaking. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616) for further information on what constitutes substantive and nonsubstantive changes to a measure. We are not proposing any changes to the policy for adopting changes to LTCH QRP measures.

5. Previously Adopted Quality Measures

a. Previously Adopted Quality Measures for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53636), for the FY 2014 payment determination and subsequent years, we adopted updated versions of National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139). For the FY 2015 payment determination and subsequent

years, we retained the application of Percent of Residents with Pressure Ulcers That Are New or Worsened (Short Stay) measure (NQF #0678) to the LTCH setting (initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750)). We also adopted two new quality measures for the LTCH QRP for the FY 2016 payment determination and subsequent years, in addition to the three previously adopted measures (the CAUTI measure, CLABSI measure, and Pressure Ulcer measure): (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680); and (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (77 FR 53624 through 53636).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863), we adopted the NQF-endorsed version of the Pressure Ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) measure (NQF #0678), for the LTCH QRP for the FY 2015 payment determination and subsequent years.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50305), we revised the data collection and submission period for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure (NQF #0680).

Set out below are the quality measures, both previously adopted measures retained in the LTCH QRP and measures adopted in FY 2013 and FY 2014 IPPS/LTCH PPS final rules, for the FY 2015 and FY 2016 payment determinations and subsequent years.

LTCH QRP Quality Measures Previously Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

NQF Measure ID	Measure title	Payment determination
NQF #0138	National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2015 and Subsequent Fiscal Years.
NQF #0139	National Health Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure.	FY 2015 and Subsequent Fiscal Years.
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	FY 2015 and Subsequent Fiscal Years.
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).	FY 2016 and Subsequent Fiscal Years.
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel	FY 2016 and Subsequent Fiscal Years.

b. Previously Adopted Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule, we adopted three additional measures for the FY 2017 payment determination and subsequent years (78 FR 50863 through 50874) and one additional measure for the FY 2018 payment determination and subsequent years (78 FR 50874 through 50877).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50305), we: (1) Revised the data collection and submission period for the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) measure (NQF #0674); and (2) adopted three new quality measures for the FY 2018 payment determination and subsequent years.

These measures are set out in the table below.

LTCH QRP Quality Measures Previously Adopted for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

NQF Measure ID	Measure title	Payment determination
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2017 and Subsequent Years.
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2017 and Subsequent Years.
NQF #2512	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals.	FY 2017 and Subsequent Years.
Application of NQF #0674.	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)	FY 2018 and Subsequent Years.
NQF #2631*	Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	FY 2018 and Subsequent Years.
NQF #2632*	Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support.	FY 2018 and Subsequent Years.
Not NQF endorsed	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	FY 2018 and Subsequent Years.

*Under review at NQF. We refer readers to: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867,* NQF #2631 and NQF #2632.

6. Previously Adopted LTCH QRP Quality Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determination and subsequent years, in addition to the measures we are retaining under our policy described in VIII.C.3. of the preamble of this proposed rule, we are proposing four quality measures to reflect the NQF endorsement of one measure and to meet the requirements of the IMPACT Act of 2014. These proposed measures are: (a) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) to reflect NQF endorsement; (b) Percent of

Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to meet the requirements of the IMPACT Act of 2014; (c) an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) to meet the requirements of the IMPACT Act of 2014; and (d) an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; under NQF review) to meet the requirements of the IMPACT Act of 2014. These quality measures are discussed in more detail below.

a. Proposal To Reflect NQF Endorsement: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512)

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874). We are proposing to adopt this measure to reflect that it is NQF-endorsed for use in the LTCH setting as of December 2014. Current specifications of this NQF-endorsed measure are available for download on the NQF Web site at: *http://www.qualityforum.org/QPS/2512*.

As adopted in the FY 2014 IPPS/LTCH PPS final rule, this is a Medicare FFS claims-based measure, and LTCHs are not required to report any additional data to CMS. Because we would calculate this measure based on claims data that are already reported to the Medicare program for payment purposes, we believe there would be no additional data collection burden on LTCHs resulting from our implementation of this measure as part of the LTCH QRP. In the FY 2014 IPPS/LTCH PPS final rule, we stated that we will calculate this measure using claims data beginning with FY 2013 and FY 2014 and provide initial feedback to LTCHs prior to public reporting of this measure. However, the NQF-endorsed measure (NQF #2512) is based on 2 consecutive calendar years of Medicare FFS claims data. Therefore, in addition to our proposal to adopt the NQF-endorsed version of this measure, we are proposing that the initial calculation of the measure and feedback to LTCHs, prior to public reporting of this measure, would be based on CY 2013 and CY 2014 Medicare FFS claims data related to readmissions post-LTCH discharge.

The description of this measure provided in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874) noted this measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each LTCH, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients if treated at a facility with the average effect on readmissions. This ratio is referred to as the standardized risk ratio or SRR. The NQF-endorsed specifications compute the risk-standardized readmission rate (RSRR) for this measure. The RSRR is the SRR multiplied by the overall national raw readmission rate for all LTCH stays; it is expressed as a percentage rate rather than a ratio.

This measure, which was developed to harmonize with the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) that is currently in use in the Hospital IQR Program, continues to use the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. This algorithm was refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216). The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs (NQF #2512) for the LTCH QRP will utilize the most recently updated version of the algorithm. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The additional post-acute care planned readmission types specified for this measure remain the same as when first adopted through the FY 2014 IPPS/LTCH PPS final rule. Documentation on the additional post-acute care planned readmissions for this measure is available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2512*.

We are inviting public comments in response to (1) our proposal to adopt the NQF-endorsed version of All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs (NQF #2512) for the LTCH QRP and (2) our proposal that the initial feedback to LTCHs, prior to public reporting of this measure, would be based on CY 2013 and CY 2014 Medicare FFS claims data related to readmissions post-LTCH discharge.

b. Proposal To Address the IMPACT Act of 2014: Quality Measure Addressing the Domain of Skin Integrity and Changes in Skin Integrity: Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is skin integrity and changes in skin integrity. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2017. To satisfy these requirements, we are proposing to adopt the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure, that we have already adopted for the LTCH QRP, as a cross-setting quality measure that satisfies the domain of skin integrity and changes in skin integrity. The reporting of data for this measure would affect the payment determination for the FY 2018 payment determination and subsequent years. In the LTCH setting, the measure assesses the percent of patients with Stage 2 through Stage 4 pressure ulcers that are new or worsened since admission.

As described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51754 through 51756), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the detailed rationale for relevance, evidence, appropriateness, importance, and applicability of this quality measure in the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51754 through 51756) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863). Measure specifications are available on the NQF Web site at: *http://www.qualityforum.org/QPS/0678*.

The IMPACT Act of 2014 requires the implementation of quality measures and resource use and other measures that are standardized and interoperable across PAC settings as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. This requirement is in line with the NQF Steering Committee report, which stated that ''to understand the impact of pressure ulcers across settings, quality measures addressing prevention, incidence, and prevalence of pressure ulcers must be harmonized

and aligned.'' [205] The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure is NQF-endorsed and has been successfully implemented using a harmonized set of data elements in three PAC settings (LTCHs, IRFs, and SNFs). As discussed in section VIII.C.6.b. of the preamble of this proposed rule, above, an application of this measure was adopted for the LTCH QRP in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51753 through 51756) for the FY 2014 payment determination, and the current NQF-endorsed version of the measure was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863) for the FY 2015 payment determination and subsequent years. The measure has been in use in the LTCH QRP since October 1, 2012, and currently, LTCHs are submitting data for this measure using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set.

The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure was adopted for use in the IRF Quality Reporting Program (QRP) in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878) for the FY 2014 payment determination and subsequent years and has been successfully submitted by IRFs using the Inpatient Rehabilitation Facility—Patient Assessment Instrument (IRF–PAI) since October 2012. It has also been implemented in the CMS Nursing Home Quality Initiative, using the Minimum Data Set (MDS) Version 3.0 since 2011, and is currently publicly reported on CMS' *Nursing Home Compare* at: *http://www.medicare.gov/nursinghomecompare/search.html*.

A TEP convened by our measure development contractor in February 2015, provided input on the technical specifications of this quality measure, as well as the applicability of this measure as a cross-setting measure across post-acute care settings, including the LTCH setting, to meet the requirements of the IMPACT Act of 2014. The TEP supported the applicability of this measure as a cross-setting measure across post-acute care settings and also supported our efforts to standardize items for data collection and submission of this measure as well as our efforts to standardize the measure for cross-setting development. In addition, the MAP met on February 9, 2015, and provided input to CMS on the measure. The MAP supported the use of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure in the LTCH QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is included in The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

We are proposing that data collection for this measure continue to occur through the LTCH CARE Data Set submitted through the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. LTCHs have been submitting data on the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure through the LTCH CARE Data Set since October 2012. By building on the existing reporting and submission infrastructure for LTCHs, we intend to minimize the administrative burden related to data collection and submission for this measure under the LTCH QRP. For more information on LTCH QRP reporting using the QIES ASAP system, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

We are proposing that data collected using standardized items through the LTCH CARE Data Set would continue to be used to calculate this quality measure. LTCH CARE Data Set items used to identify new or worsened pressure ulcers consist of: M0800A (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 2); M0800B (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 3); and M0800C (Worsening in Pressure Ulcer Status Since Prior Assessment, Stage 4). In addition, we are proposing to continue to use items from the LTCH CARE Data Set to risk-adjust this quality measure. These items consist of: GG0160C [206] (Functional Mobility; Lying to Sitting on Side of Bed), H0400 (Bowel Continence); I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD); I2900 (Diabetes Mellitus), K0200A (Height); and K0200B (Weight). More information about the LTCH CARE Data Set items is available in the LTCH QRP Manual available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

The specifications and data elements for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for LTCHs are available in the LTCH QRP Manual at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We are inviting public comment on our proposal to adopt the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure for the FY 2018 payment determination and subsequent years to fulfill the requirements of the IMPACT Act of 2014.

c. Proposal To Address the IMPACT Act of 2014: Quality Measure Addressing the Domain of Incidence of Major Falls: Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674)

Section 1899B of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is the incidence of major falls. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs, SNFs, and LTCHs is October 1, 2016, and for HHAs is January 1, 2019. To satisfy these requirements, we are proposing to adopt an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure in the LTCH QRP as a cross-setting quality measure that addresses the domain of incidence of major falls. The purpose of our proposal is to establish this measure's use as a cross-setting measure that satisfies the required adoption of such a measure under the domain of falls with major injury. There is no difference between this measure and the measure we previously adopted, beyond the proposed intent to use the measure to satisfy the requirements of the IMPACT Act of 2014. Data collection would start on April 1, 2016. The reporting of data for this measure would affect the

[205] National Quality Forum. National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers. April 2008. Available at: *http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx*.

[206] For the April 1, 2016 release of LTCH CARE Data Set, this item will be renumbered to GG0170C.

payment determination for FY 2018 and subsequent years.

For the LTCH setting, this measure would report the percentage of patients who experienced one or more falls with major injury during the LTCH stay. This measure was developed by CMS and is NQF-endorsed, currently for long-stay residents of nursing facilities. It was adopted for the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule, we adopted a revised start for data collection of April 1, 2016 and affecting FY 2018 payment determination and we adopted data collection and submission timelines for the FY 2018 payment determination and subsequent years. For information on the detailed rationale for relevance, evidence, appropriateness, importance, and applicability of this quality measure in the LTCH QRP, we refer readers to these final rules.

Measure specifications are available on the NQF Web site at: *http://www.qualityforum/QPS/0674*.

The IMPACT Act of 2014 requires the implementation of quality measures and resource use and other measures that are standardized and interoperable across PAC settings as well as the reporting of standardized patient assessment data and other necessary data specified by the Secretary. The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure is NQF-endorsed for long-stay residents of nursing facilities and has been successfully implemented in such settings. The NQF-endorsed measure has been in use as part of the CMS Nursing Home Quality Initiative since 2011. In addition, the measure is currently reported on the CMS *Nursing Home Compare* Web site at: *http://www.medicare.gov/nursinghomecompare/search.html*. As noted previously, this measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291), we revised the data collection start date for this measure with data collection to begin starting April 1, 2016, and we adopted data collection and submission timelines for the FY 2018 payment determination and subsequent years.

We reviewed the NQF's consensus endorsed measures and did not identify any NQF-endorsed cross-setting quality measures focused on falls with major injury applicable to multiple post-acute care settings. We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization. Therefore, we are proposing an application of the measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure under the Secretary's authority to select non-NQF-endorsed measure.

A TEP convened by our measure development contractor provided input on the measure specifications, as well as the feasibility and clinical appropriateness of implementing the measure across post-acute care settings, including the LTCH setting. The TEP supported the implementation of this measure across post-acute care settings and also supported CMS' efforts to standardize this measure for cross-setting development. In addition, the MAP met on February 9, 2015, and provided input to CMS on the measure. The MAP conditionally supported the use of an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure in the LTCH QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is included in The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

More information on the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure can be found on the NQF Web site at: *http://www.qualityforum.org/QPS/0674*. Updated specifications and details regarding the changes made to further harmonize this measure across post-acute care settings are located at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We are proposing that data for this proposed quality measure be collected using the LTCH CARE Data Set, with submission through the QIES ASAP system. For more information on LTCH QRP reporting through the QIES ASAP system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. Data collected through a revised LTCH CARE Data Set would be used to calculate this quality measure. Consistent with the LTCH CARE Data Set reporting requirements, the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure would apply to all patients discharged from LTCHs. Data items in the revised LTCH CARE Data Set Version 3.00 would include: J1800, Any Falls Since Admission; and J1900, Number of Falls Since Admission.

The calculation of the proposed application of the measure would be based on item J1900C, Number of Falls with Major Injury Since Admission. The measure specifications for the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. We refer readers to section VIII.C.9.b. of the preamble of this proposed rule for more information on the data collection and submission timeline for this proposed quality measure.

We are inviting public comment on our proposal to adopt an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, with data collection beginning on April 1, 2016 for the FY 2018 payment determination and subsequent years to fulfill the requirements in the IMPACT Act of 2014.

d. Proposal To Address the IMPACT Act of 2014: Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; Under NQF review)

Section 1899B(c)(1) of the Act directs the Secretary to specify quality measures on which PAC providers are required under the applicable reporting provisions to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function. The specified application date by which the Secretary must specify quality measures to address this domain for IRFs and SNFs is October 1, 2016, for LTCHs is October 1, 2018, and for HHAs is January 1, 2019. To satisfy these requirements, we are proposing to adopt an application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF

#2631; under NQF review) measure that we have already adopted in the LTCH QRP as a cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function. The reporting of data for this measure would affect the payment determination for FY 2018 and subsequent years. This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a goal that addresses function.

The National Committee on Vital and Health Statistics, Subcommittee on Health,[207] noted: ''[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations, in other words, their functional status.'' This statement is supported by research showing that patient functioning is associated with important patient outcomes such as discharge destination and length of stay in inpatient settings,[208] as well as the risk of nursing home placement and hospitalization of older adults living in the community.[209] Functioning is important to patients and their family members.[210] [211] [212]

The majority of patients who receive post-acute care services, such as care provided by SNFs, HHAs, IRFs and LTCHs, have functional limitations, and many of these patients are at risk for further decline in function due to limited mobility and ambulation.[213] The patient and resident populations treated by SNFs, HHAs, IRFs and LTCHs vary in terms of their functional abilities at the time of the post-acute care admission and their goals of care. For IRF patients and many SNF residents, treatment goals may include fostering the patient's ability to manage his or her daily activities so that the patient can complete self-care and/or mobility activities as independently as possible, and, if feasible, return to a safe, active, and productive life in a community-based setting. For HHA patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other HHA patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.[214]

Lastly, in addition to having complex medical care needs for an extended period of time, LTCH patients often have limitations in functioning because of the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). The clinical practice guideline *Assessment of Physical Function* [215] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient care in all of these post-acute care settings.

Given the variation in patient and resident populations across the post-acute care settings, the functional activities that are typically assessed by clinicians for each type of post-acute care provider may vary. For example, the activity of rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients or residents who are chronically critically ill. Managing a full flight of stairs may be assessed for higher functioning patients or residents. However, certain functional activities, such as eating, oral hygiene, lying down in to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility are important activities for patients in each post-acute care setting.

Although functional assessment data are currently collected by SNFs, HHAs, IRFs and LTCHs, this data collection has employed different assessment instruments, scales, and item definitions. The data collected cover similar topics, but are not standardized across PAC settings. Further, the different sets of functional assessment items are coupled with different rating scales, making communication about patient functioning challenging when patients transition from one type of setting to another. Collection of standardized functional assessment data across SNFs, HHAs, IRFs and LTCHs, using common data items, would establish a common language for patient functioning, which may facilitate communication and care coordination as patients transition from one type of provider to another. The collection of standardized functional status data may also help improve patient or resident functioning during an episode of care by ensuring that basic daily activities are assessed at the start and end of each episode of care with the aim of determining whether at least one functional goal has been established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration (PAC–PRD) version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of patients' status across acute care and post-acute care settings, including SNFs, HHAs, IRFs and LTCHs. The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge in order to determine patients' or residents' needs, evaluate patient progress and prepare patients or residents and families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [216] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment

[207] Subcommittee on Health National Committee on Vital Statistics, ''Classifying and Reporting Functional Status'' (2001).

[208] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ.: Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. *Archives of Physical Medicine and Rehabilitation*, 2010; 91:345–350.

[209] Miller EA, Weissert WG.: Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[210] Kurz, A. E., Saint-Louis, N., Burke, J. P., & Stineman, M. G.: Exploring the personal reality of disability and recovery: a tool for empowering the rehabilitation process. *Qual Health Res, 18*(1), 90–105 (2008).

[211] Kramer, A. M. (1997). Rehabilitation care and outcomes from the patient's perspective. *Med Care, 35*(6 Suppl), JS48–57.

[212] Stineman, M. G., Rist, P. M., Kurichi, J. E., & Maislin, G.: Disability meanings according to patients and clinicians: imagined recovery choice pathways. *Quality of Life Research, 18*(3), 389–398 (2009).

[213] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ.: Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[214] Ellenbecker CH, Samia L, Cushman MJ, Alster K: Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

[215] Kresevic DM.: Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

[216] Barbara Gage et al: ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI, International, 2012).

Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [217] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [218] The reports are available on our Post-Acute Care Quality Initiatives Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

The cross-setting function quality measure we are proposing to adopt for the FY 2018 payment determination and subsequent years to meet the IMPACT Act of 2014 requirements is a process measure that is an application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review). This quality measure was developed by the CMS. It reports the percent of patients with both an admission and a discharge functional assessment and a treatment goal that addresses function. The treatment goal provides documentation that a care plan with a goal has been established for the patient.

We are proposing to use the data that will be collected and submitted using the LTCH CARE Data Set Version 3.00 for the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) measure starting April 1, 2016 in order to calculate this cross-setting application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) quality measure. The items in the cross-setting application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) are a subset of the items included in the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review), which was finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298). Therefore, the adoption of this quality measure to satisfy the requirements of the IMPACT Act of 2014 would not result in the addition of new items to the LTCH CARE Data Set Version 3.00 and, therefore, would not result in additional burden for data collection and data submission to LTCHs.

This process measure requires the collection of functional status admission and discharge assessment data using standardized clinical assessment items, or data elements, that assess specific functional activities, that is, self-care, mobility activities. The self-care and mobility function activities on the LTCH CARE Data Set Version 3.00 are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. For this quality measure, documentation of a goal for one of the function items reflects that the patient's care plan addresses function. The function goal is recorded at admission for at least one of the standardized self-care or mobility function items using the 6-level rating scale.

To the extent that a patient had an incomplete stay (for example, for the purpose of being admitted to an acute care facility), collection of discharge functional status data might not be feasible. Therefore, for patients with incomplete stays, admission functional status data and at least one treatment goal would be required; however, discharge functional status data would not be required to be reported.

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, as well as the feasibility of implementing the measure across post-acute care settings, including the LTCH setting. The TEP supported the implementation of this measure across post-acute care settings and also supported our efforts to standardize this measure for cross-setting use.

In addition, the MAP met on February 9, 2015, and provided input to CMS on the measure. The MAP conditionally supported the use of an application of the Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) for use in the LTCH QRP as the cross-setting measure. The conditions stated by the MAP included that the measure should be endorsed by the NQF. Finally, the MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAP's recommendations for this measure is discussed in The MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act: Final Report which is available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

The measure we are proposing is an application of the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631), which is under NQF review for consideration of endorsement. The proposed measure is derived from the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function quality measure. The specifications are available for review at the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on assessment of function for post-acute care patients. We are also unaware of any other cross-setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we are proposing to adopt this functional assessment measure for use in the LTCH QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

As discussed previously, we are proposing that this cross-setting quality measure use a subset of data collected for Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; under NQF review) using the LTCH CARE Data Set, with submission through the QIES ASAP system. For more information on LTCH QRP reporting through the QIES ASAP system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

The measure calculation algorithm is:

[217] Ibid.

[218] Ibid.

Step 1. For each LTCH stay, the records of patients discharged during the 12-month target time period are identified and counted. This count is the denominator.

Step 2. The records of patients with complete stays are identified, and the number of these patient stays with complete admission functional assessment data and at least one self-care or mobility activity goal and complete discharge functional assessment data is counted.

Step 3. The records of patients with incomplete stays are identified, and the number of these patient records with complete admission functional status data and at least one self-care or mobility goal is counted.

Step 4. The counts from Step 2 (complete LTCH stays) and Step 3 (incomplete LTCH stays) are summed. The sum is the numerator count.

Step 5. The numerator count is divided by the denominator count to calculate this quality measure.

This measure is calculated at two points in time, at admission and discharge (we refer readers to section VIII.C.9.b. of the preamble of this proposed rule, Form, Manner and Timing of Quality data Submission, for more information on the proposed data collection and submission timeline for this proposed quality measure).

The items would assess specific self-care and mobility activities, and would be based on functional items included in the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set. The items have been developed and tested for reliability and validity in SNFs, HHAs, IRFs, and LTCHs. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

We are inviting public comments on our proposal to adopt the application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) that we have already adopted in the LTCH QRP as a cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function to satisfy the requirement of the IMPACT Act of 2014, with data collection starting on April 1, 2016 for the FY 2018 payment determination and subsequent years. Further, we are inviting public comments on our proposal to use a subset of data collected for the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure (NQF #2631; under NQF review) to meet the requirements for this cross-setting quality measure that addresses the domain of functional status, cognitive function, and changes in function and cognitive function to satisfy the requirement of the IMPACT Act of 2014.

Lastly, in alignment with the requirements of the IMPACT Act of 2014 to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute settings using standardized data is an important priority. Therefore, in addition to proposing a process-based measure for the domain in the IMPACT Act of 2014 of ''Functional status, cognitive function, and changes in function and cognitive function,'' which is included in this year's proposed rule, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures to further satisfy this domain. These measures will be proposed in future rulemaking in order to assess functional change for each care setting as well as across care settings.

7. LTCH QRP Quality Measures for the FY 2019 Payment Determination and Subsequent Years

At this time, we are not proposing any additional LTCH QRP quality measures for the FY 2019 payment determination and subsequent years. Under our policy discussed in section VIII.C.3. of the preamble of this proposed rule, we will retain all previously adopted quality measures and, if finalized, the additional measures proposed in this rule for the FY 2019 payment determination and subsequent years.

8. LTCH QRP Quality Measures and Concepts Under Consideration for Future Years

We are inviting public comments on importance, relevance, appropriateness, and applicability of each of the quality measures and quality measure concepts listed in the table below for future years in the LTCH QRP. Specifically, we are inviting public comments regarding the clinical importance to the LTCH patient population and the feasibility of data collection and implementation in the LTCH setting for these measures and measure concepts in order to inform and improve quality of care delivered to LTCH patients.

FUTURE MEASURES AND MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

National Quality Strategy (NQS) Priority: Patient Safety:
Ventilator Weaning (Liberation) Rate
Compliance with ventilator process Elements during LTCH Stay
Venous Thromboembolism Prophylaxis
Medication Reconciliation.*
NQS Priority: Effective Communication and Coordination of Care:
Transfer of health information and care preferences when an individual transitions.*
All-Condition Risk-Adjusted Potentially Preventable Hospital Readmission Rate.*
NQS Priority: Patient- and Caregiver-Centered Care:
Discharge to community.*
Patient Experience of Care
Percent of Patients with Moderate to Severe Pain
Advance Care Plan
NQS Priority: Affordable Care:
Medicare Spending per Beneficiary.*

* Indicates that this is a cross-setting measure domain listed in the IMPACT Act of 2014.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Years

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B of the Act, and each subsequent year, each LTCH submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under section 1886(m)(5)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with section 1886(m)(5)(C) of the Act with respect to a given rate year, any annual update to the standard Federal rate for discharges for the LTCH during the rate year must be reduced by 2 percentage points.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50861 and 50878 through 50881), we finalized the data submission timelines and submission deadlines for measures for the FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a more detailed discussion of these

timelines and deadlines. Specifically, we refer readers to the table at 78 FR 50878 of the FY 2014 IPPS/LTCH PPS final rule for the data collection period and submission deadlines for the FY 2016 payment determination and the tables at 78 FR 50881 of that final rule for the data collection timelines and submission deadlines for the FY 2017 payment determination.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50307 through 50311), we:

- Revised the previously adopted data collection period and submission deadlines for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years;
- Adopted data submission mechanisms for the FY 2018 payment determination and subsequent years for new LTCH QRP quality measures and for revisions to previously adopted quality measures;
- Adopted data collection periods and submission deadlines for certain measures under the LTCH QRP for the FY 2018 payment determination;
- Revised data collection timelines and submission deadlines for the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure for the FY 2018 payment determination and subsequent years; and
- Adopted data collection timelines and submission deadlines under the LTCH QRP for the FY 2019 payment determination and subsequent years.

b. Proposed Timing for New LTCHs To Begin Reporting Data to CMS for the FY 2017 Payment Determination and Subsequent Years

Beginning with the FY 2017 payment determination, we are proposing that a new LTCH be required to begin reporting quality data under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, if an LTCH's CCN notification letter is dated March 15, then the LTCH would be required to begin reporting quality data to CMS beginning on July 1 (March 15 + 30 days = April 14 (quarter 2)). The LTCH would be required to begin collecting quality data on the first day of the quarter subsequent to quarter 2, which is quarter 3, or July 1. The collection of quality data would begin on the first day of the calendar year quarter identified as the start date, and would include all LTCH admissions and subsequent discharges beginning on, and subsequent to, that day; however, submission of quality data would be required by previously finalized or newly proposed quarterly deadlines. In order to determine which quality measure data an LTCH would need to begin submitting, we refer readers to section VIII.C.9.c. of the preamble of this proposed rule, below, as it will vary depending upon the timing of the CY quarter identified as a start date. We also are proposing to codify this requirement for the timing of new LTCHs to begin reporting for purposes of the LTCH QRP at new proposed § 412.560(a). We are inviting public comment on our proposals to add and codify this requirement for the timing of new LTCHs to begin reporting for purposes of the LTCH QRP.

c. Proposed Revisions to Previously Adopted Data Submission Timelines Under the LTCH QRP for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years and Proposed Data Collection and Data Submission Timelines for Quality Measures Proposed in This Proposed Rule

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized new quarterly quality data submission deadlines for LTCHs. We contracted the deadlines from the original 4.5-month post-CY quarter submission deadlines, to 1.5 month (approximately 45 days) deadlines. In order to align the data submission and correction deadlines with the IRF QRP and Hospital IQR Program as we near public reporting, and to meet the requirements of the IMPACT Act of 2014, we are proposing to revise the data submission and correction deadlines for quality measures previously adopted for the LTCH QRP for the FY 2017 and FY 2018 payment determinations and subsequent years.

We are proposing to adopt new deadlines that allow 4.5 months (approximately 135 days) after the end of each calendar year quarter for quality data submission, beginning with quarter 4 2015 (October 2015 through December 2015). Under this new policy, LTCHs will have approximately 135 days following the end of each calendar year quarter, during which to submit, review, and correct their quality data for that CY quarter. We also are proposing data collection and data submission timelines for quality measures that we are proposing for the FY 2018 payment determination and subsequent years. Further, for the measures proposed in this proposed rule—Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), the application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), and the application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)—we are proposing that the data collection and data submission timelines align with the proposed data collection and data submission timelines for each respective measure starting with April 1, 2016. Because the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs (NQF #2512) is a Medicare FFS claims-based measure, the data collection and submission timelines are not applicable to this measure.

The tables below present the data collection period and data submission timelines for quality measures affecting the FY 2017 payment determination, as well as the revisions to the data collection period and data submission timelines for quality measures for the FY 2018 payment determination and subsequent years.

DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2017 PAYMENT DETERMINATION

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU determination affected
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	#0678	LTCH CARE Data Set/ QIES ASAP.	1/1/15–3/31/15, 4/1/15–6/30/15, 7/1/15–9/30/15, 10/01/15–12/31/15.	5/15/15 (Q1), 8/15/15 (Q2), 11/15/15 (Q3), Proposed 5/15/16 (Q4).	FY 2017.
NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	#0138	CDC NHSN.			
NHSN Central-Line Associated Bloodstream Infections (CLABSI) Outcome Measure.	#0139.				

DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2017 PAYMENT DETERMINATION—Continued

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU determination affected
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	#1716.				
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	#1717.				
All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long Term Care Hospitals*.	#2512	Medicare FFS Claims Data.	N/A	N/A	For future public reporting.

* This measure will not be used in determining compliance for the LTCH QRP because it is a claims-based measure and LTCHs do not report additional data to CMS.

DETAILS ON DATA COLLECTION AND SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU determination affected
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	#0678	LTCH CARE Data Set/ QIES ASAP.	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018; Subsequent Years.
NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	#0138	CDC NHSN.			
NHSN Central-Line Associated Bloodstream Infections (CLABSI) Outcome Measure.	#0139.				
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	#1716.				
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	#1717.				
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.	#0680	LTCH CARE Data Set/ QIES ASAP.	10/1/15–12/31/15, 1/1/16–3/31/16, 10/1–12/31, 1/1–3/31 for subsequent years.	5/15/16, 8/15/16, 5/15, 8/15 for subsequent years.	FY 2018; Subsequent Years.
Influenza Vaccination Coverage among Healthcare Personnel.	#0431	CDC NHSN	10/1/15 (or when vaccine becomes available)–3/31/16, 10/1 (or when vaccine becomes available)–3/31.	8/15/16, 8/15 for subsequent years.	FY 2018; Subsequent Years.
All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long Term Care Hospitals.*	#2512	Medicare FFS Claims Data.	N/A	N/A	For future public reporting.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	#0674	LTCH CARE Data Set/ QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4).	FY 2018; Subsequent Years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	#2631 (Under NQF review).				
Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.	#2632 (Under NQF review).	.....	.....	Quarterly approximately 135 days after the end of each quarter for subsequent years.	
Ventilator Associated Event	N/A	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for each subsequent year.	FY 2018; Subsequent Years.

DETAILS ON DATA COLLECTION AND SUBMISSION TIMELINE FOR QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Quality measure	NQF ID#	Submission method	Data collection period	Proposed data submission deadlines	APU determination affected
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	#2631 (Under NQF review).	LTCH CARE Data Set/ QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018; Subsequent Years.

* This measure will not be used in determining compliance for the LTCH QRP because it is a claims-based measure and LTCHs do not report additional data to CMS.

We are inviting public comments on our proposals.

10. Previously Adopted LTCH QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized specific LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of quality measures data collected using the LTCH CARE Data Set and submitted through the QIES; and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC NHSN.

In addition, we stated that we would apply the same thresholds to all measures adopted as the LTCH QRP expands and LTCHs report data on the finalized measure sets. That is, as we finalize new measures through the regulatory process, LTCHs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that a LTCH must meet or exceed both thresholds in order to avoid receiving a 2-percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. We are not proposing any changes to these policies. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314) for a detailed discussion of the finalized data completion requirements of the LTCH QRP.

11. Future LTCH QRP Data Validation Process

Historically, we have built consistency and internal validation checks into our data submission specifications to ensure that the data elements of the LTCH CARE Data Set assessments conform to requirements such as proper format and facility information. These internal consistency checks are automated and occur during the LTCH data entry and submission process, and help ensure the integrity of the data submitted by LTCHs by rejecting submissions or issuing warnings when LTCH data contain logical inconsistencies. These internal consistency checks are referred to as ''system edits'' and are further outlined in the LTCH Data Submission Specifications version 1.01, which are available for download on the LTCH Quality Reporting Technical Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(m)(5)(E) and 1899B(g) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28275 through 28276), we proposed, for the FY 2016 payment determination and subsequent years, to validate the data elements submitted to CMS for quality purposes. We also proposed policies regarding the application of the 2-percentage point reduction for LTCHs that failed to meet the data accuracy threshold.

However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50314 through 50316), we decided to further explore suggestions from commenters before finalizing the LTCH data validation process that we proposed. Therefore, we did not finalize the data validation proposals.

At this time, we are continuing to explore data accuracy validation methods and threshold policies that will limit the amount of burden and cost to LTCHs, while allowing us to establish estimations of the accuracy of LTCH QRP data. Therefore, in this proposed rule, we are not proposing any new policies related to data accuracy validation, but we plan to do so in future rulemaking cycles.

12. Proposed Public Display of Quality Measure Data for the LTCH QRP

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public. In so doing, the Secretary must ensure that LTCHs have the opportunity to review any such data with respect to the LTCH prior to its release to the public. Section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers with respect to the measures required under section 1899B of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public with respect to the PAC provider prior to such data being made public. We are proposing to display performance data related to the LTCH QRP quality measures, as applicable, required by the LTCH QRP by fall 2016 on a CMS Web site, such as the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov*), after a 30-day preview period. Additional information about preview report content and delivery will be announced on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. LTCHs would be notified

via CMS listservs, CMS mass emails and memorandums, LTCH QRP Web site announcements and Medicare Learning Network announcements regarding the release of preview reports, as well as the timing of the posting of provider data.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their hospital to discuss the quality of care provided to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. As we have done on some of the other CMS *Compare* Web sites, we will, at some point in the future, report public data using a quality rating system that gives each LTCH a rating of between one and five stars. Initially, however, we will not use the 5-star methodology, until such time that we are publicly reporting a sufficient number of quality metrics to allow for variation and the differentiation among LTCHs using this methodology. Decisions regarding how the rating system will determine an LTCH's star rating and methods used for calculations, as well as a proposed timeline for implementation will be announced via regular LTCH communication channels, including listening sessions, memos, email notification, provider association calls, open door forums, and Web postings.

The initial display of information would contain performance data on four quality measures: (1) NHSN CAUTI Outcome Measure (NQF #0138); (2) NHSN CLABSI Outcome Measure (NQF #0139); (3) Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678); and (4) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). We are proposing to publicly report data beginning with data collected on these measures for the first quarter of 2015, or discharges beginning January 1, 2015, with exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). Rates would be displayed based on four (4) rolling quarters of data and would use discharges from January 1, 2015 through December 31, 2015 (CY 2015), for calculation, with exception of the measure All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). With respect to LTCH performance related to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), we are proposing to publicly report readmission rates beginning with Medicare FFS claims data for patient discharges starting with January 1, 2013. Readmission rates will be calculated using Medicare FFS claims data for two consecutive years (for example, readmission rates will be calculated using Medicare FFS claims data for January 1, 2013 through December 31, 2014 (CY 2013 and CY 2014)) and displayed on a calendar year basis.

Calculations for the CAUTI and CLABSI measures adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. The SIR may take into account the type of patient care location, laboratory methods, hospital affiliation with a medical school, bed size of the hospital, patient age, and American Society of Anesthesiologists' classification of physical health. It compares the actual number of HAIs in a facility or State to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. An SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or State than were predicted, and the facility is classified as ''Worse than the U.S. National Benchmark.'' If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as ''Better than the U.S. National Benchmark.'' If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as ''No Different than U.S. National Benchmark.'' If the number of predicted infections is less than 1, the SIR and confidence interval cannot be calculated.

Calculations for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened measure application (NQF #0678) would be risk-adjusted. Resident- or patient-level covariate risk adjustment is performed. Resident- or patient-level covariates are used in a logistic regression model to calculate a resident- or patient-level expected quality measure (QM) score (the probability that the resident or patient will evidence the outcome, given the presence or absence of patient characteristics measured by the covariates). Then, an average of all resident- or patient-level expected QM scores for the facility is calculated to create a facility-level expected QM score. The final facility-level adjusted QM score is based on a calculation which combines the facility-level expected score and the facility level observed score. Additional information about the covariates can be found at: *http://www.qualityforum.org/QPS/0678*.

Finally, calculation for performance on the measure All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from IRFs (NQF #2502) will also be risk-adjusted. The risk adjustment methodology is available, along with the specifications for this measure, on our LTCH Quality Reporting Measures Information Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We are currently developing reports that will allow providers to view the data that is submitted to CMS via the QIES ASAP system and the CDC's NHSN (Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), the NHSN CAUTI Outcome Measure (NQF #0138) and the NHSN CLABSI Outcome Measure (NQF #0139), respectively). These reports, although not initially, will also include provider performance on any currently reported quality measure that is calculated based on CMS claims data that we plan on publicly reporting (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512)). Although real time results will not be available, the report will refresh all of the data submitted at least once a month.

We are proposing a process to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC's NHSN system by utilizing that report. Under this proposed process, providers would to have the opportunity to review and correct data they submit on all assessment-based measures. Providers can begin submitting data on the first admission of any reporting quarter. Providers are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline. The data would be populated into reports that are updated at least once a month with all data that have been submitted. That report would contain the provider's performance on each measure calculated based on assessment submissions to the QIES ASAP or CDC NHSN system. We believe that the submission deadline timeframe,

which we have proposed in this proposed rule to extend from the current 1.5 month policy to 4.5 months beyond the end of each calendar year quarter, is sufficient time for providers to be able to submit, review data, make corrections to the data, and view their data. We are proposing that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP or CDC NHSN system, we would consider the provider to have been given the opportunity to review and correct this data. We would not allow patient-level data correction after the submission deadline or for previous years. This is because we must set a deadline to ensure timely computation of measure rates and payment adjustment factors. Before we display this information, providers will be permitted 30 days to review their information as recorded in the QIES ASAP or CDC NHSN system.

We are inviting public comment on this proposal.

In addition to our proposal to publicly display LTCH performance data on the required quality measures under the LTCH QRP, we are also are proposing to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. We are proposing updating the list after reconsideration requests are processed on an annual basis. We are proposing to codify the policy to publish a list of compliant LTCHs on the LTCH QRP Web site at new proposed § 412.560(d)(3).

We are inviting comment on our proposal to begin publicly reporting LTCH QRP data on quality measures required by the LTCH QRP, beginning in fall 2016.

13. Previously Adopted and Proposed LTCH QRP Reconsideration and Appeals Procedures for the FY 2017 Payment Determination and Subsequent Years

At the conclusion of each fiscal year reporting cycle, we review the data received from each LTCH to determine if the LTCH met the reporting requirements set forth for that reporting cycle. LTCHs that are found to be noncompliant will receive a reduction in the amount of 2 percentage points to their annual payment update for the applicable fiscal year. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318), we described and adopted an updated process that enables an LTCH to request a reconsideration of our initial noncompliance decision in the event that an LTCH believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual payment due to noncompliance with the LTCH QRP reporting requirements for a given reporting period.

We wish to clarify that any LTCH that wishes to submit a reconsideration request must do so by submitting an email to CMS containing all of the requirements listed on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html*. Email sent to *LTCHQRPReconsiderations@cms.hhs.gov* is the only form of submission that will be accepted from an LTCH provider requesting reconsideration. Any reconsideration requests received through another channel, including the U.S. Postal Service (USPS) or telephone, will not be considered as a valid reconsideration request.

We are proposing to continue using the LTCH QRP reconsideration and appeals procedures that were adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318) and that have been posted on the LTCH QRP Web site for the FY 2017 payment determination and subsequent years, with an exception regarding the way in which noncompliant LTCHs are notified of this determination.

Previously, only LTCHs found to be noncompliant with the reporting requirements set forth for a given payment determination received a notification of this finding along with instructions for requesting reconsideration in the form of a certified letter via the USPS. In an effort to communicate as quickly, efficiently, and broadly as possible with LTCHs regarding annual compliance, we are proposing changes to our communications method regarding annual notification of reporting compliance in the LTCH QRP. In addition to sending a letter via regular USPS mail, beginning with the FY 2016 payment determination and for subsequent fiscal years, we are proposing the QIES as a mechanism to communicate to LTCHs regarding their compliance with the reporting requirements for the given reporting cycle.

We note that all LTCHs have been required to use the QIES system in order to report on required LTCH QRP measures since October 1, 2012. Therefore, we are proposing that all Medicare-certified LTCH compliance letters be uploaded into the QIES for each LTCH to access. Instructions to download files from QIES may be found on the Web site at: *https://www.qtso.com/LTCH.html*. We are proposing to disseminate communications regarding the availability of compliance reports in LTCHs' QIES files through routine channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, Medicare Learning Network announcements, and notices on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

The purpose of the compliance letter is to notify an LTCH that it has been identified as either being compliant or noncompliant with the LTCH QRP reporting requirements for the given reporting cycle. If the LTCH is determined to be noncompliant, the notification would indicate that the LTCH is scheduled to receive a 2 percentage point reduction to its upcoming annual payment update and that it may file a reconsideration request if it disagrees with this finding. LTCHs may request a reconsideration of a noncompliance determination through the CMS reconsideration request process.

We also are proposing that the notifications of our decision regarding received reconsideration requests will be made available through the QIES. We are not proposing to change the process or requirements for requesting reconsideration, and we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 through 50318) for a discussion of the LTCH QRP reconsideration and appeals procedures.

We also are proposing to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. We are proposing updating the list after reconsideration requests are processed on an annual basis.

We are proposing to codify the LTCH QRP reconsideration and appeal procedures at new proposed § 412.560(d) and (e).

We are inviting public comment on the proposals to change the communication mechanism to the QIES for the dissemination of compliance notifications and reconsideration decisions, to publish a list of compliant LTCHs on the LTCH QRP Web site, and

to codify these processes at new proposed § 412.560(d)(1) and (d)(3).

14. Previously Adopted and Proposed LTCH QRP Submission Exception and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50883 through 50885) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50316 through 50317) for a detailed discussion of the LTCH QRP Submission Exception and Extension requirements. For the FY 2017 payment determination and subsequent years, we are not proposing any changes to the LTCH QRP requirements that we adopted in these final rules. However, we are proposing to codify the LTCH QRP Submission Exception and Extension Requirements at new § 412.560(c) and (d).

We remind readers that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50316 through 50317), we stated that LTCHs must submit request an exception or extension by submitting a written request along with all supporting documentation to CMS via email to the LTCH mailbox at *LTCHQRPReconsiderations@cms.hhs.gov*. We further stated that exception or extension requests sent to CMS through any other channel would not be considered as a valid request for an exception or extension from the LTCH QRP's reporting requirements for any payment determination. In order to be considered, a request for an exception or extension must contain all of the requirements as outlined on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

We are inviting public comments on our proposal to codify the LTCH QRP submission exception and extension requirements.

D. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals Participating in the EHR Incentive Programs in 2016

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. The set of CQMs from which eligible hospitals and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083).

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program.

In the EHR Incentive Program Stage 3 proposed rule [219] (80 FR 16769), to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs and avoid redundant or duplicative reporting among hospital programs, we stated our intent to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years in the IPPS rulemaking. We further stated our belief that receiving and reviewing public comments for various CMS quality programs at one time and finalizing the requirements for these programs simultaneously would allow us to better align these programs for eligible hospitals and CAHs, allow more flexibility into the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency by providing us the opportunity to address public comments that affect multiple programs at one time.

ONC, in its 2015 Edition proposed rule (80 FR 16844), also indicated that it intends to propose certification policy for the reporting of CQMs for eligible hospitals and CAHs in or with annual IPPS rulemaking to better align with the reporting goals of other CMS programs.

2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2016

a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs in Table 10 at 77 FR 54083 through 54087, as well as the form and method for submission at 77 FR 54087 through 54089. In this proposed rule, for CQM reporting for the EHR Incentive Programs in 2016, we are proposing to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs, unless indicated otherwise in this proposed rule. These requirements include reporting on 16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs (77 FR 54079).

As we expand the current measures to align with the National Quality Strategy and the CMS Quality Strategy [220] and incorporate updated standards and terminologies in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in CY 2017 and subsequent years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as requesting comment on future electronic specifications for new and updated CQMs.

b. Proposed CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2016

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321), we began to shift CQM reporting to a calendar year basis for eligible hospitals and CAHs for the Medicare EHR Incentive Program. We established that

[219] Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3; proposed rule (80 FR 16731 through 16804) (''EHR Incentive Program Stage 3 proposed rule'').

[220] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*.

for eligible hospitals and CAHs that submit CQMs electronically in 2015, the reporting period is one calendar quarter from Q1, Q2, or Q3 of CY 2015 (79 FR 50321).

In the EHR Incentive Program Stage 3 proposed rule, beginning in 2015, we proposed to change the definition of ''EHR reporting period'' in § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. In connection with that proposal, we are proposing that the reporting period for CQMs in 2016 for eligible hospitals and CAHs for the Medicare and Medicaid EHR Incentive Programs would also be based on the calendar year. We believe it is important to continue our goal of aligning the EHR Incentive Program with the Hospital IQR Program because alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs.

For 2016 (FY 2018 payment determination), the Hospital IQR Program is proposing to require quarterly reporting and submission periods for eCQMs for the 3rd and 4th CY quarters. We refer readers to section VIII.A.8.b. of the preamble of this proposed rule for further discussion of the proposals for the Hospital IQR Program. We believe it is important for us to maintain our goal of alignment between the Hospital IQR and EHR Incentive Programs. Therefore, we are proposing to align the reporting period in CY 2016 for eligible hospitals and CAHs that report CQMs electronically for the Medicare EHR Incentive Program with that of the Hospital IQR Program and require quarterly reporting and submission periods for eCQMs in the 3rd and 4th CY quarters.

In addition, in this proposed rule, the Hospital IQR Program is proposing to change its submission period for eCQMs from annual to quarterly submission, and proposing to change the submission deadline from November 30, 2015 to ending 2 calendar months after the close of the reporting CY quarter (for CY 2016/FY 2018 payment determination, the proposed deadlines are November 30, 2016 for Q3 and February 28, 2017 for Q4). We refer readers to the Hospital IQR Program discussion in section VIII.A.10.d.(3) of the preamble of this proposed rule for more information about these proposals. Therefore, to coincide with the submission period in the Hospital IQR Program, we also are proposing to align the Medicare EHR Incentive Program submission period for CY 2016 with the submission period proposed for the Hospital IQR Program.

We are proposing the following CQM reporting periods and submission deadlines for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program in CY 2016:

- Eligible hospitals and CAHs Reporting CQMs by Attestation

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2016, any continuous 90-day reporting period within CY 2016; or one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016, one full calendar year reporting period for CY 2016. Attestation by February 28, 2017.

- Eligible hospitals and CAHs Reporting CQMs Electronically—Two full quarters of data (Q3 and Q4 of CY 2016) submitted via electronic reporting within 2 months after the close of each quarter (Q3 by November 30, 2016; Q4 by February 28, 2017).

We also are proposing that the CQM reporting period for eligible hospitals and CAHs participating in the Medicaid EHR Incentive Program would be any continuous 90-day reporting period within CY 2016 for eligible hospitals and CAHs demonstrating meaningful use for the first time; and one full calendar year reporting period of CY 2016 for eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2016. Providers should refer to their State Medicaid program for requirements on submission methods and deadlines.

We note that, beginning in CY 2017 and in subsequent years, we proposed in the Stage 3 proposed rule (80 FR 16739 through 16740) to require a reporting period of one full calendar year for CQM reporting for all providers participating in the EHR Incentive Programs, with a limited exception for Medicaid providers demonstrating meaningful use for the first time.

We are inviting public comment on these proposals.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2016

In the EHR Incentive Program Stage 2 final rule (77 FR 54087 through 54089), we finalized the reporting methods for eligible hospitals and CAHs for the Medicare EHR Incentive Program, which included reporting electronically or by attestation. We finalized that eligible hospitals and CAHs that are beyond their first year of meaningful use will be required to electronically submit the selected 16 CQMs. Subsequent to the Stage 2 final rule, we determined that electronic submission of aggregate-level data using QRDA–III would not be feasible in 2014 and 2015, and thus, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation for the reporting periods in 2014 and 2015 (78 FR 50904 through 50905; 79 FR 50321 through 50322).

We are proposing to continue our existing policy that eligible hospitals and CAHs in any year of participation in the Medicare EHR Incentive Program in 2016 may report CQMs by attestation or electronically using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Program, or for participation in multiple programs if the requirements of the aligned quality program are met. The options for CQM submission for eligible hospitals and CAHs in the Medicare EHR Incentive Program are as follows:

- Eligible hospital and CAH options for Medicare EHR Incentive Program participation *(single program participation)*

++ Option 1: Attest to CQMs through the EHR Registration & Attestation System.

++ Option 2: Electronically report CQMs through QualityNet Portal.

- Eligible hospital and CAH options for electronic reporting for multiple programs *(for example: EHR Incentive Program plus Hospital IQR Program participation*—Electronically report through QualityNet Portal.

For the Medicaid EHR Incentive Program, States will continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

We are proposing to continue our policy that electronic submission of CQMs would require the use of the most recent release of the CQM version for each CQM to which the EHR is certified. For electronic reporting in 2016, this means eligible hospitals and CAHs would be required to use the Spring 2015 release of the CQMs available at the CMS eCQM Library (*http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*). We note that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the

CQMs. (For further information on CQM reporting, we direct readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option (*www.CMS.gov/ehrincentiveprograms*).) However, we encourage EHR developers to test any updates, including any changes to the CQMs and changes to the CMS reporting requirements based on the CMS QRDA implementation guide, on an annual basis.

The form and method of electronic submission is further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: the CMS QRDA Implementation Guide; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the CMS eCQM Library (*http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*).

We are inviting public comments on this proposal.

3. Certified EHR Technology for CQMs for the EHR Incentive Programs in 2016

a. Edition of Certified EHR Technology Requirements in 2016

As previously stated in the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54051 through 54053), CQM data submitted by eligible hospitals and CAHs are required to be captured, calculated, and reported using CEHRT. In accordance with this policy, for CQM reporting for the Medicare and Medicaid EHR Incentive Programs in 2016, eligible hospitals and CAHs must use EHR technology certified to at least the 2014 Edition certification criteria for CQMs, which are defined at 45 CFR 170.314(c)(1) for the capture of data elements, 45 CFR 170.314(c)(2) for the calculation of CQMs, and 45 CFR 170.314(c)(3) for the submission of CQM data electronically.

However, in the 2015 Edition proposed rule (80 FR 16810 through 16872, 16900), ONC has proposed a new Edition of certification criteria for EHR technology, which may be available for some providers as early as 2016. The 2015 Edition proposed rule (80 FR 16842 through 16846) would establish three certification criteria for CQMs and set a placeholder for a fourth certification criterion. These three criteria are:

- Proposed new § 170.315(c)(1) ''CQMs—record and export''—to record and export data which aligns with the prior capture criteria.
- Proposed new § 170.315(c)(2) ''CQMs—import and calculate''—to import and calculate data which aligns with the prior calculate criteria.
- Proposed new § 170.315(c)(4) ''CQMs—filter''—to filter data which is a new function for CQM criteria in the 2015 Edition and is not currently proposed to be required by the EHR Incentive Programs.

ONC proposed (80 FR 16844) to reserve § 170.315(c)(3) ''CQMs—report''—to report data electronically, including submission testing, to be proposed in or with annual IPPS and/or PFS rulemaking. ONC believes that, going forward, proposing a 2015 Edition certification criterion for CQM reporting with CMS' annual payment rules would allow better alignment of ONC's certification policy and standards for electronically specified CQM, known as eCQMs, with reporting with other CMS programs that include eCQMs, such as the PQRS and Hospital IQR Programs, which update their measure specifications on an annual basis through rulemaking. Therefore, ONC is proposing a 2015 Edition certification criterion for ''CQMs—report'' in section VIII.D.3.b. of the preamble of this proposed rule.

b. ''CQMs—Report'' Certification Criterion in ONC's 2015 Edition Proposed Rule

As described previously in section VIII.D.3.a. of the preamble of this proposed rule, ONC reserved the 2015 Edition certification criterion for ''CQMs—report'' (at proposed new § 170.315(c)(3)) to be proposed in conjunction with IPPS and/or PFS rulemaking. The 2014 Edition certification criterion for CQMs—electronic submission (at § 170.314(c)(3)) requires CEHRT to enable a user to electronically create a data file for transmission of clinical quality measurement data using the Quality Reporting Document Architecture (QRDA) Category I and Category III standards, and which can be electronically accepted by CMS. The QRDA standard provides a document format and standard structure to electronically report clinical quality measure data.[221] The QRDA Category I standard enables an individual patient-level quality report that contains quality data for one patient for one or more quality measures. The QRDA Category III standard enables an aggregate quality report containing calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.[222]

Building off of the 2014 Edition criterion for submission of CQMs, ONC is proposing a 2015 Edition certification criterion for ''CQMs—report'' [223] at proposed new § 170.315(c)(3) as part of the proposed 2015 Edition of certification criteria that would require a certified Health IT Module to enable a user to electronically create a data file for transmission of clinical quality measurement data using the ''base'' HL7 (that is, industry-wide, non-program-specific) Quality Reporting Data Architecture (QRDA) Category I and Category III standards, at a minimum. ONC also is proposing to allow optional certification for EHRs according to the CMS ''form and manner'' requirements defined in CMS' QRDA Implementation Guide [224] as part of this proposed criterion. We reiterate that this proposed certification criterion would apply to EPs, eligible hospitals, and CAHs.

CMS anticipates proposing to require EPs, eligible hospitals, and CAHs seeking to report CQMs electronically (if using proposed new § 170.315(c)(3)) as part of meaningful use under the EHR Incentive Programs for 2016 to adhere to the additional standards and constraints on the QRDA standards for electronic reporting as described in the CMS QRDA Implementation Guide. CMS anticipates proposing to revise the definition of ''certified electronic health record technology (CEHRT)'' at 42 CFR 495.4 to require certification to the optional portion of the 2015 Edition CQM reporting criterion (proposed at § 170.315(c)(3)) in the CY 2016 Medicare Physician Fee Schedule proposed rule later this year.

As noted previously, ONC proposed standards for proposed new § 170.315(c)(1) and § 170.315(c)(2) in the 2015 Edition proposed rule (80 FR 16844), but retained a placeholder for proposed new § 170.315(c)(3) so that this certification criterion for reporting could be proposed in conjunction with the proposals for CMS quality reporting

[221] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35.*

[222] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286.*

[223] As noted in the 2015 Edition proposed rule, ONC proposed to title proposed new § 170.315(c)(3) ''CQMs—report'' to better align with the use of the term ''report'' throughout the 2015 Edition. Also, ONC is proposing to discontinue to reference ''electronic'' in the title of certification criteria as it is assumes that all functions performed by certified health IT are done electronically. See 80 FR 16844.

[224] The CMS QRDA Implementation Guide can be accessed at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.*

programs in the IPPS and PFS rules. Therefore, in this proposed rule, for the requirements for the 2015 Edition certification criteria, ONC is proposing the following at proposed new § 170.315(c)(3) for clinical quality measurement to state that technology certified to the 2015 Edition must enable a user to electronically create a data file for transmission of clinical quality measurement data which is:

- At a minimum, in accordance with the standards specified in § 170.205(h) and § 170.205(k); and
- Optionally, can be electronically accepted by CMS.

The standard specified in § 170.205(h) is the HL7 Implementation Guide (IG) for CDA Release 2: Quality Reporting Document Architecture—Category I, Draft Standard for Trial Use (DSTU) Release 2 (July 2012).[225] The standard specified in § 170.205(k) is the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 2 (November 2012).[226]

ONC previously adopted the July 2012 version of the QRDA Category I IG and the November 2012 version of the QRDA Category III IG in its 2014 Edition (77 FR 54232). Given the timing of this proposed rule and the expected deliverables for harmonized CQM and clinical decision support (CDS) standards (described further in the 2015 Edition proposed rule at 80 FR 16842 through 16843), ONC is soliciting comment on a series of three options to determine if the version of QRDA Category I or the QRDA-like standards it should adopt for the certification criterion should be a more recent update to the standard. Specifically, ONC is soliciting comment on the following options for individual patient-level quality reports (QRDA Category I):

(1) The July 2012 QRDA Category I IG;

(2) The July 2012 QRDA Category I IG with the September 2014 Errata;[227] and

(3) QRDA-like standards for individual patient-level quality reports based on the anticipated Quality Improvement and Clinical Knowledge (QUICK) [228] Fast Health Interoperability Resources (FHIR)-based Draft Standard for Trial Use CQM standards.

Option 1 includes the same version of the QRDA Category I standard ONC adopted in the 2014 Edition. Option 2 includes this same version with the September 2014 Errata, which provides guidance on implementing QRDA Category I based on a new version of the underlying information model for representing quality measures (that is, the Quality Data Model based-Health Quality Measures Format Release 2.1 [229]). Option 3 would include standards based on the harmonized CQM and CDS standards on which the industry is currently developing.

ONC is also soliciting comment on a fourth option of QRDA Category I standard it could consider adopting for this proposed certification criterion:

(4) The next release of the QRDA Category I IG (Release 3).[230]

While this option was not discussed in the 2015 Edition proposed rule, stakeholders have recently made ONC aware that the industry is in the process of updating the QRDA Category I to the next Release 3. ONC understands that Release 3 is expected to be balloted in May 2015. Release 3 would include major updates to align with the Quality Data Model, address comments from Release 2, and better align with the Consolidated CDA Release 2 used for transitions of care/summary care records.

While not discussed in the 2015 Edition proposed rule, ONC in this proposed rule is also soliciting comment on three options for aggregate-level quality reports (QRDA Category III) it could adopt for this certification criterion:

(1) The November 2012 QRDA Category III IG;

(2) The November 2012 QRDA Category III IG with the September 2014 Errata; [231] and

(3) QRDA-like standards for aggregate-level quality reports based on the anticipated Quality Improvement and Clinical Knowledge (QUICK) [232] Fast Health Interoperability Resources (FHIR)-based Draft Standard for Trial Use CQM standards.

Option 1 includes the same version of the QRDA Category III standard which ONC adopted in the 2014 Edition. Option 2 includes this same version with the September 2014 Errata, which provides guidance on implementing QRDA Category III based on a new version of the underlying information model for representing quality measures (that is, the Quality Data Model based-Health Quality Measures Format Release 2.1 [233]). Option 3 would include standards based on the harmonized CQM and CDS standards on which the industry is currently developing.

In connection with ONC, we are inviting public comment on these options and this proposal.

4. CQM Development and Certification Cycle

We stated in the Stage 2 final rule (77 FR 54055) that we do not intend to use notice and comment rulemaking as the means to update or modify CQM specifications. Given the necessity to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity, we publish annual updates to the electronic specifications for EHR submission. Although we require eligible hospitals and CAHs to submit the most updated versions of CQMs when reporting electronically, CEHRT is not required to be recertified on annual basis. CMS and ONC understand that standards for electronically representing CQMs continue to evolve, and believe there may be value in retesting certified Health IT Modules (including CEHRT) periodically to ensure that CQMs are being accurately calculated and represented, and that they can be reported to CMS in the ''form and manner'' required for the Hospital IQR Program and EHR Incentive Program. As mentioned previously, CMS and ONC encourage health IT developers to retest their certified technology annually, and are soliciting comment on the appropriate frequency for requiring retesting and recertification to the most updated versions of CQMs and most recent ''form and manner'' reporting requirements.

However, given the continuing evolution of technology and clinical standards, as well as the need for a predictable cycle from measure development to provider data submission, CMS intends to publish a request for information (RFI) on the establishment of an ongoing cycle for

[225] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*.

[226] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286*.

[227] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35*. Note that in order to access the errata, the user should download the ''HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture—Category I, DSTU Release 2 (US Realm)'' package.

[228] Available at: *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1045*.

[229] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97*.

[230] *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=210*.

[231] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286*. Note that in order to access the errata, the user should download the ''HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm)'' package.

[232] Available at: *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1045*.

[233] Available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97*.

the introduction and certification of new measures, the testing of updated measures, and the testing and certification of submission capabilities. We encourage readers to submit their insights and recommendations for our consideration upon publication of that RFI.

IX. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2015 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2016 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

X. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Data files and the cost for each file, if applicable, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2012 Medicare cost reports used to create the proposed FY 2016 prospective payment system wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.L. of the preamble of this proposed rule.

Processing year	Wage data year	PPS Fiscal year
2015	2012	2016
2014	2011	2015
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2007 through FY 2016 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2013 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.L. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2016 IPPS Update.

5. FY 2016 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a list of Core-Based Statistical Areas (CBSAs).

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp*.

There are no longer data offered on a CD. All of the data collected are now available on the following Web site free for download: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/?redirect=/CostReports/*

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 1985 through FY 2016.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 2005 through FY 2016 IPPS Update

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital impatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*.

Periods Available: FY 1994 through FY 2016 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2016 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

13. Hospital Readmissions Reduction Program File

This file contains information on the calculation of the Hospital Readmissions Reduction Program payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), and total hip arthroplasty (THA)/total knee arthroplasty (TKA) and the proxy readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors, and it contains MS–DRG relative weight information to estimate the payment adjustment factors. The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2016. Variables include a hospital's SSI days and Medicaid days used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2016 IPPS Update.

Commenters interested in discussing any data used in constructing this proposed rule should contact Chioma Obi at (410) 786–6050.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

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.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of the proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2017 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold.

We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, and 2016, we received 1, 4,

5, 3, 3, 5, 5, 7, and 9 applications, respectively.

3. ICRs for the Proposed Occupational Mix Adjustment to the Proposed FY 2016 Wage Index (Hospital Wage Index Occupational Mix Survey)

Section III.F. of the preamble of this proposed rule discusses the proposed occupational mix adjustment to the proposed FY 2016 wage index, respectively. While the preamble of this proposed rule does not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–0907.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.J.2. of the preamble of this proposed rule discusses proposed changes to the wage index based on hospital reclassifications. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. It is currently approved under OMB control number 0938–0573.

5. Proposed Elimination of the Simplified Cost Allocation Methodology for Hospitals

In section IV.H. of the preamble of this proposed rule, we are proposing to amend the regulations at 42 CFR 412.302(d)(4) to limit a hospital's ability to elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552 to cost reporting periods beginning before October 1, 2015. We are proposing to limit the election of the simplified cost allocation methodology because the allocation of the costs of capital-related movable equipment using this methodology yields less precise calculated CCRs. Currently, less than 1 percent of hospitals have elected to use the simplified cost allocation methodology. Based on FY 2013 data, only 9 of 1,269 CAHs and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology. Furthermore, we believe that advances in technology have reduced the cost of recordkeeping, which has allowed hospitals to maintain accurate statistical data and afforded them the flexibility to change to a more precise allocation methodology.

Although we are proposing to eliminate the simplified cost allocation methodology for hospitals, we believe the currently approved burden estimates for the Hospital and Health Care Complex Cost Report (OMB control number 0938–0050) are still applicable to hospitals completing the Hospital and Health Care Complex Cost Report. The time required to address this proposed revision would be subsumed in the total burden estimate for an entity to comply with all of the requirements in the cost report.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a ''starter set'' of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request previously approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR measures was part of our implementation of section 5001(a) of the Deficit Reduction Act of 2005 (DRA). Section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the ''starter set'' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures ''that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings.'' The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022.

In this proposed rule, we are proposing refinements to the measure cohorts for: (1) The Hospital 30-Day All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization measure (NQF #0468); and (2) the Hospital 30-Day All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506). We also are proposing eight additional measures to be added to the Hospital IQR Program measure set beginning with the FY 2018 payment determination and for subsequent years. Seven of these measures are claims-based, and one measure is structural. The eight new measures are: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment (claims-based); (3) Cellulitis Clinical Episode-Based Payment (claims-based); (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment (claims-based); (5) Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment (claims-based); (6) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (7) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (8) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the hospitals for the seven proposed claims-based measures. In addition, the burden associated with the structural measure we are proposing, Hospital Survey on Patient Safety Culture, is expected to be negligible; therefore, its proposed addition will not result in a significant burden increase.

We also are proposing nine measures for removal. We believe that there will be a reduction in burden for hospitals due to our proposed removal of seven of

these measures, which are chart-abstracted: (1) STK–01 Venous Thromboembolism Prophylaxis (NQF #0434); (2) STK–06: Discharged on Statin Medication* (NQF #0439); (3) STK–08: Stroke Education* (NQF endorsement removed); (4) VTE–1: Venous Thromboembolism Prophylaxis* (NQF #0371); (5) VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis* (NQF #0372); (6) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy* (NQF #0373); and (7) AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival* (NQF #0164). (An asterisk (*) indicates that the measure is proposed for retention as an electronic clinical quality measure for the FY 2018 payment determination in section VIII.A.8. of the preamble of this proposed rule.) Due to the burden associated with the collection of chart-abstracted data, we estimate that the proposed removal of AMI–7a would result in a burden reduction of approximately 219,000 hours across all hospitals. We estimate that the proposed removal of seven chart-abstracted measures will result in a burden reduction of approximately 522,000 hours across all hospitals.

Two of the nine measures proposed for removal have been previously suspended from the Hospital IQR Program. Therefore, their proposed removal would not affect burden to hospitals. These measures are: IMM–1 Pneumococcal Immunization (NQF #1653); and SCIP–Inf–4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300). The suspension of IMM–1 is currently reflected under OMB control number 0938–1022. The suspension of SCIP–Inf–4, which was formalized on January 9, 2015,[234] will be reflected in the PRA package being submitted this year under OMB control number 0938–1022.

For the FY 2018 payment determination and subsequent years, we also are proposing to require hospitals to submit 16 measures electronically for the Hospital IQR Program in a manner that would permit eligible hospitals to partially align Hospital IQR Program requirements with some requirements under the Medicare EHR Incentive Program. We believe that the total burden associated with the electronic clinical quality measure reporting proposal will be similar to the burden outlined for hospitals in the EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to attest and report all 16 electronic clinical quality measures is 2 hours and 40 minutes per submission (77 FR 54132). We believe that this estimate is accurate and appropriate to also apply to the Hospital IQR Program, given the alignment between the electronic clinical quality measure reporting requirements for both programs. In total, we expect the burden associated with our proposal to require hospitals to report electronic clinical quality measures to be 5 hours and 20 minutes per hospital for two quarters of data submission, and 17,600 hours total for two quarters of data submission across the approximately 3,300 hospitals participating in the Hospital IQR Program. We estimate that reporting these electronic clinical quality measures can be accomplished by staff with a mean hourly wage of $16.42 per hour.[235] Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits.[236] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $22.37 ($16.42 base salary + $5.95 fringe) and a total cost of $393,712 (17,600 hours × $22.37 per hour) across approximately 3,300 hospitals participating in the Hospital IQR Program to report 16 electronic clinical quality measures for two quarters (Q3 and Q4).

For validation of chart-abstracted data for the FY 2018 payment determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc.

Under OMB number 0938–1022, we estimated that the total burden for the FY 2017 payment determination was 1,781 hours per hospital and 5.9 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program. Using data on chart-abstracted measures from the 3rd quarter in 2013 through the 2nd quarter in 2014, we have revised our burden estimate to include updates to the number of records reported per measure set, as well as the time associated with data collection. Considering the proposals described in this proposed rule, as well as our updated estimates for the number of records reported and the time associated with data reporting activities, we estimate a total burden of 2,293 hours per hospital and 7.6 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2018 payment determination. This burden estimate includes the full measure set proposed for the Hospital IQR Program FY 2018 payment determination and accounts for burden changes associated with all newly proposed measures as well as measures proposed for removal, as discussed above in this section.

In addition, this burden estimate accounts for other activities such as population and sampling, reviewing reports for claims-based measure sets, HAI validation templates, as well as all other forms and structural measures. The estimate excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under OMB control numbers 0920–0666 and 0938–0981, respectively. The burden estimates in this proposed rule are the estimates for which we are requesting OMB approval.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

In section VIII.B.5 of the preamble of this proposed rule, we are proposing that PCHs will submit data on three additional measures beginning with the FY 2018 program: (1) CDCNHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and (3)

[234] QualityNet. Available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890406532&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2015-02-IP.pdf&blobcol=urldata&blobtable=MungoBlobs.*

[235] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

[236] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel Measure (NQF #0431). In conjunction with our proposal in section VIII.B.2. of the preamble of this proposed rule to remove the six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years, the PCHQR measure set would consist of 16 measures beginning with the FY 2018 program.

With respect to our proposal to add three measures beginning with the FY 2018 program, this estimate excludes the burden associated with two of these measures (the CDC NHSN MRSA measure and the CDC NHSN CDI measure) both of which are submitted under separate information collection requests and are approved under a separate OMB control numbers (0920–0666).[237] Using the same methodology as the FY2015 IPPS/LTCH PPS final rule,[238] for the third proposed new measure (CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel measure), we estimate that it will take 10 minutes annually per PCH, or an additional 1.83 hours for all PCHs annually to report the measure.[239]

Our proposal to remove six SCIP measures would reduce the burden experienced by PCHs. We estimate a reduction in hourly burden of 6,468 [240] hours per year beginning with Q4 2015 and for subsequent program years across the 11 PCHs.

In summary, as a result of our proposals, we estimate a reduction of 6,466.17 [241] hours of burden per year associated with the proposals above for all 11 PCHs beginning with the FY 2018 program. Coupled with our estimated salary costs,[242] we estimate that these proposed changes would result in a reduction in annual labor costs of $426,767.22 beginning with the FY 2018 PCHQR Program.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.F. of the preamble of the proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt one new measure beginning with the FY 2018 program year, the 3-Item Care Transition Measure (CTM–3) (NQF #0228). We also are proposing to adopt one new measure beginning with the FY 2021 program year, the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1893) (MORT–30–COPD).

As required under section 1886(o)(2)(A) of the Act, both of these additional measures are required for the Hospital IQR Program. Therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

9. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in sections VIII.C.5.a and VIII.C.5.b. of the preamble of this proposed rule, we are retaining the following 12 previously finalized quality measures for use in the LTCH QRP:

LTCH QRP Quality Measures Previously Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

NQF ID	Measure title	Payment determination	Final rule(s) in which measure was finalized
NQF #0138	National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2015 payment determination and subsequent years.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2013 IPPS/LTCH PPS final rule.
NQF #0139	National Health Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure.	FY 2015 payment determination and subsequent years.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2013 IPPS/LTCH PPS final rule.
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay).	FY 2015 payment determination and subsequent years*.	FY 2012 IPPS/LTCH PPS final rule; updated in FY 2014 IPPS/LTCH PPS final rule.
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).	FY 2016 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel.	FY 2016 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.

* Proposed in this FY 2016 IPPS/LTCH PPS proposed rule for the FY 2018 payment determination and subsequent years

LTCH QRP Quality Measures Previously Adopted for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

NQF ID	Measure title	Payment determination	Final rule(s) in which measure was finalized
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2017 and Subsequent Years ..	FY 2014 IPPS/LTCH PPS final rule.
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2017 payment determination and subsequent years.	FY 2014 IPPS/LTCH PPS final rule.

[237] OMB Control Number History. Available at: *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0920-0666*.

[238] FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50444).

[239] Ibid.

[240] [(49 cases per measure × 4 quarters) + 0.5 (abstraction/training time)] × 11 PCHs = 6,468 hours per year.

[241] 6,468 hours – 1.83 hours = 6,466.17 hours.

[242] 6,466.17 hours * $66/hour. [We are now estimating an hourly salary of $33 (*http://swz.salary.com/salarywizard/Staff-Nurse-RN-Hourly-Salary-Details.aspx*). After accounting for employee benefits and overhead, this results in a total cost of $66 per labor hour]

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2017 AND FY 2018 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS—Continued

NQF ID	Measure title	Payment determination	Final rule(s) in which measure was finalized
NQF #2512	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals **.	FY 2017 payment determination and subsequent years **.	FY 2014 IPPS/LTCH PPS final rule.
Application of NQF #0674.	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	FY 2018 payment determination and subsequent years **.	FY 2014 IPPS/LTCH PPS final rule.
NQF #2631 *	Functional Status Quality Measure: Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
NQF #2632 *	Functional Status Quality Measure: Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.
Not NQF endorsed.	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	FY 2018 payment determination and subsequent years.	FY 2015 IPPS/LTCH PPS final rule.

* Under review at NQF. We refer readers to: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*, NQF #2631 and NQF #2632.
** Proposed in this FY 2016 IPPS/LTCH PPS proposed rule for the FY 2018 payment determination and subsequent years

As discussed in sections VIII.C.6.a. through c. of the preamble of this proposed rule, we are proposing three previously finalized quality measures for use in the LTCH QRP for the FY 2018 payment determination and subsequent years. We are proposing two of these measures in order to establish their use as cross-setting measures that satisfy the required addition of quality measures under the domains of skin integrity and incidence of major falls, as mandated by section 1899B of the Act, as added by the IMPACT Act of 2014: Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678), and an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We are proposing a third previously finalized measure, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From Long-Term Care Hospitals (NQF #2512), in order to establish the newly NQF-endorsed status of this measure.

Finally, as discussed in sections VIII.C.6.d. of the preamble of this proposed rule, for the FY 2018 payment determination and subsequent years we are proposing the addition of one new quality measure to the LTCHQR Program: Cross-Setting Functional Status Process Measure: an application of Percent of Patients or Residents with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; under review). This measure satisfies the addition of a quality measure under the third initially required domain of functional status, as mandated by section 1899B of the Act as added by the IMPACT Act of 2014.

Six of the measures being retained in this FY 2016 IPPS/LTCH PPS proposed rule are currently collected via the CDC NHSN. The NHSN is a secure, Internet-based HAI tracking system maintained and managed by the CDC. The NHSN enables healthcare facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, and other adverse events within their organizations. NHSN data collection occurs via a Web-based tool hosted by the CDC and provided free of charge to facilities. In this proposed rule, we have not proposed to adopt any new quality measures that are collected via the CDC's NHSN. Therefore, at this time, there is no additional burden related to this submission method. Any burden related to NHSN-based quality measures we have retained in this proposed rule, has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), and has been previously approved under OMB control number 0920–0666, with an expiration date of November, 31, 2016.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), which we have proposed in this proposed rule, is a Medicare FFS claims-based measure. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the LTCHs.

The remaining 6 measures will be collected utilizing the LTCH CARE Data Set (LCDS). The LCDS, in its current form (version 2.0), has been approved under OMB control number 0938–1163. Version 2.0 of the LCDS contains data elements related to patient demographic data, various voluntary questions, as well as data elements related to the following quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680)

Version 3.0 of the LCDS is under development and will contain those data elements included in version 2.0, as well as additional data elements in order to allow for the collection of data associated with the following quality measures:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF # 2631—under NQF review) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)
- Functional Status Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632—under NQF review) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule)

Each time we add new data elements to the LCDS related to newly proposed or finalized LTCH QRP quality measures, we are required by the PRA to submit the expanded data collection instrument to OMB for review and

approval. Section 1899B(m) of the Act, as added by IMPACT Act of 2014, provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in subsection 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data. We believe that version 3.0 of the LTCH CARE Data Set falls under the PRA provisions in 1899B(m) of the Act. We believe that all additional data elements added to version 3.0 of the LCDS are for the purpose of standardizing patient assessment data, as required under section 1899B(a)(1)(B) of the Act.

A comprehensive list of all data elements included in version 3.0 of the LCDS is available in the LTCH QRP Manual, as is a crosswalk outlining the differences between version 2.0 and 3.0 of the LCDS. The Manual accessible on the following LTCH Quality Reporting Measures Information Web page: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. For a discussion of burden related to version 3.0 of the LCDS, we refer readers to section I.M. of Appendix A of this proposed rule.

While the reporting of quality measures is an information collection, the PRA does not apply in accordance with the amendments to the Act made by IMPACT Act of 2014. More specifically, section 1899B(m) of the Act provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in subsection 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data.

10. ICRs for the Electronic Health Record (EHR) Incentive Program and Meaningful Use

In section VIII.D. of the preamble of this proposed rule, we discuss our proposals to align the Medicare EHR Incentive Program reporting and submission timelines for electronically submitted clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines for 2016. Because these proposals for data collection would align with the reporting requirements in place for the Hospital IQR Program and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare EHR Incentive Program, we do not believe there is any additional burden for this collection of information.

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–1632–P; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

C. Response to Public 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 public 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 public comments in the preamble of that document.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public Health, Security.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

Title 42—Public Health

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Public Law 113–67, and sec. 112 of Public Law 113–93.

■ 2. Section 412.23 is amended by—

■ a. In paragraph (e)(3)(i), removing the cross-reference ''paragraphs (e)(3)(ii) through (iv)'' wherever it appears and adding in its place the cross-reference ''paragraphs (e)(3)(ii) through (vi)''.

■ b. Adding new paragraph (e)(3)(vi).

■ c. Revising paragraph (e)(6)(ii) introductory text.

The addition and revision reads as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(3) * * *

(vi) For cost reporting periods beginning on or after October 1, 2015, the Medicare inpatient days and discharges that are paid at the site neutral payment rate specified at § 412.522(c)(1) or paid under a Medicare Advantage plan (Medicare Part C) will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section. The provisions of this paragraph (e)(3)(vi) do not apply to a hospital classified as a subsection (d) hospital (as defined in section 1886(d)(1)(B) the Act) as of December 10, 2013.

* * * * *

(6) * * *

(ii) *Exception.* The moratorium specified in paragraph (e)(6)(i) of this section is not applicable to the establishment and classification of a long-term care hospital that meets the requirements of paragraphs (e) introductory text and (e)(1) through (5) of this section, or a long-term care hospital satellite facility that meets the requirements of § 412.22(h), if the long-term care hospital or long-term care satellite facility meets one or more of the following criteria on or before December 27, 2007, or prior to April 1, 2014, as applicable:

* * * * *

■ 3. Section 412.64 is amended by revising paragraphs (d)(1)(vi), (h)(4) introductory text, and (h)(4)(vi) introductory text, to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vi) For fiscal years 2015 and 2016, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.2 percentage point.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2016,

CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

(vi) For discharges on or after October 1, 2012 and before October 1, 2016, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

* * * * *

■ 4. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section. For fiscal year 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

* * * * *

■ 5. Section 412.302 is amended by revising paragraph (d)(4) to read as follows:

§ 412.302 Introduction to capital costs.

* * * * *

(d) * * *

(4) For cost reporting periods beginning before October 1, 2015, hospitals may elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552.

■ 6. Section 412.503 is amended by adding a definition of ''Subsection (d) hospital'' in alphabetical order, to read as follows:

§ 412.503 Definitions.

* * * * *

Subsection (d) hospital means, for purposes of § 412.526, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

* * * * *

■ 7. Section 412.507 is revised to read as follows:

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system. If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met. If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate, that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment. If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier is met.

(b) *Permitted charges.* (1) A long-term care hospital that receives a payment at the full LTCH prospective payment system standard Federal payment rate or the site neutral payment rate may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, and for items and services as specified under § 489.20(a) of this chapter.

(2) A long-term care hospital that receives a payment at less than the full LTCH prospective payment system standard Federal payment rate for a short-stay outlier case, in accordance with § 412.529 (which would not include any discharge paid at the site neutral payment rate), may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay that were not the basis for the short-stay adjusted payment.

■ 8. Section 412.517 is amended by adding a new paragraph (c) to read as follows:

§ 412.517 Revision of LTC–DRG group classifications and weighting factors.

* * * * *

(c) Beginning in FY 2016, the annual recalibration of the weighting factors described in paragraph (a) of this section is determined using long-term care hospital discharges described in § 412.522(a)(2).

■ 9. Section 412.521 is amended by revising paragraph (a)(2) to read as follows:

§ 412.521 Basis of payment.

(a) * * *

(2) Except as provided for in § 412.526, the amount of payment under the prospective payment system is based on either the long-term care hospital prospective payment system standard Federal payment rate established in accordance with § 412.523, including adjustments described in § 412.525, or the site neutral payment rate established in accordance with § 412.522(c), or, if applicable during a transition period, the blend of the LTCH PPS standard Federal payment rate and the applicable site neutral payment rate described in § 412.522(c)(3).

* * * * *

■ 10. A new § 412.522 is added to read as follows:

§ 412.522 Application of site neutral payment rate.

(a) *General.* For discharges in cost reporting periods beginning on or after October 1, 2015—

(1) Except as provided for in paragraph (b) of this section, all discharges are paid based on the site neutral payment rate as determined under the provisions of paragraph (c) of this section.

(2) Discharges that meet the criteria for exclusion from site neutral payment rate specified in paragraph (b) of this section are paid based on the standard Federal prospective payment rate established under § 412.523.

(b) *Criteria for exclusion from the site neutral payment rate*—(1) *General.* A discharge that meets the following criteria is excluded from the site neutral payment rate specified under this section.

(i) The discharge from the long-term care hospital does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation based on the LTC–DRG assignment of the discharge under § 412.513; and

(ii) The admission to the long-term care hospital was immediately preceded by a discharge from a subsection (d) hospital and meets either the intensive care unit criterion specified in paragraph (b)(2) of this section or the ventilator criterion specified in paragraph (b)(3) of this section. In order for an admission to a long-term care hospital to be considered immediately preceded for purposes of this section, the patient discharged from the subsection (d) hospital must be directly admitted to the long-term care hospital.

(2) *Intensive care unit criterion.* In addition to meeting the requirements of paragraph (b)(1) of this section, the discharge from the subsection (d) hospital that immediately preceded the admission to the long-term care hospital includes at least 3 days in an intensive care unit (as defined in § 413.53(d) of this chapter), as evidenced by at least one of the revenue center codes on the claim for the discharge that indicate such services were provided for the requisite number of days during the stay.

(3) *Ventilator criterion.* In addition to meeting the requirements of paragraph (b)(1) of this section, the discharge from the long-term care hospital is assigned to a LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours, as evidenced by the procedure code on the discharge bill indicating such services were provided during the stay.

(c) *Site neutral payment rate*—(1) *General.* Subject to the provisions of paragraph (c)(2) of this section, the site neutral payment rate is the lower of—

(i) The inpatient hospital prospective payment system comparable per diem amount determined under § 412.529(d)(4), including any applicable outlier payments specified in § 412.525(a); or

(ii) 100 percent of the estimated cost of the case determined under the provisions of § 412.529(d)(2). The provisions for cost- to-charge ratios at § 412.529(f)(4)(i) through (iii) apply to the calculation of the estimated cost of the case under this paragraph.

(2) *Adjustments.* CMS adjusts the payment rate determined under paragraph (c)(1) of this section to account for—

(i) Outlier payments, by applying a reduction factor equal to the estimated proportion of outlier payments under § 412.525(a) payable for discharges from a long-term care hospital described in paragraph (a)(1) of this section to total estimated payments under the long-term care hospital prospective payment system to discharges from a long-term care hospital described in paragraph (a)(1) of this section.

(ii) A 3-day or less interruption of a stay and a greater than 3-day interruption of a stay, as provided for in § 412.531. For purposes of the application of the provisions of § 412.531 to discharges from a long-term care hospital described under paragraph (a)(1) of this section, the long-term care hospital prospective payment system standard Federal payment-related terms, such as ''LTC–DRG payment,'' ''full Federal LTC–DRG prospective payment,'' and ''Federal prospective payment,'' mean the site neutral payment rate calculated under paragraph (c) of this section.

(iii) The special payment provisions for long-term care hospitals-within-hospitals and satellite facilities of long-term care hospitals specified in § 412.534.

(iv) The special payment provisions for long-term care hospitals and satellite facilities of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite facility of the long-term care hospital, as provided in § 412.536.

(3) *Transition.* For discharges in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2017, payment for discharges under paragraph (c)(1) of this section are made using a blended payment rate, which is determined as—

(i) 50 percent of the site neutral payment rate amount for the discharge as determined under paragraph (c)(1) of this section; and

(ii) 50 percent of the standard Federal prospective payment rate amount for the discharge as determined under § 412.523.

(4) *Reconciliation of payments under the site neutral payment rate.* Payments under paragraph (c) of this section are reconciled in accordance with the following provisions:

(i) Any reconciliation of payments under the site neutral payment rate is based on the cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

(ii) At the time of any reconciliation under paragraph (c)(4)(i) of this section, payments under the site neutral payment rate may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment is based upon a widely available index to be established in advance by the Secretary, and is applied from the midpoint of the cost reporting period to the date of reconciliation.

(d) *Discharge payment percentage.* (1) For purposes of this section, the discharge payment percentage is a ratio, expressed as a percentage, of Medicare discharges that meet the criteria for exclusion from the site neutral payment rate as described under paragraph (a)(2) of this section to total Medicare discharges paid under this Subpart O during the cost reporting period.

(2) CMS will inform each long-term care hospital of its discharge payment percentage, as determined under paragraph (d)(1) of this section, for each cost reporting period beginning on or after October 1, 2015.

■ 11. Section 412.523 is amended by adding a new paragraph (c)(3)(xii) and revising paragraph (d)(1) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2015, and ending September 30, 2016.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2015, and ending September 30, 2016, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.9 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(1) *Outlier payments.* CMS adjusts the LTCH PPS standard Federal payment rate by a reduction factor of 8 percent, the estimated proportion of outlier payments under § 412.525(a) payable for discharges described in § 412.522(a)(2).

* * * * *

■ 12. Section 412.525 is amended by revising paragraphs (a)(1), (2), and (3) and adding a new paragraph (a)(5), to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

(a) * * *

(1) CMS provides for an additional payment to a long-term care hospital if its estimated costs for a patient exceed the applicable long-term care hospital prospective payment system payment plus an applicable fixed-loss amount. For each long-term care hospital prospective payment system payment year, CMS annually establishes a fixed-loss amount that is the maximum loss

that a long-term care hospital would incur under the applicable prospective payment system rate for a case with unusually high costs before receiving an additional payment.

(2) The fixed-loss amount for discharges from a long-term care hospital described under § 412.522(a)(2) is determined for the long-term care hospital prospective payment system payment year, using the LTC–DRG relative weights that are in effect at the start of the applicable long-term care hospital prospective payment system payment year.

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient's care (determined by multiplying the hospital-specific cost-to-charge ratio by the Medicare allowable covered charge) and the sum of the applicable long-term care hospital prospective payment system payment and the applicable fixed-loss amount.

* * * * *

(5) For purposes of this paragraph (a)—

(i) *Applicable long-term care hospital prospective payment system payment* means:

(A) The site neutral payment rate established under § 412.522(c) for long-term care hospital discharges described under § 412.522(a)(1); or

(B) The standard Federal prospective payment rates established under § 412.523 for long-term care hospital discharges described under § 412.522(a)(2).

(ii) *Applicable fixed-loss amount* means:

(A) For long-term care hospital discharges described under § 412.522(a)(1), the fixed-loss amount established for such cases as provided at § 412.522(c)(2)(i).

(B) For long-term care hospital discharges described under § 412.522(a)(2), the fixed-loss amount established for such cases as provided at § 412.523(e).

* * * * *

■ 13. A new § 412.560 is added to read as follows:

§ 412.560 Participation, data submission, and other requirements under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.

(a) *Participation in the LTCHQR Program.* A long-term-care hospital must begin submitting quality data under the LTCHQR Program by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

(b) *Submission of data requirements and payment impact.* (1) Except as provided in paragraph (c) of this section, a long-term care hospital must submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, as applicable, in a form and manner, and at a time, specified by CMS.

(2) A long-term care hospital that does not submit data in accordance with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year will have its annual update to the standard Federal rate for discharges for the long-term care hospital during the fiscal year reduced by 2 percentage points.

(c) *Exception and extension request requirements.* Upon request by a long-term care hospital, CMS may grant an exception or extension with respect to the quality data reporting requirements, for one or more quarters, in the event of certain extraordinary circumstances beyond the control of the long-term care hospital, subject to the following:

(1) A long-term care hospital that wishes to request an exception or extension with respect to quality data reporting requirements must submit its request to CMS within 30 days of the date that the extraordinary circumstances occurred.

(2) A long-term care hospital must submit its request for an exception or extension to CMS via email. Email is the only form that may be used to submit to CMS a request for an exception or an extension.

(3) The email request for an exception or extension must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address. (The mailing address may not be a post office box.)

(v) A statement of the reason for the request for the exception or extension.

(vi) Evidence of the impact of the extraordinary circumstances, including, but not limited to, photographs, newspaper articles, and other media.

(vii) The date on which the long-term care hospital will be able to again submit quality data under the LTCHQR Program and a justification for the proposed date.

(4) CMS may grant an exception or extension to a long-term care hospital that has not been requested by the long-term care hospital if CMS determines that—

(i) An extraordinary circumstance affects an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems directly affected the ability of the long-term care hospital to submit quality data.

(d) *Reconsiderations of noncompliance decisions*—(1) *Written notification of noncompliance decision.* CMS will send a long-term care hospital written notification of a decision of noncompliance with the quality data reporting requirements for a particular fiscal year. CMS also will use the Quality Improvement and Evaluation system (QIES) Assessment Submission and Processing (ASAP) System to provide notification of noncompliance to the long-term care hospital.

(2) *Request for reconsideration of noncompliance decision.* A long-term care hospital may request a reconsideration of CMS' decision of noncompliance no later than 30 calendar days from the date of the written notification of noncompliance. The reconsideration request by the long-term care hospital must be submitted to CMS via email and must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including each individual's name, title, email address, telephone number, and physical mailing address. (The physical address may not be a post office box.)

(v) CMS's identified reason(s) for the noncompliance decision from the written notification of noncompliance.

(vi) The reason for requesting reconsideration of CMS' noncompliance decision.

(vii) Accompanying documentation that demonstrates compliance of the long-term care hospital with the quality reporting requirements. This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email. Any reconsideration request that fails to provide sufficient evidence of compliance will not be reviewed.

(3) *CMS decision on reconsideration request.* CMS will notify the long-term care hospital, in writing, of its final decision regarding any reconsideration request. CMS also will use the QIES ASAP System to provide notice of its

final decision on the reconsideration request.

(e) *Appeals of reconsideration requests.* A long-term care hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to further amend 45 CFR part 170 as previously proposed to be amended on March 30, 2015 (80 FR 16902) as follows:

Title 45—Public Welfare

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 14. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C.300jj–14; 5 U.S.C. 552.

■ 15. Section 170.315 as proposed to be added on March 30, 2015 (80 FR 16905) is amended by adding paragraph (c)(3) to read as follows:

§ 170.315 2015 Edition health IT certification criteria.

* * * * *

(c) * * *

(3) *Clinical quality measures—report.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) *Mandatory.* At a minimum, in accordance with the standards specified in § 170.205(h) and § 170.205(k) of this chapter; and

(ii) *Optional.* That can be electronically accepted by CMS.

* * * * *

Dated: April 13, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 15, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2015, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2015

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2016 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2016. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2015.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that would be applicable to Medicare LTCHs for FY 2016.

In general, except for SCHs and hospitals located in Puerto Rico, for FY 2016, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.D. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that the MDH program expired for discharges beginning on April 1, 2015 under current law.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.2. of this Addendum for a complete description.)

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2016. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2016. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2016. In section V. of this Addendum, we discuss proposed policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2016. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2016

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2016.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts and Puerto Rico-specific standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2016, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.A. of the preamble of this proposed rule for a complete discussion on the proposed FY 2016 inpatient hospital update. Below is a table with these four options:

FY 2016	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful HR user
Proposed market basket rate-of-increase	2.7	2.7	2.7	2.7
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.35	0.0	−1.35
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.9	0.55	1.225	−0.125

• A proposed update of 1.9 percent to the Puerto Rico-specific standardized amount (that is, the proposed FY 2016 estimate of the market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.6 percentage point for MFP and less 0.2 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act.

• An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.

• An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.

• An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2015 budget neutrality factor and applying a revised factor.

• As discussed below and in section III.G. of the preamble of this proposed rule, an adjustment to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).

• An adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, are budget neutral as required under section 410A(c)(2) of Public Law 108–173.

• An adjustment to remove the FY 2015 outlier offset and apply an offset for FY 2016, as provided for under section 1886(d)(3)(B) of the Act.

• As discussed below and in section II.D. of the preamble of this proposed rule, a recoupment to meet the requirements of section 631 of ATRA to adjust the standardized amount to offset the estimated amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

For FY 2016, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2016 wage index for the rural floor. We note that, in section III.G.2.b. of the preamble to this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2016. Therefore, for FY 2016, in this proposed rule, we are proposing to continue to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which would be reflected in the FY 2016 wage index.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act requires us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2016, we are proposing to continue to use the national and Puerto Rico-specific labor-related and nonlabor-related shares (which are based on the FY 2010-based hospital market basket) that were used in FY 2015. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2016, as discussed in section III. of the preamble of this proposed rule, we are proposing to continue to use a labor-related share of 69.6 percent for the national standardized amounts, and 63.2 percent for the Puerto Rico-specific standardized amount, if the hospital has a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indexes are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 69.6 percent of the national standardized amount.

For FY 2016, all Puerto Rico hospitals have a proposed wage index value that is less than 1.0000 because the proposed average hourly rate of every hospital in Puerto Rico divided by the proposed national average hourly rate (the sum of all salaries and hours for all hospitals in the 50 United States and Puerto Rico) results in a wage index that is below 1.0000. However, when we divide the proposed average hourly rate of every hospital located in Puerto Rico by the proposed Puerto Rico-specific national average hourly rate (the sum of all salaries and hours for all hospitals located only in Puerto Rico), the result is a proposed Puerto Rico-specific wage index value for some hospitals that is either above, or below

1.0000, depending on the hospital's location within Puerto Rico. Therefore, for hospitals located in Puerto Rico, we are proposing to apply a labor-related share of 63.2 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto Rico-specific wage index values are less than or equal to 1.0000, we are proposing to apply a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount and Puerto Rico-Specific Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the FY 2016 national average standardized amount and Puerto Rico-specific standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount and Puerto Rico-Specific Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to use the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2016 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.A. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2016 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) first quarter 2015 forecast of the FY 2010-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2016) of 0.6 percentage point, which is calculated based on IGI's first quarter 2015 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2016 by the estimated market basket percentage increase less 0.2 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services.

Based on IGI's 2015 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2016 is 2.7 percent. As discussed above, for FY 2016, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that could be applied to the standardized amount. We refer readers to section IV.A. of the preamble of this proposed rule for a complete discussion on the proposed FY 2016 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth under section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing to establish an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.9 percent for FY 2016.

Although the update factors for FY 2016 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2016 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2016 standardized amount to remove the effects of the FY 2015 geographic reclassifications and outlier payments before applying the FY 2016 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2016 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

In order to appropriately estimate aggregate payments in our modeling, we make several inclusions and exclusions so that the appropriate universe of claims and charges are included. We discuss IME Medicare Advantage payment amounts, fee-for-service only claims, and charges for anti-hemophilic blood factor and organ acquisition below.

Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

In addition, consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is a fee-for-service claim).

Finally, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2016, we are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital VBP Program which adjust payments to certain IPPS hospitals beginning with discharges on or after October 1, 2012. Because the adjustments made under these programs affect the estimation of aggregate IPPS payments, in this proposed rule, consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act are reduced to account for certain excess readmissions. Under the Hospital Readmissions Reduction Program, for discharges beginning on October 1, 2012 discharges from an ''applicable hospital'' are paid at an amount equal to the product of the ''base operating DRG payment amount'' and an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year plus any applicable add-on payments. We refer readers to section IV.E. of the preamble of this proposed rule for full details of our proposed FY 2016 policy changes to the Hospital Readmissions Reduction Program. We also note that the Hospital Readmissions Reduction Program provided for under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which, for discharges beginning on October 1, 2012, value-based incentive payments are made in a fiscal year to eligible subsection (d) hospitals based on their performance on measures established for a performance period for that fiscal year. As specified under section 1886(o)(7)(B)(i) of the Act, these value-based incentive payments are funded by a reduction applied to each eligible hospital's base-operating DRG payment amount, for each discharge occurring in the fiscal year. As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments with respect to a fiscal year is equal to the total amount of base-operating DRG payment reductions, as estimated by the Secretary. In a given fiscal year, hospitals may earn a value-based incentive payment amount for a fiscal year that is greater than, equal to, or less than the reduction amount, based on their performance on quality measures under the Hospital VBP Program. Thus, the Hospital VBP Program is estimated to have no net effect on overall payments. We refer readers to section IV.F. of the preamble of this proposed rule for details regarding the Hospital VBP Program.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations. For example, when we calculate the budget neutrality factor for MS–DRG reclassification and recalibration of the relative weights, we compare aggregate payments estimated using the prior year's GROUPER and relative weights to estimated payments using the new GROUPER and relative weights. (We refer readers to section II.A.4.a. of this Addendum for details.) Other factors, such as the DSH and IME payment adjustments, are the same on both sides of the comparison because we are only seeking to ensure that aggregate payments do not increase or decrease as a result of the changes of MS–DRG reclassification and recalibration.

In order to properly determine aggregate payments on each side of the comparison, as we did for FY 2014 and FY 2015, for FY 2016 and subsequent years, we are proposing to continue to apply the proposed hospital readmissions payment adjustment and the proposed hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply the proposed readmissions payment adjustment factor and the proposed hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed FY 2016 readmissions payment adjustment factors, we are proposing to use excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2016, in this proposed rule, we are proposing to calculate the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2016 as hospitals have had the opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our proposed policy regarding the reporting of hospital-specific readmission rates for FY 2016 in section IV.E.3.f of the preamble of this proposed rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for FY 2016, in this proposed rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2016 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2016 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, will be

available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2016 (as we did for FY 2014 and FY 2015), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We note that, when calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.D. of the preamble to this proposed rule and below, we are proposing to continue the FY 2014 finalized methodology under which we would take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

In addition, we are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2016. We did not include this adjustment for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include this adjustment for FY 2016 because FY 2016 will be the second year for which hospitals will experience this reduction and data on the prior year's performance are now available. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2016.

a. Proposed Recalibration of MS–DRG Relative Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.H. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2016, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

For FY 2016, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2015 labor-related share percentages, the FY 2015 relative weights, and the FY 2015 pre-reclassified wage data, and applied the proposed FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2015 labor-related share percentages, the proposed FY 2016 relative weights, and the FY 2015 pre-reclassified wage data, and applied the same proposed FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.998335. As discussed in section IV. of this Addendum, we also are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor of 0.998335 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2015.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality adjustment factor, it was necessary to use a three-step process to comply with the requirements that MS–DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. Under the first step, we determined a proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor of 0.998335 (by using the same methodology described above to determine the proposed MS–DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Under the second step, to compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2016 relative weights and the FY 2015 pre-reclassified wage indexes, applied the FY 2015 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2016 hospital readmissions payment adjustment and the estimated FY 2016 hospital VBP payment adjustment; and
- Aggregate payments using the proposed FY 2016 relative weights and the proposed FY 2016 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2016 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2016 hospital readmissions payment adjustments and estimated FY 2016 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2015 to FY 2016. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 0.998681 for proposed changes to the wage index. Finally, we multiplied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor of 0.998335 (derived in the first step) by the proposed

budget neutrality adjustment factor of 0.998681 for proposed changes to the wage index (derived in the second step) to determine the proposed MS–DRG reclassification and recalibration and updated wage index budget neutrality adjustment factor of 0.997018.

b. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2016, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2016 labor-related share percentages, proposed FY 2016 relative weights and proposed FY 2016 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proposed FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2016 labor-related share percentages, proposed FY 2016 relative weights, and proposed FY 2016 wage data after such reclassifications, and applied the same proposed FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks proposed for FY 2016, and apply the proposed policies explained in section III. of the preamble to this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.988486 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2016 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2015 budget neutrality adjustment factor. We note that the proposed FY 2016 budget neutrality adjustment reflects FY 2016 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of the proposed rule.

c. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural and imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this proposed rule, in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor calculated under the original methodology through FY 2013 (76 FR 51594). In the FY 2013 IPPS/LTCH PPS final rule, we established an alternative methodology for calculating the imputed floor and established a policy that the minimum wage index value for an all-urban state would be the higher of the value determined under the original methodology or the value computed using the alternative methodology (77 FR 53368 through 53369). Consistent with the methodology for treating the imputed floor, similar to the methodology we used in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we included this alternative methodology for computing the imputed floor index in the calculation of the uniform, national rural floor budget neutrality adjustment for FY 2014. For FY 2015, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49971), we extended the imputed floor for another year using the higher of the value determined under the original methodology or the alternative methodology. As discussed in section III.H.2. of the preamble of this proposed rule, we are proposing to extend the imputed floor using the higher of the value determined under the original methodology or the alternative methodology for FY 2016. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, we would follow our policy of including the proposed imputed floor in the proposed rural floor budget neutrality adjustment to the wage index.

Under the new OMB labor market area delineations adopted beginning with the FY 2015 wage indexes, New Jersey, Rhode Island, and Delaware are all-urban States. Therefore, for FY 2016, the proposed imputed floor was applied to the wage index for hospitals located in these three States.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2016, we are proposing to calculate a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals located in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals located in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed FY 2016 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we will use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the new OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2016 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2016 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San German, PR (CBSA 41900) and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor and imputed floor budget neutrality adjustment factors and the Puerto Rico-specific rural floor budget neutrality adjustment factor, we are proposing to use FY 2014 discharge data to simulate payments and the proposed post-reclassified national and Puerto Rico-specific wage indexes and compared the following:

- The national and Puerto Rico-specific simulated payments without the proposed national rural floor and proposed imputed floor and proposed Puerto Rico-specific rural floor applied; and
- The national and Puerto Rico-specific simulated payments with the proposed national rural floor and proposed imputed floor and proposed Puerto Rico-specific rural floor applied.

Based on this comparison, we determined a proposed national rural budget neutrality adjustment factor of 0.990135 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.987626. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor budget neutral wage index and the proposed Puerto Rico-specific adjustment was applied to the Puerto Rico-specific wage indexes to produce a proposed Puerto Rico-specific rural floor budget neutral wage index.

d. Wage Index Transition Budget Neutrality

As discussed in section III.G. of the preamble of this proposed rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we determined that the transition to using the new OMB labor market area delineations would have the largest impact on hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban

where the urban area became rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we finalized a policy to generally assign these counties the urban wage index value of the CBSA to which they are physically located in for FY 2014 for FYs 2015, 2016, and 2017. Fiscal year 2016 will be the second year of this 3-year transition policy. We note that the 1-year blended wage index transitional policy for all hospitals that would experience any decrease in their wage index value expires in FY 2015.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), in the past, CMS has budget neutralized transitional wage indexes. We stated that because we established a policy that allows for the application of a transitional wage index only when it benefits the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the OMB delineations without any transitional provisions. Therefore, as we did for FY 2015, for FY 2016, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national and Puerto Rico-specific standardized amounts to ensure that total payments for the effect of the 3-year transitional wage index provisions would equal what payments would have been if we had fully adopted the new OMB delineations without providing these transitional provisions. To calculate the proposed transitional wage index budget neutrality factor for FY 2016, we used FY 2014 discharge data to simulate payments and compared the following:

- Aggregate payments using the OMB delineations for FY 2016, the proposed FY 2016 relative weights, proposed FY 2016 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, and application of the proposed FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments; and
- Aggregate payments using the OMB delineations for FY 2016, the proposed FY 2016 relative weights, proposed FY 2016 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, application of the 3-year transitional wage indexes, and application of the same proposed FY 2016 hospital readmissions payment adjustments and the estimated FY 2016 hospital VBP payment adjustments applied above.

Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.999995. Therefore, for FY 2016, we are proposing to apply a transitional wage index budget neutrality adjustment factor of 0.999995 to the national average and Puerto Rico-specific standardized amounts to ensure that the effects of these proposed transitional wage indexes are budget neutral.

We note that the proposed budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2016 that would result from the second year of the 3-year transitional wage index policies. Therefore, we are proposing to apply this proposed budget neutrality adjustment factor as a one-time adjustment to the FY 2016 national and Puerto Rico-specific standardized amounts in order to offset the increase in payments in FY 2016 as a result of this second year of the 3-year transitional wage index. For subsequent fiscal years, we would not take into consideration the adjustment factor applied to the national and Puerto Rico-specific standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, this adjustment will not be applied cumulatively).

e. Proposed Case-Mix Budget Neutrality Adjustment

(1) Background

Below we summarize the proposed recoupment adjustment to the FY 2016 payment rates, as required by section 631 of ATRA, to account for the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies for FY 2016 in this proposed rule and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix. (2) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment totaling $11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the $11 billion recoupment required by section 631 of ATRA in FY 2014, a one-time −9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014 and FY 2015, we applied a −0.8 percent adjustment to the standardized amount. For FY 2016, we are proposing to apply a −0.8 percent adjustment to the standardized amount. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment would not apply to the Puerto Rico-specific standardized amount and hospital-specific payment rates.

f. Proposed Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.I. of the preamble of this proposed rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration program that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration program for an additional 5-year period, and allowed up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In previous final rules, we have adjusted the national IPPS payment rates by an amount sufficient to account for the added costs of this demonstration program. In other words, we have applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration program. We believe the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For FY 2016, we are proposing to adjust the national IPPS payment rates according to the proposed methodology set forth in section IV.I. of the preamble of this proposed rule, to account for the estimated additional costs of the demonstration program for FY 2016. In addition, we are proposing to subtract from the budget neutrality offset amount for FY 2016 the amount by which the budget neutrality offset amount that was finalized in the FY 2009 IPPS final rule exceeds the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2009). The proposed total budget neutrality offset amount that we are proposing to be applied to the FY 2016 IPPS rates is $17,738,497. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2016, we computed a proposed factor of 0.999808 for the rural community hospital demonstration program budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate.

g. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases

involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2016 is 80 percent, the same marginal cost factor we have used since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) Proposed FY 2016 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes.

For FY 2016, we are proposing to continue to use the same methodology that we used in FY 2014 and FY 2015. As we have done in the past, to calculate the proposed FY 2016 outlier threshold, we simulated payments by applying proposed FY 2016 payment rates and policies using cases from the FY 2014 MedPAR file. Therefore, in order to determine the proposed FY 2016 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2014 to FY 2016. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals.

In the FY 2015 IPPS/LTCH final rule (79 FR 50375), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that, consistent with our longstanding policy since FY 2005, we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. We also stated we would consider how best to provide additional information on the charge inflation factor for future years. In response to those comments, below we are providing a table that provides covered charges and cases by quarter in the periods used to calculate the charge inflation factor.

Quarter	Covered charges (January 1, 2013, through December 31, 2013)	Cases (January 1, 2013, through December 31, 2013)	Covered charges (January 1, 2014, through December 31, 2014)	Cases (January 1, 2014, through December 31, 2014)
1	$126,534,546,428	2,640,744	$125,988,476,809	2,480,809
2	118,741,812,697	2,507,483	121,297,544,913	2,433,390
3	115,745,380,133	2,425,636	116,785,744,335	2,321,731
4	119,331,676,066	2,406,770	89,923,763,220	1,764,002
Total	480,353,415,324	9,980,633	453,995,529,277	8,999,932

Under this new methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2016, we are proposing to compare the average covered charge per case of $48,129 ($480,353,415,324/9,980,633) from the second quarter of FY 2013 through the first quarter of FY 2014 (January 1, 2013, through December 31, 2013) to the average covered charge per case of $50,444 ($453,995,529,277/8,999,932) from the second quarter of FY 2014 through the first quarter of FY 2015 (January 1, 2014, through December 31, 2014). This rate-of-change is 4.8 percent (1.048116) or 9.8 percent (1.098547) over 2 years.

As we have done in the past, in this FY 2016 IPPS/LTCH PPS proposed rule, we are proposing to establish the proposed FY 2016 outlier threshold using hospital CCRs from the December 2014 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of this proposed rule. In the following instances, we substituted and used the proposed FY 2016 statewide average operating and/or capital CCR instead of the operating and/or capital CCR from the PSF if a hospital's operating and/or capital CCR is 0 or blank, if a hospital's operating and/or capital CCR is above the ceilings described below. For FY 2016, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We are proposing that, if more recent data became available, we would use that data to calculate the final FY 2016 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we did for FY 2014 and FY 2015, for FY 2016, we are proposing to adjust the CCRs from the December 2014 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2013 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2014 update of the PSF. We note that we used total transfer-adjusted cases from FY 2014 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, we calculated a proposed December 2013 operating national average case-weighted CCR of 0.288792 and a proposed December 2014 operating national average case-

weighted CCR of 0.280581. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2013 operating national average case-weighted CCR from the December 2014 operating national average case-weighted CCR and then dividing the result by the December 2013 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.971568.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2013 capital national average case-weighted CCR of 0.025014 and a December 2014 capital national average case-weighted CCR of 0.024500. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2013 capital national average case-weighted CCR from the December 2014 capital national average case-weighted CCR and then dividing the result by the December 2013 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.979474.

Consistent with our methodology used in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe that it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average ''age'' of hospitals' CCRs from the time the MAC inserts the CCR in the PSF until the beginning of FY 2016 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

As discussed above, for FY 2016, we are proposing to apply the second year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments would be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State would receive a wage index less than 1.0000 due to the proposed rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2016, it was necessary to apply the proposed 3-year transitional wage indexes and adjust the proposed wage index of those eligible hospitals in a frontier State when calculating the proposed outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2016. If we did not take the above into account, our estimate of total FY 2016 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2016 outlier payments, we are proposing not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where (1) a hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.E. and IV.F. respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F), the new uncompensated care payment under section 1886(r)(2), like the empirically justified Medicare DSH payment under section 1886(r)(1), may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A). As we did for FYs 2014 and 2015, we also are proposing for FY 2016 to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used in FYs 2014 and 2015 to calculate the outlier fixed-loss cost threshold, for FY 2016, we are proposing to include estimated FY 2016 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we are proposing an outlier fixed-loss cost threshold for FY 2016 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $24,485.

We note that the proposed FY 2016 fixed-loss cost threshold is lower than the FY 2015 final outlier fixed-loss cost threshold of $24,626. We believe that the decrease in the charge inflation factor (compared to the FY 2015 charge inflation factor) contributed to a lower proposed outlier fixed-loss threshold for FY 2016. As charges decrease, so does the amount of outlier payments. As a result, it was necessary for us to lower the proposed outlier fixed-loss cost threshold to increase the amount of outlier payments expended in order to reach the 5.1 percent target.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2016 will result in outlier payments that will equal 5.1 percent of

operating DRG payments and 6.43 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2016 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2016 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate
National	0.948999	0.935731
Puerto Rico	0.926818	0.925658

We are proposing to apply the outlier adjustment factors to the proposed FY 2016 payment rates after removing the effects of the FY 2015 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.22 or capital CCRs greater than 0.173, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet on the CMS Web site) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2015, these statewide average ratios would replace the ratios posted on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Tables.html.* Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2016 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2014 and FY 2015 Outlier Payments

In the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59681), we stated that, based on available data, we estimated that actual FY 2014 outlier payments would be approximately 5.68 percent of actual total MS–DRG payments. This estimate was computed based on simulations using the FY 2013 MedPAR file (discharge data for FY 2013 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2014 claims, but instead reflected the application of FY 2014 payment rates and policies to available FY 2013 claims.

Our current estimate, using available FY 2014 claims data, is that actual outlier payments for FY 2014 were approximately 5.34 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2014, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2014. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2014 are equal to 5.1 percent of total MS–DRG payments.

We currently estimate that, using the latest CCRs from the December 2014 update of the PSF, actual outlier payments for FY 2015 will be approximately 4.88 percent of actual total MS–DRG payments, approximately 0.22 percentage point lower than the 5.1 percent we projected when setting the outlier policies for FY 2015. This estimate of 4.88 percent is based on simulations using the FY 2014 MedPAR file (discharge data for FY 2014 claims).

5. Proposed FY 2016 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2016. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2016.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2016 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). This table also includes the proposed Puerto Rico-specific standardized amounts. The labor-related share applied to the proposed Puerto Rico-specific standardized amount is the proposed labor-related share of 63.2 percent, or 62 percent, depending on which provides higher payments to the hospital. (Section 1886(d)(9)(C)(iv) of the Act, as amended by

section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the changes from the FY 2015 national standardized amount to the proposed FY 2016 national standardized amount. The second through fifth columns display the proposed changes from the FY 2015 standardized amounts for each applicable FY 2016 standardized amount. The first row of the table shows the updated (through FY 2015) average standardized amount after restoring the FY 2015 offsets for outlier payments, demonstration budget neutrality, geographic reclassification budget neutrality, new labor market delineation wage Index transition budget neutrality and the retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2015 adjustment factors are not removed from this table.

COMPARISON OF FY 2015 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2016 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2015 Base Rate after removing: ..... 1. FY 2015 Geographic Reclassification Budget Neutrality (0.990429). 2. FY 2015 Rural Community Hospital Demonstration Program Budget Neutrality (0.999313). 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013 and FY 2014, FY 2015 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9329).	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23; Nonlabor (30.4%): $1,888.74.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23; Nonlabor (30.4%): $1,888.74.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23; Nonlabor (30.4%): $1,888.74.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,324.23; Nonlabor (30.4%): $1,888.74.
4. FY 2015 Operating Outlier Offset (0.948999) ..... 5. FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.998854).	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04; Nonlabor (38%): $2,360.93.	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04; Nonlabor (38%): $2,360.93.	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04; Nonlabor (38%): $2,360.93.	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,852.04; Nonlabor (38%): $2,360.93.
Proposed FY 2016 Update Factor	1.019	1.0055	1.01225	0.99875.
Proposed FY 2016 MS-DRG Recalibration and Wage Index Budget Neutrality Factor.	0.997018	0.997018	0.997018	0.997018.
Proposed FY 2016 Reclassification Budget Neutrality Factor.	0.988486	0.988486	0.988486	0.988486.
Proposed FY 2016 Rural Community Demonstration Program Budget Neutrality Factor.	0.999808	0.999808	0.999808	0.999808.
Proposed FY 2016 Operating Outlier Factor	0.948999	0.948999	0.948999	0.98999.
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015 and FY 2016 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9255	0.9255	0.9255	0.9255.
Proposed FY 2016 New Labor Market Delineation Wage Index Three Year Hold Harmless Transition Budget Neutrality Factor.	0.999995	0.999995	0.999995	0.999995.
Proposed National Standardized Amount for FY 2016 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: $3,813.40; Nonlabor: $1,665.63.	Labor: $3,762.88; Nonlabor: $1,643.56.	Labor: $3,788.14; Nonlabor: $1,654.60.	Labor: $3,737.62; Nonlabor: $1,632.53.
Proposed National Standardized Amount for FY 2016 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,397.00; Nonlabor: $2,082.03.	Labor: $3,351.99; Nonlabor: $2,054.45.	Labor: $3,374.50; Nonlabor: $2,068.24.	Labor: $3,329.49; Nonlabor: $2,040.66.

The following table illustrates the proposed changes from the FY 2015 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the proposed changes from the FY 2015 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index greater than 1.0000. The third column shows the proposed changes from the FY 2015 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than or equal to 1.0000. The first row of the table shows the updated (through FY 2015) Puerto Rico-specific payment rate after restoring the FY 2015 offsets for Puerto Rico-specific outlier payments, rural community hospital demonstration program budget neutrality, and the geographic reclassification budget neutrality. The MS–DRG recalibration budget neutrality adjustment factor is cumulative and is not removed from this table.

COMPARISON OF FY 2015 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE PROPOSED FY 2016 PUERTO RICO-SPECIFIC PAYMENT RATE

	Proposed update (1.9 percent); wage index is greater than 1.0000; labor/non-labor share percentage (63.2/36.8)	Proposed update (1.9 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
FY 2015 Puerto Rico Base Rate, after removing: ..... 1. FY 2015 Geographic Reclassification Budget Neutrality (0.990429)	Labor: $1,758.02; Nonlabor: $1,023.66.	Labor: $1,724.64; Nonlabor: $1,057.04.

COMPARISON OF FY 2015 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE PROPOSED FY 2016 PUERTO RICO-SPECIFIC PAYMENT RATE—Continued

	Proposed update (1.9 percent); wage index is greater than 1.0000; labor/non-labor share percentage (63.2/36.8)	Proposed update (1.9 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
2. FY 2015 Rural Community Hospital Demonstration Program Budget Neutrality (0.999313).		
3. FY 2015 Puerto Rico Operating Outlier Offset (0.926334).		
4. FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.998854).		
Proposed FY 2016 Update Factor	1.019	1.019.
Proposed FY 2016 MS-DRG Recalibration Budget Neutrality Factor	0.998335	0.998335.
Proposed FY 2016 Reclassification Budget Neutrality Factor	0.988486	0.988486.
Proposed FY 2016 Rural Community Hospital Demonstration Program Budget Neutrality Factor.	0.999808	0.999808.
Proposed FY 2016 New Labor Market Delineation Wage Index Three Year Hold Harmless Transition Budget Neutrality Factor.	0.999995	0.999995.
Proposed FY 2016 Puerto Rico Operating Outlier Factor	0.926818	0.926818.
Proposed Puerto Rico-Specific Payment Rate for FY 2016	Labor: $1,638.15; Nonlabor: $953.86.	Labor: $1,607.05; Nonlabor: $984.96.

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2016. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2016 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make such adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to continue to use the same COLA factors in FY 2016 that were used in FY 2015 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2016.

PROPOSED FY 2016 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur in FY 2018.

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2016

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs, for FY 2016 equals the Federal rate (which includes uncompensated care payments). We note that the MDH program expired for discharges beginning on April 1, 2015 under current law.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.D. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2016 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below.

The prospective payment rate for hospitals located in Puerto Rico for FY 2016 equals 25 percent of the Puerto Rico-specific payment rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—For hospitals located in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS–DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal payment rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by a specified formula. The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate (which, as discussed in section IV.D. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082). We also refer readers to section IV.D. of the preamble of this proposed rule for a complete discussion on empirically justified Medicare DSH and uncompensated care payments.

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2016

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs are the following:

FY 2016	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.35	0.0	−1.35
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Hospital Specific Rate	1.9	0.55	1.225	−0.125

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs, we refer readers to section IV.A. of the preamble of this proposed rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, a SCH's hospital-specific rate is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.998335, as discussed in section III. of this Addendum. The resulting rate is used in determining the proposed payment rate that an SCH would receive for its discharges beginning on or after October 1, 2015. We note that, in this proposed rule, for FY 2016, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2015, and Before October 1, 2016

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico-Specific Rate

The Puerto Rico-specific prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (obtained from Table 1C published in section VI. of this Addendum and available via the Internet).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5—Multiply the result in Step 4 by 25 percent.

b. National Prospective Payment Rate

The national prospective payment rate is determined as follows:

Step 1—Select the applicable national average standardized amount.

Step 2—Multiply the labor-related portion of the national average standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (obtained from Table 5 listed in section VI. of this Addendum and available via the Internet on the CMS Web site).

Step 5—Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico-specific rate and the national prospective payment rate computed above equals the prospective payment rate for a given discharge for a hospital located in Puerto Rico. This payment rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care payments into consideration when calculating outlier payments.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2016

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the proposed capital Federal rate for FY 2016, which would be effective for discharges occurring on or after October 1, 2015.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Effective October 1, 2004, in accordance with section 504 of Public Law 108–173, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 25 percent of the applicable standardized amount specific to Puerto Rico hospitals and 75 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 2004, we also revised the methodology for computing capital payments made to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185).

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2016. In particular, we explain why the proposed FY 2016 capital Federal rate increases approximately 0.8 percent, compared to the FY 2015 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 2.0 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2016 under that framework is 1.3 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.3 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed below in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2016 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2016.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2016, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 0.5 percent for FY 2016. The proposed net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected

total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2016 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2014 DRG reclassification and recalibration as part of our update for FY 2016. We estimate that FY 2014 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2016.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. A forecast error of 0.0 percentage point is calculated for the proposed FY 2016 update. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.0 percentage point was calculated for the FY 2014 update. That is, current historical data indicate that the forecasted FY 2014 CIPI (1.2 percent) used in calculating the FY 2014 update factor was equal to the actual realized price increases (also 1.2 percent). Therefore, we are not proposing to make an adjustment for a forecast error in the update for FY 2016.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CIPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2016 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2016, we are proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2009 and extending through FY 2013. Based on these data, we estimated that case-mix constant intensity declined during FYs 2009 through 2013. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to propose to continue to apply a zero intensity adjustment for FY 2016. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2016.

Above, we described the basis of the components used to develop the proposed 1.3 percent capital update factor under the capital update framework for FY 2016 as shown in the table below.

PROPOSED CMS FY 2016 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.3
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2014 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

*The capital input price index is based on the FY 2010-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2015 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2016. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2015, Chapter 3, available on the Web site at: *http://www.medpac.gov*.)

2. Proposed Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2015, we estimated that outlier payments for capital will equal 6.18 percent of inpatient capital-related payments based on the capital Federal rate in FY 2015. Based on the proposed thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs would equal 6.43 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2016. Therefore, we are proposing to apply an outlier adjustment factor of 0.9357 in determining the proposed capital Federal rate for FY 2016. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2016 will be higher than the percentage for FY 2015.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2016 outlier adjustment of 0.9357 is a −0.27 percent change from the FY 2015 outlier adjustment of 0.9382. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2016 is 0.9973 (0.9357/0.9382). Thus, the outlier adjustment would decrease the proposed FY 2016 capital Federal rate by 0.27 percent compared to the FY 2015 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

To determine the proposed factors for FY 2016, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG classifications and relative weights and the FY 2015 GAF to estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG classifications and relative weights and the proposed FY 2016 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9982 for FY 2016 to the previous cumulative FY 2015 adjustment factor of 0.9884, yielding a proposed adjustment factor of 0.9867 through FY 2016. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9980 for FY 2016 to the previous cumulative FY 2015 adjustment factor of 1.0082, yielding a proposed cumulative adjustment factor of 1.0062 through FY 2016.

We then compared estimated aggregate capital Federal rate payments based on the FY 2015 MS–DRG relative weights and the proposed FY 2016 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2016 MS–DRG classifications and relative weights and the proposed FY 2016 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9994 both nationally and for Puerto Rico. The proposed cumulative adjustment factors for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2016 are 0.9861 nationally and 1.0056 for Puerto Rico. (We note that all the values are calculated with unrounded numbers.) The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are determined separately) for changes in the GAF (including geographic reclassification) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The proposed cumulative adjustment factor accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. It also incorporates the effects on the proposed GAFs of FY 2016 geographic reclassification decisions made by the MGCRB compared to FY 2015 decisions. However, it does not account for proposed changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2016

For FY 2015, we established a capital Federal rate of $434.97 (79 FR 59684). We are proposing to establish an update of 1.3 percent in determining the FY 2016 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $438.40 for FY 2016. The proposed national capital Federal rate for FY 2016 was calculated as follows:

- The proposed FY 2016 update factor is 1.0013, that is, the proposed update is 1.3 percent.
- The proposed FY 2016 budget neutrality adjustment factor that is applied to the proposed capital Federal rate for proposed changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9976.
- The proposed FY 2016 outlier adjustment factor is 0.9357.

(We note that, as discussed in section VI.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2016.)

Because the proposed FY 2016 capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2016 affects the computation of the proposed FY 2016 national capital Federal rate in comparison to the FY 2015 national capital Federal rate. The proposed FY 2016 update factor has the effect of increasing the capital Federal rate by 1.3 percent compared to the FY 2015 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.24 percent. The proposed FY 2016 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.27 percent compared to the FY 2015 capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by 0.79 percent compared to the FY 2015 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2015 CAPITAL FEDERAL RATE AND PROPOSED FY 2016 CAPITAL FEDERAL RATE

	FY 2015	Proposed FY 2016	Change	Percent change
Update Factor [1]	1.0150	1.0130	1.0130	1.3
GAF/DRG Adjustment Factor [1]	0.9993	0.9976	0.9976	−0.24
Outlier Adjustment Factor [2]	0.9382	0.9357	0.9973	−0.27
Capital Federal Rate	$434.97	$438.40	.0079	0.79

[1] The proposed update factor and the proposed GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the proposed incremental change from FY 2015 to FY 2016 resulting from the application of the proposed 0.9976 GAF/DRG budget neutrality adjustment factor for FY 2016 is a proposed net change of 0.9976 (or −0.24 percent).

[2] The proposed outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the proposed capital Federal rate. Thus, for example, the proposed net change resulting from the application of the proposed FY 2016 outlier adjustment factor is 0.9357/0.9382, or 0.9973 (or −0.27 percent).

5. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments made to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, beginning with discharges occurring on or after October 1, 2004, capital payments made to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico

capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality adjustment factor for MS–DRG reclassifications and recalibration nationally and for Puerto Rico. The proposed budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF and the proposed budget neutrality factor for MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) are discussed in section III.A.3. of this Addendum.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico).

For FY 2015, the special capital rate for hospitals located in Puerto Rico was $209.45 (79 FR 59683). With the changes we are proposing to make to the factors used to determine the proposed capital Federal rate, the proposed FY 2016 special capital rate for hospitals in Puerto Rico is $213.77.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2016

For purposes of calculating payments for each discharge during FY 2016, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2016 are in section II.A. of this Addendum. For FY 2016, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $24,485.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

2. Forecast of the CIPI for FY 2016

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2015), we are forecasting the FY 2010-based CIPI to increase 1.3 percent in FY 2016. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.6 percent increase in other capital expense prices in FY 2016, partially offset by a projected 1.2 percent decline in vintage-weighted interest expense prices in FY 2016. The weighted average of these three factors produces the forecasted 1.3 percent increase for the FY 2010-based CIPI as a whole in FY 2016.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Proposed Rate-of-Increase Percentages for FY 2016

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In this proposed rule, the FY 2016 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs is the estimated percentage increase in the FY 2016 IPPS operating market basket, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2015 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2016 is 2.7 percent (that is, the estimate of the market basket rate-of-increase). However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2016.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2016. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Updates to the Payment Rates for the LTCH PPS for FY 2016

A. Proposed LTCH PPS Standard Federal Rate for FY 2016

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2016.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at § 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012, 2013, 2014, and 2015, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (c)(3)(ix).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.D.2. of the preamble of this proposed rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.D.2.a. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2015, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase of 2.9 percent and the 0.7 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xi) of the regulations, we established an annual update of 2.2 percent to the standard Federal rate for FY 2015 (79 FR 50391through 50392).

For FY 2016, as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate based on the full estimated increase in the LTCH PPS market basket, less the MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In addition, as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, the annual update will be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

Specifically, in this proposed rule, based on the best available data, we are proposing to establish an annual update to the standard Federal rate of 1.9 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less the proposed MFP adjustment of 0.6 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. For LTCHs that fail to submit the required quality reporting data for FY 2016 in accordance with the LTCH QRP, the proposed annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act (as discussed in greater detail in section VII.D.2.c. of the preamble of this proposed rule). Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of −0.1 percent for LTCHs that fail to submit the required quality reporting data for FY 2016. This proposed −0.1 percent update is calculated based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less a proposed MFP adjustment of 0.6 percentage point, less an additional adjustment of 0.2 percentage point required by the statute, and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2016 LTCH PPS Standard Federal Payment Rate

We continue to believe that the annual update to the LTCH PPS standard Federal payment rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, for FY 2016, we are proposing to apply the annual update to the LTCH PPS standard Federal rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2016, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2016 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the proposed changes related to the proposed area wage adjustment (that is, proposed changes to the wage data and proposed labor-related share) in accordance with § 412.523(d)(4). We also are proposing that if more recent data become available, we would use that data, if appropriate, to determine the update to the LTCH PPS standard Federal payment rate for FY 2016 in the final rule.

For FY 2015, we established an annual update to the LTCH PPS standard Federal rate of 2.2 percent for FY 2015 based on the full estimated LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xi), we established an annual update to the standard Federal rate for FY 2015 of 2.2 percent. That is, we applied an update factor of 1.022 to the FY 2014 Federal rate of $40,607.31 to determine the FY 2015 standard Federal rate. The standard Federal rate for FY 2015 was further adjusted by an adjustment factor of 0.98734 for FY 2015 under the final year of the 3-year phase-in of the one-time prospective adjustment at § 412.523(d)(3)(ii). We also applied an area wage level budget neutrality factor for FY 2015 of 1.0016703 to the standard Federal rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established a standard Federal rate for FY 2015 of $41,043.71 (calculated as $40,607.31 × 1.022 × 0.98734 × 1.001670) (79 FR 50392).

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 1.9 percent, which was determined using the methodology previously described. Therefore, consistent with our proposal, under proposed § 412.523(c)(3)(xii), we are proposing to apply a factor of 1.019 to the FY 2015 standard Federal rate of $41,043.71 to determine the proposed FY 2016 LTCH PPS standard Federal payment rate. These proposed factors are based on IGI's first quarter 2015 forecast, which are the best available data at this time. For LTCHs that fail to submit quality reporting data for FY 2016 under the LTCH QRP, consistent with our proposal, under proposed § 412.523(c)(3)(xii), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing to reduce the annual update to the LTCH PPS standard Federal payment rate by an additional 2.0 percentage points consistent with section 1886(m)(5) of the Act. In those cases, the LTCH PPS standard Federal payment rate would be updated by −0.1 percent (that is, a proposed update factor of 0.999) for FY 2016 for LTCHs that fail to submit the required quality reporting data for FY 2016 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are proposing to apply a proposed area wage level budget neutrality factor to the FY 2016 standard Federal rate of 1.001444, which was determined using the methodology previously described. We are proposing to apply this area wage level budget neutrality factor to the FY 2016 LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment

(that is, the annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish a LTCH PPS standard Federal payment rate of $41,883.93 (calculated as $41,043.71 × 1.019 × 1.001444) for FY 2016. For LTCHs that fail to submit quality reporting data for FY 2016 in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are proposing to establish a LTCH PPS standard Federal payment rate of $41,061.87 (calculated as $41,043.71 × 0.999 × 1.001444) for FY 2016. Consistent with our historical practice, we are proposing that if more recent data is available, we would use such data to calculate the standard Federal rates for FY 2016 in the final rule. We note, as discussed in section VII.B. of the preamble to this proposed rule, under our proposed application of the site neutral payment rate required under section 1886(m)(6) of the Act, this LTCH PPS standard Federal payment rate would only be used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate).

B. Proposed Adjustment for Area Wage Levels for the LTCH PPS Standard Federal Payment Rate for FY 2016

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSAs) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area.

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the new OMB labor market area delineations based on the 2010 Decennial Census data. We made these revisions because we believe that these OMB delineations are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. At the time of the development of this proposed rule, OMB had not issued any further updates subsequent to OMB Bulletin No. 13–01, which was dated February 28, 2013, and established revised delineations based on 2010 Census Bureau data that were subsequently adopted in the FY 2015 IPPS/LTCH PPS final rule. (The OMB bulletins are available on the OMB Web site at: *http://www.whitehouse.gov/omb*. Go to ''Information For Agencies'' and click on ''Bulletins''.) Therefore, for FY 2016, we are proposing to continue to use the CBSA-based labor market area delineations currently used under the LTCH PPS (as adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185)). We believe that these CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All-Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS and the development of the RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, we determined the labor-related share for FY 2013 as the sum of the FY 2013 relative importance of each labor-related cost category of the FY 2009-based LTCH-specific market basket. For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479). Consistent with our historical practice, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50393through 50394), we determined the LTCH PPS labor-related share for FY 2015 based on the FY 2015 relative importance of each labor-related cost category, which reflected the different rates of price change for these cost categories between the base year (FY 2009) and FY 2015. Specifically, based on IGI's second quarter 2014 forecast of the FY 2009-based LTCH-specific market basket, we established a labor-related share under the LTCH PPS for FY 2015 of 62.306 percent.

For FY 2016, we are proposing to establish a labor-related share for the LTCH PPS standard Federal payment rate payments based on IGI's first quarter 2015 forecast of the FY 2009-based LTCH-specific market basket. Consistent with our historical practice, we also are proposing that if more recent data become available, we would use such data, if appropriate, to determine the final FY 2016 labor-related share. In addition, we are proposing to specify the labor-related share to one decimal place, which is consistent with the IPPS labor-related share and the LTCH market basket update. The following table shows the proposed FY 2016 labor-related share relative importance using IGI's first quarter 2015 forecast of the FY 2009-based LTCH-specific market basket. The sum of the relative importance for FY 2016 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All Other: Labor-Related Services) is 58.1 percent. We are proposing to establish that the portion of capital-related costs that is influenced by the

local labor market would continue to be estimated to be 46 percent. Because the relative importance for capital-related costs would be 9.0 percent of the FY 2009-based LTCH-specific market basket in FY 2016, we are proposing to take 46 percent of 9.0 percent to determine the labor-related share of capital-related costs for FY 2016, which would result in 4.1 percent (0.46 × 9.0). We then added that 4.1 percent for the capital-related cost amount to the 58.1 percent for the operating cost amount to determine the total proposed labor-related share for FY 2016. Therefore, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to establish a labor-related share under the LTCH PPS for FY 2016 of 62.2 percent. This proposed labor-related share is determined using the same methodology as used in calculating all previous fiscal years LTCH labor-related shares.

PROPOSED FY 2016 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2009–BASED LTCH–SPECIFIC MARKET BASKET

	Proposed FY 2016 labor-related share relative importance
Wages and Salaries	44.8
Employee Benefits	8.1
Professional Fees: Labor-Related	2.2
Administrative and Business Support Services	0.5
All Other: Labor-Related Services	2.5
Subtotal	58.1
Proposed Labor-Related Portion of Capital Costs (46 percent)	4.1
Proposed Total Labor-Related Share	62.2

4. Proposed Wage Index for FY 2016 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2015 LTCH PPS final rule (79 FR 50394through 50396), we calculated the FY 2015 LTCH PPS area wage index values using the same data used for the FY 2015 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2011), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2015 LTCH PPS area wage index values consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time, and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2016 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2012, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2012 wage data because these data are the most recent complete data available. We also noted that these are the same data used to compute the proposed FY 2016 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. We are proposing to compute the proposed FY 2016 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, as previously discussed in section V.B.2. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We also are proposing to continue to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, under our proposed methodology for determining the FY 2016 LTCH PPS standard Federal payment rate area wage index values, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2012 IPPS wage data that we are proposing to use to determine the proposed FY 2016 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2016 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2012 IPPS wage data that we are proposing to use to determine the proposed FY 2016 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for proposed rural areas with no IPPS wage data for FY 2016. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The proposed FY 2016 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2015, through September 30, 2016, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Proposed Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In this proposed rule, for FY 2016 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2016 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2015 wage index values, including the 50/50 blended area wage index values, as applicable, and the FY 2015 labor-related share of 62.306 percent (as established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50393 and 50397).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2016 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the Internet on the CMS Web site) and the proposed FY 2016 labor-related share of 62.2 percent (based on the latest available data as previously discussed previously in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2015 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2016 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2016 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the proposed FY 2016 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2016 LTCH PPS standard Federal payment rate after the application of the proposed FY 2016 annual update (discussed previously in section V.A.2. of this Addendum).

We note that, under the statutory dual-rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) would be paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate were in effect at the time of discharge to calculate the proposed FY 2016 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above. (For additional information on our proposed application of site neutral payment rate required under section 1886(m)(6) of the Act, we refer readers to section VII.B. of the preamble of this proposed rule.)

For this proposed rule, using the steps in the methodology described above, we determined a proposed FY 2016 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.001444. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2016 LTCH PPS standard Federal payment rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 1.001444, in accordance with § 412.523(d)(4). The proposed FY 2016 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

C. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

Under our current methodology, we update the COLA factors for Alaska and Hawaii every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) (77 FR 53712 through 53713). This methodology is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to section VII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).)

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Under our finalized policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Therefore, in this proposed rule, for FY 2016, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2014 IPPS/LTCH PPS final rule. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice, we are proposing to establish that the COLA factors shown in the following table would be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2016

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Overview

a. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of the BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. Under our current HCO policy at § 412.525(a), we set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under the current HCO policy, we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted payment under the LTCH PPS standard Federal payment rate plus a fixed-loss amount. Specifically, in accordance with existing § 412.525(a)(3), we make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted payment under the LTCH PPS standard Federal payment rate and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital incurs under the outlier policy for a case with unusually high costs before the LTCH will receive any additional payments. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the current LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (the adjusted LTCH PPS standard Federal payment rate payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the current HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that an LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

b. Application of the Site Neutral Payment Rate

Section 1206 of Public Law 113–67 establishes a new dual-rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges, beginning in FY 2016. To implement this statutory change, as discussed in section VII.B. of the preamble of this proposed rule, we are proposing to pay hospitals for LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) based on the LTCH PPS standard Federal payment rate, which includes HCO payments determined under existing § 412.525(a). Furthermore, we are proposing that the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4) (including any applicable adjustments, such as outlier payments), or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2), consistent with the statute.

Under the new statutory dual-rate LTCH PPS payment structure, as discussed in section VII.B.7.b. of the preamble of this proposed rule, we are proposing to establish two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. We are proposing to revise the regulations by making the proposed changes to the HCO policy to account for the new statutory dual-rate LTCH PPS payment structure by revising paragraphs (a)(1), (a)(2), and (a)(3), and adding a new paragraph (a)(4) to existing § 412.525 of the regulations. Under our proposed HCO policy revised in accordance with the new statutory LTCH PPS payment structure, we are proposing to establish a fixed-loss amount and target for LTCH PPS standard Federal payment rate cases using the current LTCH PPS HCO policy, but limiting the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges. Therefore, we are not proposing any modifications to the HCO methodology as it applies to LTCH PPS standard Federal payment rate cases other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. Specifically, under our proposal, LTCH PPS standard Federal payment rate cases would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which would be the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount for such cases. The fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to be equal to 8 percent of estimated total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

Furthermore, we are proposing to revise the HCO policy under existing § 412.525(a) to provide for high-cost outlier payments under the site neutral payment rate. Specifically, we are proposing that site neutral payment rate cases would receive an additional payment for HCOs that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold for site neutral payment rate discharges, which we are proposing would be the sum of site neutral payment rate for the case and the IPPS fixed-loss amount. In addition, in order to maintain budget neutrality, we are proposing to make the HCO payments for site neutral payment rate cases budget neutral by applying a proposed budget neutrality factor to the LTCH PPS payments for those site neutral payment rate cases. (Additional details on the proposed budget neutrality adjustment for HCO payments to site neutral payment rate cases is discussed subsequently in section V.D.4. of this Addendum.)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO cases under § 412.525(a), SSO cases paid under the LTCH PPS in accordance with § 412.529, and proposed site neutral payment rate cases paid in accordance with proposed § 412.522(c) (as discussed in section VII.B.4. of the preamble of this proposed rule). Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for HCO, SSO, and proposed site neutral payment rate cases (to determine the estimated costs of these cases), we are discussing the determination of CCRs under the LTCH PPS for these three types of cases simultaneously in this section.

In determining HCO payments in accordance with § 412.525(a), SSO payments in accordance with § 412.529 and proposed site neutral payment rate payments in accordance with proposed § 412.522(c), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B), for HCOs, § 412.529(f)(4)(ii) for SSOs, and proposed § 412.522(c)(1)(ii) for proposed site neutral payment rate cases. (We note that, in some instances under the provisions of the regulations at § 412.525(a)(4)(iv) and § 412.529(f)(4), and proposed § 412.522(c)(1)(ii), we may use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or that is requested by the hospital.) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single ''overall'' or ''total'' LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total charges.

Specifically, an LTCH's CCR is calculated by dividing an LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, an LTCH is assigned the applicable statewide average CCR if, among other things, an LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Therefore, under our established policy, generally, if an LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In this proposed rule, using our established methodology for determining the LTCH total CCR ceiling, based on IPPS total CCR data from the December 2014 update of the PSF, we are proposing to establish a total CCR ceiling of 1.345 under the LTCH PPS for FY 2016 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs, § 412.529(f)(4)(iii)(B) for SSOs, and proposed § 412.522(c)(1)(ii) for site neutral payment rate cases. We also are proposing that if more recent data become available, we would use that data to determine the LTCH PPS CCR ceiling for the FY 2016 final rule.

c. LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on ''total'' IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) the SSO policy at § 412.529(f)(4)(iii), and the proposed site neutral payment rate policy at proposed § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2014 update of the PSF, we are proposing to establish proposed LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2015 through September 30, 2016, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also are proposing that if more recent data become available, we would use that data to determine the LTCH PPS statewide average total CCRs for FY 2016.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and Massachusetts have areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of December 2014. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and Massachusetts in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO, SSO, and Proposed Site Neutral Payment Rate Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the SSO policy at § 412.529(f)(4)(iv), and as proposed for site neutral payment rate cases at proposed § 412.522(c)(4), the payments for HCO, SSO, and site neutral payment rate cases are subject to reconciliation. Specifically, any reconciliation of payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. Our proposal to establish a reconciliation process for payments made to LTCHs for site neutral payment rate cases is discussed in section VII.B.4.a. of the preamble of this proposed rule. For additional information on the existing reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2016

When we implemented the LTCH PPS, under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under the HCO policy at § 412.525(a), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted standard Federal rate payment and the fixed-loss amount).

As noted above and as discussed in greater detail in section VII.B.7.b. of the preamble of this proposed rule, under the new statutory dual-rate LTCH PPS payment structure, we are proposing to establish two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. Under this proposal, for LTCH PPS standard Federal payment rate cases, we are proposing to establish a fixed-loss amount and target using the current LTCH PPS HCO policy, but to limit the data used under that policy to LTCH cases that would have been paid as LTCH PPS standard Federal payment rate cases, if that payment rate had been in effect at the time of those discharges. Therefore, we are not proposing to make any modifications to the existing LTCH PPS HCO payment methodology as it applies to LTCH PPS standard Federal payment rate cases, other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. As such, LTCH PPS standard Federal payment rate cases would continue to receive an additional payment for any HCO case that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which would be the sum of the LTCH PPS payment for the LTCH PPS standard Federal payment rate case and the fixed-loss amount. The fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to equal 8 percent of estimated total LTCH PPS standard Federal payment rate cases, and a budget neutrality factor will continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments

for LTCH PPS standard Federal payment rate cases would be budget neutral. Below we present our proposed calculation of the proposed LTCH PPS fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016, which is consistent with the methodology used to establish the FY 2015 LTCH PPS fixed-loss amount. (Additional discussion of our HCO payment policy proposals for site neutral payment rate cases is discussed subsequently in section V.D.4. of this Addendum.)

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50399 through 50400), we presented our policies regarding the methodology and data we used to establish a fixed-loss amount of $14,972 for FY 2015, which was calculated using our existing methodology (based on the data and the rates and policies presented in that final rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2015, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the March 2014 update of the FY 2013 MedPAR file and CCRs from the March 2014 update of the PSF, as these data were the most recent complete LTCH data available at that time.

In this proposed rule, we are proposing to continue to use our existing methodology to calculate a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the proposed rates and policies for these cases presented in this proposed rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the December 2014 update of the FY 2014 MedPAR file and CCRs from the December 2014 update of the PSF), we are proposing to determine a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2016 that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments for these cases in FY 2016. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount of $18,768 for LTCH PPS standard Federal payment rate cases for FY 2016, and also to continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $18,768).

We note that the proposed fixed-loss amount of $18,768 for LTCH PPS standard Federal payment rate cases for FY 2016 is higher than the FY 2015 fixed-loss amount of $14,792. This increase is largely attributable to the implementation of the new statutory dual-rate LTCH PPS payment structure, under which we have proposed to have separate HCO target amounts for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases. The FY 2015 fixed-loss amount was determined based data from all LTCH cases—both those that would have been paid as site neutral payment rate cases and those that would have been paid as LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at that time. However, under our proposal, the proposed fixed-loss amount of $18,768 for FY 2016 would only be used to determine HCO payments made for LTCH PPS standard Federal payment rate cases. We currently estimate that the FY 2015 fixed-loss amount of $14,972 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 8.6 percent of total estimated FY 2015 LTCH PPS payments to those cases, which exceeds the 8 percent target. Therefore, we believe that it is necessary and appropriate to increase the fixed-loss amount to maintain that, for LTCH PPS standard Federal payment rate cases, estimated HCO payments would equal 8 percent of estimated total LTCH PPS payments for those cases as required under the proposed revisions to § 412.525(a). (For further information on the existing 8 percent HCO ''target'' requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Maintaining the fixed-loss amount at the current level would result in HCO payments that are more than the current regulatory 8-percent target that we are proposing would apply to total payments for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount would result in more cases qualifying as outlier cases, as well as higher outlier payments for qualifying HCO cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller. Consistent with our historical practice, we are proposing that if more recent data is available, we would use such data to calculate the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases in the final rule.

b. Application of the High-Cost Outlier Policy to SSO Cases

Under our proposals to implement the dual-rate LTCH PPS payment structure required by statute, we are proposing that LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) would continue to be paid based on the LTCH PPS standard Federal payment rate, and would include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. (For additional information on our proposed payments for LTCH standard payment rate cases, we refer readers to section VII.B.4.c. of the preamble of this proposed rule.) Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as an HCO. Therefore, for an SSO case in FY 2016, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $18,768 and the amount paid under the SSO policy as specified in § 412.529).

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under the new dual-rate LTCH PPS payment structure, the statute establishes two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, as discussed in section VII.B. of the preamble of this proposed rule, we are proposing to pay for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) based on the LTCH PPS standard Federal payment rate. In addition, consistent with the statute, we are proposing that the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). Furthermore, we are proposing have two separate HCO targets-one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases.

For site neutral payment rate cases, we are proposing that such cases would receive an additional HCO payment for costs that exceed the HCO threshold that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold. We are proposing that the HCO threshold for site neutral payment rate cases would be the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. (We note that, as discussed in section VII.B.7.b. of the preamble of this proposed rule, in light of our HCO proposals in accordance with our implementation of the new statutory dual-rate LTCH PPS payment structure, any site neutral payment rate case that is paid 100 percent of the estimated cost of the case (because that amount is lower than the IPPS comparable per diem amount) would not be eligible to receive a HCO payment because, by definition, the estimated costs of such cases would never exceed the IPPS comparable amount by any threshold.) Under this proposal, we are proposing that HCO payments for site neutral payment rate cases would be budget neutral, such that the proposed site neutral payment rate HCO payments would not result in any change in estimated aggregate LTCH PPS payments. In order to achieve this, under proposed new § 412.522(c)(2)(i), we are proposing to apply a budget neutrality factor to the payments for all site neutral payment rate cases, which would be established on an estimated basis. (For additional details on our HCO policy

proposals for site neutral payment rate cases, we refer readers to section VII.B.7.b. of the preamble of this proposed rule.)

As we discussed in section VII.B.7.b. of the preamble of this proposed rule, in order to estimate the magnitude a proposed budget neutrality adjustment for HCO payments for site neutral payment rate cases, we relied on the assumption by our actuaries that site neutral payment rate cases would have lengths of stay and costs comparable to IPPS cases assigned to the same MS–DRG. Because site neutral payment rate cases are expected to have lengths of stay and costs comparable to IPPS cases assigned to the same MS DRG, we project that our proposal to use the IPPS fixed-loss threshold for the site neutral payment rate cases would result in HCO payments for site neutral payment rate cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. Therefore, under proposed new § 412.522(c)(2)(i), we are proposing to adjust all payments for site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments.

The statutory LTCH PPS payment changes required by section 1886(m)(6) of the Act (that is, the application of the site neutral payment rate) are effective for LTCH PPS discharges occurring in cost reporting periods beginning on or after October 1, 2015. In this proposed rule, to estimate total LTCH PPS site neutral payment rate payments in Federal FY 2016, we are proposing an adjustment to account for the varying effective dates of the statutory dual-rate LTCH PPS payment structure. In order to estimate FY 2016 LTCH PPS payments based on site neutral payment rate cases, it is necessary to account for the fact that LTCHs whose cost reporting periods begin after October 1, 2015, will receive the LTCH PPS standard Federal payment rates for all of their LTCH PPS cases, including their cases that would be site neutral payment rate cases, until the start of their next cost reporting period. For purposes of estimating site neutral payment rate payments in FY 2016, we examined LTCHs whose cost reporting periods begin in the first quarter of FY 2016 (that is, October through December 2015). We modeled that all of the FY 2016 site neutral payment rate cases associated with these LTCHs would be paid at the proposed transitional blended payment rate (that is, 50 percent of the applicable site neutral payment rate amount for the discharge as determined under proposed new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate determined under § 412.523). All of the first quarter FY 2016 site neutral payment rate cases for LTCHs whose cost reporting periods begin after the start of the first quarter of FY 2016 were modeled as being paid at the LTCH PPS standard Federal payment rate for all discharges in that quarter. We then examined LTCHs whose cost reporting periods begin in the second quarter of FY 2016 (that is, January through March 2016). We modeled that all of the second, third, and fourth quarter FY 2016 site neutral payment rate cases associated with these LTCHs would be paid at the transitional blended payment rate. All of the second quarter FY 2016 site neutral payment rate cases for LTCHs whose cost reporting periods begin after the start of the second quarter of FY 2016 were modeled as being paid at the LTCH PPS standard Federal payment rate for all discharges in that quarter. Similarly, we examined LTCHs whose cost reporting periods begin in the third quarter of FY 2016 (that is, April through June 2016). We modeled that all of the third and fourth quarter FY 2016 site neutral payment rate cases associated with these LTCHs would be paid at the transitional blended payment rate. For all of the third quarter FY 2016 site neutral payment rate cases for LTCHs whose cost reporting periods begin after the start of the third quarter of FY 2016, we modeled as being paid at the LTCH PPS standard Federal payment rate. Finally, we examined LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016 (that is, July through September of 2016). We modeled all of the fourth quarter FY 2016 site neutral payment rate cases associated with these LTCHs as being paid at the transitional blended payment rate. We believe that this approach is reasonable for the purpose of taking into account in our FY 2016 payment estimates given the fact that LTCHs whose cost reporting periods begin after October 1, 2015 will receive the LTCH PPS standard Federal payment rate as payment for all of their LTCH PPS cases, including their cases that would be categorized as site neutral payment rate cases, until the start of their next cost reporting period. Based on the fiscal year start dates recorded in the December update of the Provider Specific File, of the 418 LTCHs in our database of LTCH claims from the December 2014 update of the FY 2014 MedPAR files used for this proposed rule, the following percentages apply in the approach described above: 10.85 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the first quarter of FY 2016; 31.41 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the second quarter of FY 2016; 10.83 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the third quarter of FY 2016; and 46.91 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016.

Using the approach described above to account for when LTCHs' first cost reporting period begins on or after October 1, 2015, and based on the applicable LTCH claims in our database from the December 2014 update of the FY 2014 MedPAR files, we estimate that site neutral payment rate HCO payments would be approximately 2.3 percent of total LTCH PPS payments for site neutral payment rate cases in FY 2016. Therefore, we are proposing to apply a budget neutrality factor of 0.976996 to all payments for site neutral payment rate cases in FY 2016 so that the estimated HCO payments payable to those cases do not result any increase in aggregate LTCH PPS payments, in accordance with proposed new § 412.522(c)(2)(i).

E. Proposed Update to the IPPS Comparable/Equivalent Amounts To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule, we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. As explained in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50766 through 50767), we believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of

care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50400 through 50401), we discussed that, for FY 2015, based on the latest data available at that time, we projected that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the proposed payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments equaling 85.26 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act. Therefore, the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 for FY 2015 includes an applicable operating Medicare DSH payment amount that would be equal to 85.26 percent of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act.

For FY 2016, as discussed in greater detail in section IV.D.3.d.(2) of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) would be adjusted to 63.69 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount would then be used to determine the amount of uncompensated care payments that will be made to eligible IPPS hospitals in FY 2016. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act would be adjusted to 47.77 percent (the product of 75 percent and 63.69 percent) and the resulting amount would be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2016, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments of 72.77 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is, 25 percent + 47.77 percent = 72.77 percent).

We also are proposing that, consistent with our historical practice of using the most recent data available, if more recent data become available for the final rule, we would use such data to determine the percentage of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act used in the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 for FY 2016. In this proposed rule, for FY 2016, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 would include an applicable operating Medicare DSH payment amount that will be equal to 72.77 percent of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2016

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under the new statutory dual-rate LTCH PPS payment structure that begins in FY 2016, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate would be paid based on the LTCH PPS standard Federal payment rate (as discussed in section VII.B. of the preamble of this proposed rule). Under § 412.525(c), the proposed LTCH PPS standard Federal rate is adjusted to account for differences in area wages by multiplying the proposed labor-related share of the LTCH PPS standard Federal payment for a case by the applicable LTCH PPS wage index (FY 2016 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet). The proposed LTCH PPS standard Federal payment is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2016 factors are shown in the chart in section V.D. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2016 of $41,883.93, as discussed in section V.A.2. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal rate for FY 2016 in the following example:

Example: During FY 2016, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The proposed FY 2016 LTCH PPS wage index value for CBSA 16974 is 1.0295 (obtained from Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2016 of 0.9071 (obtained from Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2016 in accordance with the LTCHQRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2016, we computed the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2016 LTCH PPS standard Federal payment rate ($41,883.93) by the proposed labor-related share (62.2 percent) and the proposed wage index value (1.0295). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (37.8 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9071) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2016 ($38,690.05). The table below illustrates the components of the calculations in this example.

Proposed LTCH PPS Standard Federal Prospective Payment Rate	$41,883.93
Proposed Labor-Related Share	× 0.622
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $26,051.80
Proposed Wage Index (CBSA 16974)	× 1.0295
Proposed Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $26,820.33
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,883.93 × 0.378)	+ $15,832.13
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $42,652.46
MS–LTC–DRG 189 Proposed Relative Weight	× 0.9071
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $38,690.05

VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2015, for the FY 2016 rulemaking cycle, the IPPS and LTCH tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available only through the Internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in section III. I. of the preamble to this proposed rule, we are proposing to streamline and consolidate the wage index tables for FY 2016 and subsequent fiscal years. In previous fiscal years, the wage index tables have consisted of the following 12 tables: Table 2 (acute care hospitals' case-mix indexes; hospital wage indexes; hospital average hourly wages, and

3-year average of hospital average hourly wages); Table 3A (relevant fiscal year and 3-year average hourly wage for acute care hospitals in urban areas by CBSA); Table 3B (relevant fiscal year and 3-year average hourly wage for acute care hospitals in rural areas by CBSA); Table 4A (wage index and capital geographic adjustment factor (GAF) for acute care hospitals in urban areas by CBSA and by State); Table 4B (wage index and capital GAF for acute care hospitals in rural areas by CBSA and by State); Table 4C (wage index and capital GAF for acute care hospitals that are reclassified by CBSA and by State); Table 4D (States designated as frontier, with acute care hospitals receiving at a minimum the frontier State floor wage index; urban areas with acute care hospitals receiving the statewide rural floor or imputed rural floor wage index); Table 4E (urban CBSAs and constituent counties for acute care hospitals); Table 4F (Puerto Rico wage index and capital GAF for acute care hospitals by CBSA); Table 4J (out-migration adjustment for acute care hospitals); Table 9A (hospital reclassifications and redesignations); and Table 9C (hospitals redesignated as rural under section 1886(d)(8)(e) of the Act). With the exception of Table 4E, we are proposing to consolidate the information from the 11 other tables listed above into 2 new tables. The wage index tables provided in previous fiscal years either display information by CMS Certification Number (CCN) or by CBSA number. The new Table 2 contains information by CCN and information from the following tables that have been provided in previous fiscal years: Tables 2, 4J, 9A, and 9C. The new Table 3 contains information by CBSA and information from the following tables that have been provided in previous fiscal years: Tables 3A, 3B, 4A, 4B, 4C, 4D, and 4F. We believe these two new tables will be easier for the public to navigate and find all the relevant data and information from the tables provided in previous fiscal years. Finally, in previous fiscal years, Table 4E provided a list of urban CBSAs and constituent counties. Because of formatting technicalities, we found it difficult to consolidate the information from Table 4E into the proposed two new tables. Therefore, we are proposing to provide the data previously published as Table 4E for each annual proposed and final rule as one of our data files on our Web page (the same Web page where the county to CBSA crosswalk is posted).

As discussed in sections II.G.3.e., II.G.10.a., II.G.11., and II.G.13. of the preamble of this proposed rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2016: Table 6B—New Procedure Codes; Table 6I—Complete MCC List; Table 6J—Complete CC List; Table 6K—Complete List of CC Exclusions; Table 6L—Principal Diagnosis Is Its Own MCC List; Table 6M—Principal Diagnosis Is Its Own CC List; Table 6M.1—Additions to the Principal Diagnosis Is Its Own CC List; and Table 6P—ICD–10–PCS Code Translations for Proposed MS–DRG Changes. Table 6P contains multiple tables 6P.1a through 6P.2a that list the ICD–10–PCS code translations relating to specific MS–DRG proposals. In addition, under the HAC Reduction Program established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. However, as discussed in section IV.G. of the preamble of this proposed rule, we are not providing the hospital-level data as a table associated with this proposed rule. The hospital-level data for the FY 2016 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, a hospital's Factor 3 is the proportion of the uncompensated care amount that a DSH eligible hospital will receive under section 3133 of the Affordable Care Act. Factor 3 is the hospital's estimated number of Medicaid days and Medicare SSI days relative to the estimate of all DSH hospitals' Medicaid days and Medicare SSI days. Table 18 associated with this proposed rule contains the FY 2016 Medicare DSH uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2016.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2016 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2016 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2016
Table 3.—Proposed Wage Index Table by CBSA—FY 2016
Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2016
Table 6B.—New Procedure Codes—FY 2016
Table 6I.—Proposed Complete Major CC List—FY 2016
Table 6J.—Proposed Complete CC List—FY 2016
Table 6K.—Proposed Complete List of CC Exclusions—FY 2016
Table 6L.—Proposed Principal Diagnosis Is Its Own MCC List—FY 2016
Table 6M.—Proposed Principal Diagnosis Is Its Own CC List—FY 2016
Table 6M.1.—Proposed Additions to the Principal Diagnosis Is Its Own CC List—FY 2016
Table 6P.—ICD–10–PCS Code Translations for Proposed MS–DRG Changes—FY 2016
Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2014 MedPAR Update—December 2014 GROUPER V32.0 MS–DRGs
Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2014 MedPAR Update—December 2014 GROUPER V33.0 MS–DRGs
Table 8A.—Proposed FY 2016 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2016 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals.
Table 10.—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2017
Table 15.—Proposed FY 2016 Proxy Readmissions Adjustment Factors
Table 16.—Proposed Proxy Hospital Inpatient Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2016
Table 18.—Proposed FY 2016 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2016 proposed rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1632–P:

Table 8C.—Proposed FY 2016 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, Short-Stay Outlier (SSO) Threshold, and ''IPPS Comparable Threshold'' for LTCH PPS Discharges Occurring from October 1, 2015 through September 30, 2016
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring From October 1, 2015 through September 30, 2016
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2015 through September 30, 2016
Table 13A.—Proposed Composition of Low-Volume Quintiles for MS–LTC–DRGs—FY 2016
Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2016

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (69.6 PERCENT LABOR SHARE/30.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2016

Hospital submitted quality data and is a meaningful EHR user (update = 1.9 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.225 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.55 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.125 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,813.40	$1,665.63	$3,788.14	$1,654.60	$3,762.88	$1,643.56	$3,737.62	$1,632.53

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2016

Hospital submitted quality data and is a meaningful EHR user (update = 1.9 percent)		Hospital did not submit quality data and is a meaningful EHR user (update = 1.225 percent)		Hospital submitted quality data and is not a meaningful EHR user (update = 0.55 percent)		Hospital did not submit quality data and is not a meaningful EHR user (update = −0.125 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,397.00	$2,082.03	$3,374.50	$2,068.24	$3,351.99	$2,054.45	$3,329.49	$2,040.66

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1; PUERTO RICO: 63.2 PERCENT LABOR SHARE/36.8 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1 OR 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1—FY 2016

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	NA	NA	$3,397.00	$2,082.03
Puerto Rico	$1,638.15	$953.86	1,607.05	984.96

[1] For FY 2016, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATES—FY 2016

	Rate
National	$468.51
Puerto Rico	230.93

TABLE 1E— PROPOSED LTCH PPS STANDARD FEDERAL RATE—FY 2016

	Full update (1.9 percent)	Reduced update * (−0.1 percent)
Standard Federal Rate	$41,883.93	$41,061.87

* For LTCHs that fail to submit quality reporting data for FY 2016 in accordance with the LTCH Quality Reporting Program (LTCHQRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. 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 (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2016 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated

$278 million increase in proposed FY 2016 operating payments (or 0.3 percent change) and an estimated $160 million increase in proposed FY 2016 capital payments (or 2.0 percent change). These proposed changes are relative to payments made in FY 2015. The impact analysis of the proposed capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by $250 million in FY 2016 relative to FY 2015.

Our operating impact estimate includes the proposed −0.8 percent documentation and coding adjustment applied to the IPPS standardized amount, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the proposed 1.9 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update less 0.6 percentage point for the proposed multifactor productivity adjustment and less 0.2 percentage point required under the Affordable Care Act). The estimates of proposed IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall proposed payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

B. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2016, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included In and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2015, there were 3,366 IPPS acute care hospitals included in our analysis. This represents approximately 56 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,329 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and proposed policy changes to the LTCH PPS for FY 2016 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2015, there were 99 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 248 rehabilitation hospitals and 884 rehabilitation units, and approximately 430 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 495 psychiatric hospitals and 1,122 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2016 percentage increase in the IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2016 and subsequent fiscal years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2015 forecast of the FY 2010-based market basket increase, we are estimating that the FY 2016 update based on the IPPS operating market basket is 2.7 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.6 percentage point for FY 2016) and a 0.2 percentage point reduction to the market basket update resulting in a proposed 1.9 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.A. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNCHIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the FY 2016 IPPS operating market basket, estimated at 2.7 percent, without the reductions described above under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases

experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit, or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and proposed payment rate updates for the IPPS for FY 2016 for operating costs of acute care hospitals. The proposed FY 2016 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2016 operating payments will increase by 0.3 percent compared to FY 2015. In addition to the applicable percentage increase, this amount reflects the proposed FY 2016 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this proposed rule of −0.8 percent to the IPPS national standardized amounts. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this proposed rule. However, there are other proposed changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented below are taken from the FY 2014 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2014 MedPAR file, we simulated payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The proposed impact of payments under the capital IPPS, or the proposed impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2016 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- The effects of the proposed application of the documentation and coding adjustment and the applicable percentage increase (including the proposed market basket update, the proposed multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2012, compared to the FY 2011 wage data, to calculate the proposed FY 2016 wage index.
- The combined effects of the proposed recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act and the proposed wage index (including the updated wage data and the continued implementation of the new OMB labor market area delineations), including the proposed wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that would be effective for FY 2016.
- The effects of the proposed rural floor and imputed floor with the application of the proposed national budget neutrality factor to the wage index.
- The effects of the second year of the 3-year transition for urban hospitals that were located in an urban county that become rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The total estimated change in payments based on the proposed FY 2016 policies relative to payments based on FY 2015 policies that include the applicable percentage increase of 1.9 percent (or 2.7 percent market basket update with a proposed reduction of 0.6 percentage point for the multifactor productivity adjustment, and a 0.2 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2016 changes, our analysis begins with a FY 2015 baseline simulation model using: the FY 2015 applicable percentage increase of 2.2 percent and the documentation and coding recoupment adjustment of −0.8 percent to the Federal standardized amount; the FY 2015 MS–DRG GROUPER (Version 32); the FY 2015 CBSA designations for hospitals based on the new OMB definitions; the FY 2015 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2016, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.225 percent. At the time that this impact was prepared, 26 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2015 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2016 using a proposed reduced update for these 26 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2016.

For FY 2016, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not an meaningful EHR user will be subject to a reduction of one-half of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act.

Therefore, for FY 2016, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.55 percent. At the time that this impact analysis was prepared, 153 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2015 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2016 using a proposed reduced update for these 153 hospitals. We did not include these hospitals in the model for estimation purposes for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include these 153 hospitals for estimation purposes in FY 2016 because FY 2016 will be the second year in which hospitals will experience this reduction and data on the prior year's performance are now available. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2016 using a proposed reduced update for these 153 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update increase for FY 2016.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of −0.125 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a one-half reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 24 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2016 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act. We did not include these hospitals in the model for estimation purposes for FY 2015 because that was the first year hospitals experienced a reduction to their applicable percentage increase due to whether they are meaningful EHR users and data were not available at that time. However, we believe it is appropriate to include these 24 hospitals for estimation purposes in FY 2016 because FY 2016 will be the second year in which hospitals will experience this reduction and data on the prior year's performance are now available. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2016 using a proposed reduced update for these 24 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update increase for FY 2016.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2016 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our final comparison illustrates the percent change in payments per case from FY 2015 to FY 2016. Three factors not discussed separately have significant impacts here. The first factor is the proposed update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2016 using a proposed applicable percentage increase of 1.9 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.7 percent with a proposed reduction of 0.6 percentage point for the multifactor productivity adjustment and a 0.2 percentage point reduction as required under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.225 percent. This proposed update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of 0.55 percent, which includes a reduction of one-half of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of −0.125 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs also are equal to the applicable percentage increase, or 1.9 percent if the hospital submits quality data and is a meaningful EHR user. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 1.9 percent.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2015 to FY 2016 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2015 that are no longer reclassified in FY 2016. Conversely, payments may increase for hospitals not reclassified in FY 2015 that are reclassified in FY 2016.

A third significant factor is that we currently estimate that actual outlier payments during FY 2015 will be 4.9 percent of total MS–DRG payments. When the FY 2015 IPPS/LTCH PPS final rule was published, we projected FY 2015 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the lower than expected outlier payments during FY 2015 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2015 payments per case to estimated proposed FY 2016 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2016. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,366 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,530 hospitals located in urban areas included in our analysis. Among these, there are 1,390 hospitals located in large urban areas (populations over 1 million), and 1,140 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 836 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' proposed FY 2016 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,479; 1,383; 1,096; and 887, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,325 nonteaching hospitals in our analysis, 794 teaching hospitals with fewer than 100 residents, and 247 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, RRCs). There were 211 RRCs, 327 SCHs, and 125 hospitals that are both SCHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2013 or FY 2012 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2016. The second grouping shows the MGCRB rural reclassifications.

TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2016

	Number of Hospitals (1) [1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment (2) [2]	Proposed FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3) [3]	Proposed FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4) [4]	Proposed FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5) [5]	FY 2016 MGCRB Reclassifications (6) [6]	Proposed Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7) [7]	Application of the Proposed Frontier Wage Index and Proposed Out-Migration Adjustment (8) [8]	All Proposed FY 2016 Changes (9) [9]
All Hospitals	3,366	1.1	0	0	0	0	0	0.1	0.3
By Geographic Location:									
Urban hospitals	2,530	1.1	0	0	0	-0.1	0	0.1	0.3
Large urban areas	1,390	1.1	0.1	0.1	0.2	-0.3	0	0.1	0.3
Other urban areas	1,140	1.1	0	-0.1	-0.2	0.1	0.1	0.2	0.3
Rural hospitals	836	1.5	-0.2	-0.4	-0.5	1.4	-0.3	0.1	-0.3
Bed Size (Urban):									
0-99 beds	666	1.1	-0.2	-0.1	-0.2	-0.6	0	0.3	0
100-199 beds	777	1.1	-0.1	0.1	0.1	0	0.2	0.2	0.3
200-299 beds	446	1.1	0	0	-0.1	0.1	0.1	0.1	0.4
300-499 beds	428	1.1	0	0	0	-0.2	0.1	0.2	0.4
500 or more beds	213	1.1	0.1	0	0.2	-0.2	-0.2	0	0.3
Bed Size (Rural):									
0-49 beds	329	1.4	-0.2	-0.3	-0.5	0.4	-0.3	0.3	-1
50-99 beds	298	1.5	-0.3	-0.3	-0.5	0.9	-0.3	0.2	-0.9
100-149 beds	121	1.6	-0.2	-0.3	-0.4	1.4	-0.2	0.2	0.3
150-199 beds	48	1.4	-0.2	-0.5	-0.6	2.1	-0.3	0.1	0.3
200 or more beds	40	1.3	-0.1	-0.6	-0.5	2.4	-0.3	0	0.1
Urban by Region:									
New England	120	1.1	0	0.9	1	1.3	1.6	0	0.1
Middle Atlantic	318	1.1	0.1	0.4	0.4	0.5	-0.4	0.1	0.6
South Atlantic	407	1.1	0	0.1	0.1	-0.4	-0.4	0.1	0.3
East North Central	396	1.1	0	-0.1	-0.1	-0.4	-0.5	0	0.3
East South Central	150	1.1	0	-0.3	-0.3	-0.6	-0.4	0	-0.3
West North Central	165	1.1	0	-0.4	-0.4	-0.7	-0.4	0.8	0.4
West South Central	382	1.1	0	-0.4	-0.4	-0.5	-0.5	0	-0.3
Mountain	161	1.2	-0.1	0	-0.1	0	-0.1	0.2	0.4
Pacific	380	1	0	0	-0.1	-0.1	1.8	0.1	0.8
Puerto Rico	51	1.2	0	-1.1	-1	-1	0.1	0.1	-2.8
Rural by Region:									

The final category shows the impact of the proposed policy changes on the 14 cardiac hospitals.

	Number of Hospitals (1)[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment (2)[2]	Proposed FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3)[3]	Proposed FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4)[4]	Proposed FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5)[5]	FY 2016 MGCRB Reclassifications (6)[6]	Proposed Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7)[7]	Application of the Proposed Frontier Wage Index and Proposed Out-Migration Adjustment (8)[8]	All Proposed FY 2016 Changes (9)[9]
New England	22	1.3	-0.1	-0.5	-0.6	1.9	-0.4	0	-1.2
Middle Atlantic	55	1.5	-0.1	0.4	0.2	0.7	-0.3	0.1	-0.6
South Atlantic	128	1.4	-0.2	-0.1	-0.4	2.2	-0.4	0.2	0
East North Central	116	1.5	-0.2	-0.1	-0.3	1.3	-0.2	0.1	0.1
East South Central	164	1.1	0	-1	-0.9	2.6	-0.5	0.1	-1.2
West North Central	101	1.8	-0.3	-0.3	-0.5	0.2	0	0.3	0.7
West South Central	165	1.4	-0.1	-1	-0.9	1.5	-0.4	0.1	-1.1
Mountain	61	1.6	-0.3	-0.2	-0.4	0.2	-0.1	0.2	0.9
Pacific	24	1.6	-0.4	0.2	-0.3	0.1	-0.2	0	1
By Payment Classification:									
Urban hospitals	2,479	1.1	0	0	0.1	-0.1	0	0.1	0.3
Large urban areas	1,383	1.1	0.1	0.1	0.2	-0.3	0	0.1	0.3
Other urban areas	1,096	1.1	0	-0.1	-0.2	0.1	0.1	0.2	0.4
Rural areas	887	1.4	-0.2	-0.3	-0.5	1.1	-0.2	0.3	-0.3
Teaching Status:									
Nonteaching	2,325	1.2	-0.1	-0.1	-0.1	0.1	0.2	0.1	0.2
Fewer than 100 residents	794	1.1	0	0	0	-0.1	0	0.2	0.3
100 or more residents	247	1.1	0.1	0.1	0.3	0	-0.2	0	0.3
Urban DSH:									
Non-DSH	680	1.1	-0.1	0.1	0	0.1	0	0.2	1
100 or more beds	1,572	1.1	0	0	0.1	-0.1	0	0.1	0.2
Less than 100 beds	333	1.1	-0.1	0.1	0	-0.7	0	0.2	0.2
Rural DSH:									
SCH	253	1.8	-0.3	-0.1	-0.4	0	-0.1	0	0.8
RRC	220	1.4	-0.2	-0.3	-0.5	1.6	-0.2	0.4	0.1
100 or more beds	33	0.9	0	-0.6	-0.5	1.8	-0.4	0.1	-1.5
Less than 100 beds	275	1	-0.1	-0.5	-0.5	1.3	-0.5	0.5	-2.7
Urban teaching and DSH:									
Both teaching and DSH	846	1.1	0.1	0	0.1	-0.2	-0.1	0.1	0.2
Teaching and no DSH	132	1.1	-0.1	0.1	0	0.6	0.2	0.1	1.2

	Number of Hospitals (1)[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment (2)[2]	Proposed FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3)[3]	Proposed FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4)[4]	Proposed FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5)[5]	FY 2016 MGCRB Reclassifications (6)[6]	Proposed Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7)[7]	Application of the Proposed Frontier Wage Index and Proposed Out-Migration Adjustment (8)[8]	All Proposed FY 2016 Changes (9)[9]
No teaching and DSH	1,059	1.1	0	-0.1	-0.1	-0.1	0.4	0.1	0.2
No teaching and no DSH	442	1.1	-0.1	0.2	0.1	-0.3	-0.1	0.2	1.1
Special Hospital Types:									
RRC	211	1.1	-0.1	-0.6	-0.6	2.1	-0.3	0.5	-0.6
SCH	327	1.8	-0.3	-0.2	-0.4	0	-0.1	0	1
SCH and RRC	125	1.8	-0.3	-0.1	-0.4	0.4	0	0	1.2
Type of Ownership:									
Voluntary	1,934	1.1	0	0	0	0	0	0.1	0.4
Proprietary	880	1.1	0	-0.1	-0.1	0	0.1	0.1	-0.1
Government	529	1.1	0	-0.1	0	-0.2	0.1	0.1	0
Medicare Utilization as a Percent of Inpatient Days:									
0-25	713	1	0.1	0	0.1	-0.2	0.3	0.1	-0.6
25-50	2,110	1.1	0	0	0	0	-0.1	0.1	0.4
50-65	332	1.2	-0.1	-0.1	-0.2	0.5	0	0.1	0.5
Over 65	66	1.1	-0.1	0.4	0.2	0.2	0.1	0	0.6
FY 2016 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	861	1.1	0	0	0	2	0	0	0.6
Non-Reclassified Hospitals	2,505	1.1	0	0	0	-0.9	0	0.2	0.1
Urban Hospitals Reclassified	585	1.1	0	0	0.1	1.9	0	0	0.7
Urban Nonreclassified Hospitals	1,894	1.1	0	0	0.1	-0.9	0	0.1	0.2

	Number of Hospitals (1)[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment (2)[2]	Proposed FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3)[3]	Proposed FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4)[4]	Proposed FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5)[5]	FY 2016 MGCRB Reclassifications (6)[6]	Proposed Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7)[7]	Application of the Proposed Frontier Wage Index and Proposed Out-Migration Adjustment (8)[8]	All Proposed FY 2016 Changes (9)[9]
Rural Hospitals Reclassified Full Year	276	1.4	-0.2	-0.4	-0.5	2.3	-0.3	0	0.1
Rural Nonreclassified Hospitals Full Year	505	1.6	-0.2	-0.3	-0.5	-0.3	-0.2	0.3	-0.7
All Section 401 Reclassified Hospitals:	58	1.4	-0.2	0	-0.2	-1	0.1	1.4	-0.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	1.2	-0.1	-0.4	-0.5	3.7	-0.5	0	-0.7
Specialty Hospitals									
Cardiac specialty Hospitals	14	1.1	0.3	-0.7	-0.3	-1.1	0	0.9	1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2014, and hospital cost report data are from reporting periods beginning in FY 2013 and FY 2012.

[2] This column displays the payment impact of the proposed hospital rate update and the proposed documentation and coding adjustment including the proposed 1.9 percent adjustment to the national standardized amount and hospital-specific rate (the estimated 2.7 percent market basket update reduced by the proposed 0.6 percentage point for the multifactor productivity adjustment and the 0.2 percentage point reduction under the Affordable Care Act) and the proposed -0.8 percent documentation and coding adjustment to the national standardized amount.

[3] This column displays the payment impact of the proposed changes to the Version 33 GROUPER, the proposed changes to the relative weights and the proposed recalibration of the MS-DRG weights based on FY 2014 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998335 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2012 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 0.998681.

[5] This column displays the combined payment impact of the proposed changes in Columns 3 through 4 and the proposed cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The proposed cumulative wage and recalibration budget neutrality factor of 0.997018 is the product of the proposed wage budget neutrality factor and the proposed recalibration budget neutrality factor.

[6] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the proposed FY 2016 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2016. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.988486.

[7] This column displays the effects of the proposed rural floor and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor (which includes the proposed imputed floor) applied to the wage index is 0.990135. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a budget neutrality factor of 0.999995.

[8] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are nonbudget neutral policies.

[9] This column shows the proposed changes in payments from FY 2015 to FY 2016. It reflects the impact of the proposed FY 2016 hospital update and the proposed adjustment for documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2016 compared to FY 2015. It incorporates all of the proposed changes displayed in Columns 2, 5, 6, 7, and 8, (the proposed changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the proposed percentage changes shown here due to rounding and interactive effects.

a. Effects of the Proposed Hospital Update and Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 2.7 percent market basket update, the proposed reduction of 0.6 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2016 documentation and coding recoupment adjustment of −0.8 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA. As a result, we are proposing to make a 1.1 percent update to the national standardized amount. This column also includes the proposed 1.9 percent update to the hospital-specific rates which includes the proposed 2.7 percent market basket update, the proposed reduction of 0.6 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act.

Overall, hospitals would experience a 1.1 percent increase in payments primarily due to the combined effects of the proposed hospital update and the proposed documentation and coding adjustment on the national standardized amount and the proposed hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate, namely SCHs, would experience a 1.9 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 1.1 percent.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 3)

Column 3 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2016 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2016, the MS–DRGs are calculated using the FY 2014 MedPAR data grouped to the Version 33 (FY 2016) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 3 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.998335 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience increases in their payments under the proposed relative weights. Rural hospitals would experience a 0.2 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents would experience an increase in payments by 0.1 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed Wage Index Changes (Column 4)

Column 4 shows the impact of proposed updated wage data using FY 2012 cost report data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2016 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01). (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index).

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2016 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012. The estimated impact of the proposed updated wage data using the FY 2012 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the proposed percentage change in payments when going from a model using the FY 2015 wage index, based on FY 2011 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2016 pre-reclassification wage index based on FY 2012 wage data with the labor-related share of 69.6 percent, under the new OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other proposed payment parameters such as use of the Version 33 MS–DRG GROUPER constant. The proposed FY 2016 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2016, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 69.6 percent are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2016 wage budget neutrality factor is 0.998681, and the proposed overall payment change is 0.0 percent.

Column 4 shows the impacts of updating the wage data using FY 2012 cost reports. Overall, the new wage data and the labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals as shown in Column 4.

In looking at the wage data itself, the proposed national average hourly wage increased 1.02 percent compared to FY 2015. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 1.02 percent increase in average hourly wage. Of the 3,302 hospitals with wage data for both FYs 2015 and 2016, 1,673 or 50.7 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2016 relative to FY 2015. Among urban hospitals, 9 would experience a decrease of 10 percent or more, and 13 urban hospitals would experience an increase of 10 percent or more. One hundred and fifty-four urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 9 would experience a decrease of at least 5 percent but less than 10 percent, but no rural hospitals would experience an increase of greater than or equal to 5 percent but less than 10 percent. No rural hospital would experience increases or decreases of 10 percent or more. However, 806 rural hospitals would experience increases or decreases of less than 5 percent, while 2,305 urban hospitals would experience increases or decreases of less than 5 percent. Six urban hospitals would not experience a change in their wage index, and all rural hospitals would experience a change in their proposed wage indexes. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the proposed wage index before the application of proposed geographic reclassification, the proposed rural and imputed floors, the proposed out-migration adjustment, and other proposed wage index exceptions and adjustments. (We refer readers to sections

III.G.2. through III.I. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the proposed ''post-reclassified wage index'' or proposed ''payment wage index,'' which is the proposed wage index that includes all such proposed exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 69.6 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the chart below may illustrate a somewhat larger or smaller change than would occur in a hospital's proposed payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2016 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	13	0
Increase greater than or equal to 5 percent and less than 10 percent	60	0
Increase or decrease less than 5 percent	2,305	806
Decrease greater than or equal to 5 percent and less than 10 percent	94	9
Decrease 10 percent or more	9	0
Unchanged	6	0

d. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 5)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a proposed wage budget neutrality factor of 0.998681 and a proposed recalibration budget neutrality factor of 0.998335 (which is also applied to the proposed Puerto Rico-specific standardized amount and the proposed hospital-specific rates). The product of the two proposed budget neutrality factors is the proposed cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.997018, or approximately 0.3 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this proposed rule, we are estimating that the proposed changes in the MS–DRG relative weights and proposed updated wage data with wage and budget neutrality applied would result in a 0.0 percent change in payments.

e. Effects of Proposed MGCRB Reclassifications (Column 6)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2016.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS proposed rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.988486 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories would experience increases in payments due to MGCRB reclassifications.

New Table 2 listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the proposed reclassifications for FY 2016.

f. Effects of the Proposed Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 7)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011, 2012, 2013, 2014, and 2015 IPPS/LTCH PPS final rules, and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban state and thus eligible for an imputed floor. For FY 2016, we are proposing to extend the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology. As a result, New Jersey, Rhode Island, and Delaware would be able to receive an imputed floor. In New Jersey, 16 out of 64 hospitals would receive the imputed floor, and 4 out of 11 hospitals in Rhode Island would receive the imputed floor for FY 2016. For FY 2016, no hospitals would benefit from the imputed floor in Delaware because the CBSA wage index for each CBSA in Delaware under the new OMB delineations is equal to or higher than the imputed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. We have calculated a proposed FY 2016 rural floor budget neutrality factor to be applied to the wage index of 0.990135, which would reduce proposed wage indexes by 0.99 percent.

Column 7 shows the projected impact of the proposed rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2016 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2016 wage index of providers with the proposed rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the

budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 383 hospitals would benefit from the rural and imputed floors in FY 2016, while the remaining 2,983 IPPS hospitals in our model would have their wage index reduced by the proposed rural floor budget neutrality adjustment of 0.990135 (or 0.99 percent). We project that, in aggregate, rural hospitals would experience a 0.3 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas would experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 1.6 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts. Thirty-nine urban providers in Massachusetts are expected to receive the rural floor wage index value, including the proposed rural floor budget neutrality of 0.990135, increasing payments overall to Massachusetts by an estimated $98 million. We estimate that Massachusetts hospitals would receive approximately a 3.1 percent increase in IPPS payments due to the application of the proposed rural floor in FY 2016.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent change in payments as a result of the application of the proposed Puerto Rico rural floor with the application of the proposed Puerto Rico rural floor budget neutrality adjustment. We are proposing to apply a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.987626 or 1.2 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals. The increases in payments experienced by the urban Puerto Rico hospitals that benefit from a rural floor are offset by the decreases in payments by the urban Puerto Rico hospitals that do not benefit from the rural floor that have their wage indexes downwardly adjusted by the rural floor budget neutrality adjustment. As a result, overall, urban Puerto Rico hospitals would experience a 0.1 percent change in payments due to the application of the proposed rural floor with rural floor budget neutrality.

There are 16 hospitals out of the 64 hospitals in New Jersey that would benefit from the proposed extension of the imputed floor and would receive the proposed imputed floor wage index value under the OMB labor market area delineations, including the proposed rural floor budget neutrality of 0.990135 which we estimate would increase payments to those imputed floor hospitals by $20 million (overall, the State would not see an increase in payments due to the other hospitals in the State that would experience decreases in payments due to the proposed rural floor budget neutrality adjustment). Four Rhode Island hospitals would benefit from the proposed imputed rural floor calculated under the alternative methodology and would receive an additional $4.5 million (overall, the State would receive an additional $2.6 million). No hospitals would benefit from the proposed imputed floor in Delaware because the CBSA wage index for each CBSA in Delaware under the new OMB delineations is equal to or higher than the proposed imputed rural floor.

Column 7 also shows the projected effects of the second year of the 3-year hold harmless provision for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. As discussed in section III.G.2. of the preamble of this proposed rule, under this transition, hospitals that were located in an urban county that became rural under the new OMB delineations will generally be assigned the urban wage index value of the CBSA in which they are physically located in FY 2014 for a period of 3 fiscal years (that is, FYs 2015, 2016, and 2017). In addition, as discussed in section III.G.3. of the preamble of this proposed rule, under this transition, hospitals that were deemed urban where the urban area became rural under the new OMB delineations will generally be assigned the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index, if applicable) to which they were designated in FY 2014. For FY 2016, we are applying the 3-year transition wage index adjustments in a budget neutral manner, with a budget neutrality factor of 0.999995.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the proposed rural floor and imputed floor with budget neutrality at the State level. Column 1 of the table below displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that would receive the proposed rural floor or imputed floor wage index for FY 2016. Column 3 displays the percentage of total payments each State would receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2016 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2016 wage index of providers with the proposed rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State would gain or lose due to the application of the proposed rural floor and imputed floor with national budget neutrality.

PROPOSED FY 2016 IPPS ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals	Number of hospitals that would receive the proposed rural floor or imputed floor	Proposed percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality	Proposed difference (in millions)
	(1)	(2)	(3)	(4)
Alabama	86	3	−0.4	$−7.28
Alaska	6	1	−0.3	−0.53
Arizona	55	4	−0.5	−8.36
Arkansas	46	2	−0.3	−3.08
California	303	207	2.4	233.75
Colorado	47	5	0.3	3.78
Connecticut	31	7	−0.5	−7.46
Delaware	6	0	−0.6	−2.53
Washington, DC	7	0	−0.5	−2.4
Florida	170	14	−0.3	−16.98
Georgia	105	0	−0.5	−12.17
Hawaii	12	1	−0.4	−1.11
Idaho	14	0	−0.4	−1.17
Illinois	127	2	−0.5	−24.84
Indiana	91	0	−0.5	−11.83

PROPOSED FY 2016 IPPS ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals	Number of hospitals that would receive the proposed rural floor or imputed floor	Proposed percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality	Proposed difference (in millions)
	(1)	(2)	(3)	(4)
Iowa	35	0	−0.5	−4.3
Kansas	53	0	−0.4	−3.7
Kentucky	65	1	−0.4	−7.09
Louisiana	98	1	−0.5	−6.53
Maine	20	0	−0.5	−2.4
Massachusetts	61	39	3.1	98.3
Michigan	96	0	−0.5	−21.72
Minnesota	50	0	−0.3	−6.2
Mississippi	64	0	−0.5	−4.86
Missouri	78	2	−0.4	−8.38
Montana	12	2	0.2	0.45
Nebraska	25	0	−0.4	−2.44
Nevada	24	4	0.3	2.35
New Hampshire	13	2	−0.2	−1.19
New Jersey	64	16	0	0.43
New Mexico	25	0	−0.3	−1.37
New York	156	2	−0.6	−43.7
North Carolina	84	0	−0.4	−14.21
North Dakota	6	0	−0.3	−0.81
Ohio	132	6	−0.5	−17.27
Oklahoma	86	4	−0.4	−4.94
Oregon	34	0	−0.5	−4.67
Pennsylvania	153	5	−0.5	−21.49
Puerto Rico	51	10	0.1	0.15
Rhode Island	11	4	0.7	2.59
South Carolina	56	5	−0.2	−2.38
South Dakota	19	0	−0.3	−0.97
Tennessee	99	19	−0.4	−9.65
Texas	317	3	−0.5	−30.36
Utah	34	2	−0.4	−1.95
Vermont	6	0	−0.3	−0.61
Virginia	78	1	−0.4	−11.47
Washington	49	6	0.1	1.49
West Virginia	29	3	−0.2	−1.24
Wisconsin	66	0	−0.5	−7.58
Wyoming	11	0	−0.2	−0.24

g. Effects of the Application of the Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 8)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 4 States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 47 hospitals located in those States will receive a frontier wage index of 1.0000. Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, but since then and including in this proposed rule, its rural floor value has been greater than 1.0000 so it has not been subject to the frontier wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $58 million. Rural and urban hospitals located in the West North Central region would experience an increase in payments by 0.3 and 0.8 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 325 providers that would receive the out-migration wage adjustment in FY 2016. Rural hospitals generally qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit Section 401 hospitals and RRCs in that they would experience a 1.4 percent and 0.5 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $39 million.

h. Effects of All Proposed FY 2016 Changes (Column 9)

Column 9 shows our estimate of the proposed changes in payments per discharge from FY 2015 and FY 2016, resulting from all proposed changes reflected in this proposed rule for FY 2016. It includes combined effects of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 0.3 percent for FY 2016 relative to FY 2015. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2016 documentation and coding recoupment adjustment of -0.8 percent on the national standardized amount as part of the recoupment required under section 631 of the ATRA. In addition, this column includes the proposed annual hospital update of 1.9 percent to the national standardized amount. This proposed annual hospital update includes the 2.7 percent market basket update, the proposed reduction of 0.6 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction under section 3401 of the Affordable Care Act. Hospitals paid under the hospital-specific rate would receive a 1.9 percent hospital update described above. As described in Column 2, the proposed annual hospital update with the proposed documentation and coding recoupment adjustment for hospitals paid under the national standardized amount combined with the proposed annual hospital update for hospitals paid under the hospital-specific rate would result in a 1.1 percent increase in payments in FY 2016 relative to FY 2015. The impact of moving from our estimate of FY 2015 outlier payments, 4.9 percent, to the proposed estimate of FY 2016 outlier payments, 5.1 percent, would result in an increase of 0.2 percent in FY 2016 payments relative to FY 2015. There also might be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the proposed values in Column 9 may not equal the sum of the proposed estimated percentage changes described above.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 0.3 percent for FY 2016. Hospitals in urban areas would experience a 0.3 percent increase in payments per discharge in FY 2016 compared to FY 2015. Hospital payments per discharge in rural areas are estimated to decrease by 0.3 percent in FY 2016.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2016 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2015 with the proposed estimated average payments per discharge for FY 2016, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The proposed estimated percentage changes shown in the last column of Table II equal the proposed estimated percentage changes in average payments per discharge from Column 9 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2016 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2015 payment per discharge	Estimated average FY 2016 payment per discharge	Proposed FY 2016 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,366	11,336	11,366	0.3
By Geographic Location:				
Urban hospitals	2,530	11,690	11,727	0.3
Large urban areas	1,390	12,444	12,480	0.3
Other urban areas	1,140	10,777	10,813	0.3
Rural hospitals	836	8,398	8,377	−0.3
Bed Size (Urban):				
0–99 beds	666	9,223	9,225	0
100–199 beds	777	9,866	9,896	0.3
200–299 beds	446	10,616	10,661	0.4
300–499 beds	428	11,934	11,976	0.4
500 or more beds	213	14,306	14,342	0.3
Bed Size (Rural):				
0–49 beds	329	6,996	6,927	−1
50–99 beds	298	7,914	7,844	−0.9
100–149 beds	121	8,286	8,311	0.3
150–199 beds	48	9,104	9,135	0.3
200 or more beds	40	10,004	10,017	0.1
Urban by Region:				
New England	120	12,840	12,848	0.1
Middle Atlantic	318	13,135	13,212	0.6
South Atlantic	407	10,396	10,424	0.3
East North Central	396	10,960	10,997	0.3
East South Central	150	10,003	9,973	−0.3
West North Central	165	11,472	11,522	0.4
West South Central	382	10,612	10,583	−0.3
Mountain	161	12,047	12,089	0.4
Pacific	380	14,921	15,038	0.8
Puerto Rico	51	7,666	7,448	−2.8
Rural by Region:				
New England	22	11,325	11,195	−1.2
Middle Atlantic	55	8,473	8,422	−0.6
South Atlantic	128	7,839	7,841	0
East North Central	116	8,731	8,744	0.1
East South Central	164	7,522	7,433	−1.2
West North Central	101	9,275	9,339	0.7

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2016 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2015 payment per discharge (2)	Estimated average FY 2016 payment per discharge (3)	Proposed FY 2016 changes (4)
West South Central	165	7,196	7,115	−1.1
Mountain	61	9,731	9,815	0.9
Pacific	24	11,521	11,634	1
By Payment Classification:				
Urban hospitals	2,479	11,718	11,757	0.3
Large urban areas	1,383	12,450	12,487	0.3
Other urban areas	1,096	10,804	10,845	0.4
Rural areas	887	8,565	8,539	−0.3
Teaching Status:				
Nonteaching	2,325	9,451	9,471	0.2
Fewer than 100 residents	794	11,012	11,047	0.3
100 or more residents	247	16,464	16,513	0.3
Urban DSH:				
Non-DSH	680	10,091	10,195	1
100 or more beds	1,572	12,096	12,121	0.2
Less than 100 beds	333	8,643	8,656	0.2
Rural DSH:				
SCH	253	8,611	8,677	0.8
RRC	220	9,267	9,277	0.1
100 or more beds	33	7,695	7,580	−1.5
Less than 100 beds	275	6,640	6,459	−2.7
Urban teaching and DSH:				
Both teaching and DSH	846	13,227	13,257	0.2
Teaching and no DSH	132	11,441	11,580	1.2
No teaching and DSH	1,059	9,897	9,913	0.2
No teaching and no DSH	442	9,448	9,555	1.1
Special Hospital Types:				
RRC	211	9,459	9,405	−0.6
SCH	327	9,962	10,065	1
SCH and RRC	125	10,597	10,719	1.2
Type of Ownership:				
Voluntary	1,934	11,504	11,550	0.4
Proprietary	880	10,007	9,996	−0.1
Government	529	12,252	12,248	0
Medicare Utilization as a Percent of Inpatient Days:				
0–25	713	13,536	13,454	−0.6
25–50	2,110	11,258	11,304	0.4
50–65	332	9,423	9,470	0.5
Over 65	66	9,484	9,541	0.6
FY 2016 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	861	11,360	11,431	0.6
Non-Reclassified Hospitals	2,505	11,325	11,338	0.1
Urban Hospitals Reclassified	585	11,961	12,048	0.7
Urban Nonreclassified Hospitals	1,894	11,624	11,644	0.2
All Rural Hospitals Reclassified	276	8,861	8,869	0.1
Rural Nonreclassified Hospitals	505	7,846	7,790	−0.7
All Section 401 Reclassified Hospitals	58	9,792	9,722	−0.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	7,786	7,731	−0.7
Specialty Hospitals:				
Cardiac Specialty Hospitals	14	12,652	12,780	1

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

1. Effects of Proposed Policy on MS–DRGs for Preventable HACs, Including Infections

In section II.F. of the preamble of this proposed rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the

selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3. of the preamble of this proposed rule, it is possible to have two severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

As discussed in section II.F. of the preamble of this proposed rule, for FY 2016, we are not proposing to add or remove any categories of HACs for FY 2016.

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

Year	Savings (in millions)
FY 2016	$28
FY 2017	29
FY 2018	31
FY 2019	32
FY 2020	34

2. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss the nine technologies for which we received applications for add-on payments for new medical services and technologies for FY 2016, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2015. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.5. of the preamble of this proposed rule, we have not yet determined whether any of the nine technologies for which we received applications for consideration for new technology add-on payments for FY 2016 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these nine technologies for any potential new technology add-on payments for FY 2016. We note that if any of the nine technologies are found to be eligible for new technology add-on payments for FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2016.

In section II.I.4. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for Voraxaze®, the Zenith® F.Graft, and the Zilver® PTX® Drug Eluting Peripheral Stent for FY 2016 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue making new technology add-on payments for Kcentra™, the Argus® II Retinal Prosthesis System, the CardioMEMS™ HF Monitoring System, the MitraClip® System, and the RNS® System in FY 2016 because these technologies are still considered new. We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in add-on payments for FY 2016 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For Kcentra™, based on the applicant's estimate from FY 2014, we currently estimate that new technology add-on payments for Kcentra™ will increase overall FY 2016 payments by $5,449,888. For the Argus® II Retinal Prosthesis System, based on the applicant's estimate from FY 2014, we currently estimate that new technology add-on payments for the Argus® II Retinal Prosthesis System will increase overall FY 2016 payments by $3,601,437. For the CardioMEMS™ HF Monitoring System, based on the applicant's estimate from FY 2015, we currently estimate that new technology add-on payments for the CardioMEMS™ HF Monitoring System will increase overall FY 2016 payments by $11,315,625. For the MitraClip® System, based on the applicant's estimate from FY 2015, we currently estimate that new technology add-on payments for the MitraClip® System will increase overall FY 2016 payments by $27,000,000. For the RNS® System, based on the applicant's estimate from FY 2015, we currently estimate that new technology add-on payments for the RNS® System will increase overall FY 2016 payments by $12,932,500.

3. Effects of the Proposed Changes to Medicare DSH Payments for FY 2016

As discussed in section IV.D. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the former statutory formula for Medicare DSH payments. The remainder, equal to an estimate of 75 percent of what otherwise formerly would have been paid as Medicare DSH payments that is reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments, is available to make additional payments to each hospital that qualifies for Medicare DSH payments. Each Medicare DSH hospital will receive an additional payment based on its estimated share of the total amount of uncompensated care for all Medicare DSH hospitals. The uncompensated care payment methodology has redistributive effects based on the proportion of a Medicare DSH's low-income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the low-income insured patient days for all Medicare DSH hospitals (that is, Factor 3). The reduction to Medicare DSH payments due to the uncompensated care payment methodology is not budget neutral.

In this FY 2016 IPPS/LTCH PPS proposed rule, the amount to be distributed as uncompensated care payments to DSH eligible hospitals is 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 63.69 percent; for FY 2015, the uncompensated care payment was 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 76.19 percent. In addition, for FY 2016, we are proposing to use data from the more recent of hospitals' full year 2012 or full year 2011 cost reports from the March 2015 update of the HCRIS database, 2012 cost report data submitted to CMS by IHS hospitals, and the most recent data (which we anticipate to be 2013 data at the time we are developing the final rule) on SSI ratios to calculate Factor 3. That is, we are proposing to hold constant the 2012 and 2011 cost report years used to obtain Medicaid days in the FY 2015 IPPS/LTCH PPS final rule but to use updated cost report data from a later extract of the HCRIS, to continue to use the 2012 cost report data submitted to CMS by IHS hospitals, and to use the most recent SSI ratios to calculate Factor 3 for FY 2016.

To estimate the impact of the combined effect of proposed changes to reductions in the uninsured and additional statutory adjustments (Factor 2) and Medicaid patient days (a component of Factor 3) on the calculation of Medicare DSH payments, we compared DSH payments estimated in the FY 2015 IPPS/LTCH PPS final rule to proposed DSH payments based on proposals in this FY 2016 IPPS/LTCH PPS proposed rule.

For FY 2015, for each hospital, we calculated the sum of (a) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2015 in the

absence of section 3133 of the Affordable Care Act and (b) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133, adjusted by a Factor 2 of 76.19 percent and multiplied by Factor 3 as stated in the FY 2015 IPPS/LTCH PPS final rule and correction notice.

For FY 2016, we calculated the sum of (a) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2016 absent section 3133 and (b) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments absent section 3133, adjusted by a Factor 2 of 63.69 percent, as proposed, and multiplied by a Factor 3 calculated using the more recent of the hospitals' full year 2012 or full year 2011 cost report from the December 2014 update of the HCRIS database, 2012 cost report data submitted to CMS by IHS hospitals, and 2012 SSI ratios. We note that we used the most recent data available to estimate Factor 3 for FY 2016, as some of the data sources to be used under our proposed changes are not yet available.

Our analysis included 2,234 hospitals projected to receive Medicare DSH payments in FY 2016 and did not include hospitals in the Rural Community Hospital Demonstration, hospitals that departed the Medicare program as of December 31, 2014, Maryland hospitals, SCHs that are expected to be paid based on their hospital-specific rates, and hospitals that are not included in 2010 MedPAR file (for example, new hospitals). In addition, low-income insured days from merged or acquired hospitals were combined into the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. The estimated impact of these proposed changes across a consistent universe of estimated FY 2016 DSHs, by hospital characteristic, is presented in the table below.

MODELED DISPROPORTIONATE SHARE PAYMENT FOR ESTIMATED FY 2016 DSH HOSPITALS BY HOSPITAL TYPE: MODEL DSH DOLLARS

[in millions]

	Number of estimated FY 2016 DSH Hospitals	FY 2015 final rule estimated DSH $*	FY 2016 NPRM estimated DSH $*	Percentage change
	(0)	(1)	(2)	(4)
Total	2,234	$10,993	$9,738	−11.4
By Geographic Location:				
Urban Hospitals	1,745	10,443	9,253	−11.4
Large Urban Areas	921	6,595	5,838	−11.5
Other Urban Areas	824	3,848	3,415	−11.3
Rural Hospitals	488	549	485	−11.7
Unknown	1	1	0	−15.0
Bed Size (Urban):				
0 to 99 Beds	261	165	143	−12.9
100 to 249 Beds	776	2,443	2,160	−11.6
250 to 499 Beds	507	4,104	3,642	−11.3
500+ Beds	201	3,732	3,307	−11.4
Bed Size (Rural):				
0 to 99 Beds	352	220	192	−13.1
100 to 249 Beds	123	263	234	−10.9
250 to 499 Beds	12	65	58	−10.1
500+ Beds	1	1	1	−10.9
Urban by Region:				
East North Central	288	1,412	1,249	−11.5
East South Central	125	664	590	−11.2
Middle Atlantic	211	1,845	1,640	−11.1
Mountain	104	491	431	−12.3
New England	80	431	386	−10.5
Pacific	284	1,733	1,555	−10.3
Puerto Rico	31	78	65	−17.3
South Atlantic	291	1,944	1,708	−12.1
West North Central	95	484	426	−11.9
West South Central	236	1,360	1,204	−11.5
Rural by Region:				
East North Central	59	50	44	−12.3
East South Central	145	185	164	−11.6
Middle Atlantic	26	35	31	−12.8
Mountain	21	15	13	−13.5
New England	9	16	14	−10.9
Pacific	8	10	10	−7.7
South Atlantic	83	117	104	−11.1
West North Central	29	22	19	−13.3
West South Central	108	98	87	−11.5
By Payment Classification:				
Urban Hospitals	1,756	10,437	9,247	−11.4
Large Urban Areas	935	6,605	5,847	−11.5
Other Urban Areas	821	3,832	3,400	−11.3
Rural Hospitals	477	555	491	−11.6
Unknown	1	1	0	−15.0
Teaching Status:				
Nonteaching	1,397	3,394	2,993	−11.8
Fewer than 100 residents	601	3,660	3,249	−11.2
100 or more residents	235	3,939	3,496	−11.2
Unknown	1	1	0	−15.0

MODELED DISPROPORTIONATE SHARE PAYMENT FOR ESTIMATED FY 2016 DSH HOSPITALS BY HOSPITAL TYPE: MODEL DSH DOLLARS—Continued

[in millions]

	Number of estimated FY 2016 DSH Hospitals (0)	FY 2015 final rule estimated DSH $* (1)	FY 2016 NPRM estimated DSH $* (2)	Percentage change (4)
Type of Ownership:				
Voluntary	1,344	7,161	6,353	−11.3
Proprietary	448	1,616	1,426	−11.7
Government	442	2,216	1,959	−11.6
Medicare Utilization Percent:				
0–25	381	2,828	2,485	−12.1
25–50	1,460	7,405	6,579	−11.2
50–65	331	686	608	−11.3
Over 65	61	73	65	−10.9
Unknown	1	1	0	−15.0

Source: Dobson | DaVanzo analysis of 2011–2012 Hospital Cost Reports, 2010 MedPAR, and FY2015 Final Rule IPPS Impact File.

* Estimated DSH dollars calculated by [0.25 * estimated section 1886(d)(5)(F) payments] + [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, the Model DSH is $9,378 million in 2016 and $10,993 million in 2015. For the FY 2015 IPPS/LTCH PPS final rule, Factor 2 is equal to 76.19 percent. The proposed Factor 2 for FY 2016 is 63.69 percent.

** Percent change is determined as the difference between Medicare DSH payments modeled for the FY 2016 IPPS/LTCH PPS proposed rule (column 2) and Medicare DSH payments modeled for the FY 2015 IPPS/LTCH PPS final rule (column 1) divided by Medicare DSH payments modeled for the FY 2015 final rule (column 1) times 100 percent .

The impact analysis found that changes from the FY 2015 IPPS/LTCH PPS final rule were primarily driven by two components: (1) A reduction in the percentage of individuals who are uninsured, from 13.75 percent in the FY 2015 IPPS/LTCH PPS final rule to 11.5 percent in this FY 2016 proposed rule; and (2) changes in the number of Medicaid days for 2012 (or 2011) obtained from each hospitals' March 2014 HCRIS update of their Medicare cost report (used in the FY 2015 IPPS/LTCH PPS final rule) to the Medicaid days reported in the December 2014 HCRIS update (used in this FY 2016 proposed rule). The change in the percentage of individuals who are uninsured is a national estimate affecting all hospitals equally, while the change in Medicaid days is hospital-specific. For purposes of this proposed rule, the SSI ratios used in this analysis are the same 2012 SSI ratios used in the FY 2015 IPPS/LTCH PPS final rule and correction notice because the 2013 ratios are not yet available.

The impact analysis table above shows that across all projected disproportionate share hospitals, FY 2016 DSH payments, including both empirically justified DSH payments and uncompensated care payments, are estimated at approximately $9.738 billion, or a decrease of 11.4 percent from FY 2015 DSH payments ($10.993 billion). This is solely the result of a proposed reduction in Factor 2. As a result, we project that proposed payments for FY 2016 to hospitals paid under the IPPS would be reduced overall by 1.0 percent as compared to overall payments to hospitals paid under the IPPS in FY 2015.

Differences in the percent reduction in DSH payments were relatively small across most hospital categories because the overall average percent change in Medicaid days was relatively small compared to the overall percent reduction in the estimate of the percentage of individuals who are uninsured. Variation in the reductions in DSH payments were influenced by the change in the number of Medicaid days (the number of Medicaid days increased by 0.453 percent for all included hospitals from the FY 2015 IPPS/LTCH PPS final rule to this FY 2016 IPPS/LTCH PPS proposed rule) and each hospital characteristic group's relative proportion of Medicaid to SSI days. We note that SSI days used in this analysis have not changed since the FY 2015 IPPS/LTCH PPS final rule; however, we anticipate using 2013 SSI days for the FY 2016 IPPS/LTCH PPS final rule. Rural hospitals are expected to experience a slightly larger decrease compared to urban hospitals, as defined by geographic location or payment classification. Among rural and urban hospitals, small hospitals (0 to 99 beds) are expected to receive greater reductions in DSH payments compared to their larger counterparts, respectively. By region, urban hospitals located in Puerto Rico are expected to receive disproportionately larger reductions in DSH payments, while Pacific urban hospitals are expected to receive disproportionately smaller reductions in DSH payments. Rural hospitals located in the Mountain region also are projected to receive larger reductions in DSH payments, while rural hospitals in the Pacific region are projected to receive smaller reductions relative to the universe of projected FY 2016 DSHs. Although urban hospitals in Puerto Rico are projected to receive disproportionately larger reductions in DSH payments, they are still expected to receive more in Medicare DSH and uncompensated care payments under section 3133 than if they were paid the amount they previously would have received under the former statutory formula for Medicare DSH payments. Nonteaching hospitals are projected to receive a larger reduction in DSH payments than both small and large teaching hospitals. Government hospitals are projected to receive larger reductions in DSH payments than not-for-profit hospitals, but smaller reductions compared to for-profit hospitals. In addition, hospitals with higher Medicare utilization are projected to receive smaller reductions in DSH payments relative to hospitals with lower Medicare utilization.

4. Effects of Proposed Reduction Under the Hospital Readmissions Reduction Program

In section IV.E. of the preamble of this proposed rule, we discuss our proposals for FY 2016 for the Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating DRG payments to account for excess readmissions. For FY 2016, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for five applicable conditions: Acute myocardial infarction, heart failure, pneumonia, total hip and total knee arthroplasty and chronic obstructive pulmonary disease. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in the statute as 0.97 (or a 3.0 percent reduction). A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.E. of the preamble of this proposed rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this proposed rule, we estimate that 2,655 hospitals will have their base operating DRG payments reduced by their proxy FY 2016 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions

Reduction Program would result in no material change in payments relative to FY 2015.

5. Effects of Proposed Changes Under the FY 2016 Hospital Value-Based Purchasing (VBP) Program

In section IV.F. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2016 through a reduction to the FY 2016 base operating DRG payment for each discharge of 1.75 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2017 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

We estimate the available pool of funds for value-based incentive payments in the FY 2016 program year, which, in accordance with section 1886(o)(7)(C)(iv) of the Act, will be 1.75 percent of base operating DRG payments, or a total of approximately $1.49 billion. This estimated available pool for FY 2016 is based on the historical pool of hospitals that were eligible to participate in the FY 2015 program year and the payment information from the December 2014 update to the FY 2014 MedPAR file.

The proposed estimated impacts of the FY 2016 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2015 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2014 update to the FY 2014 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2016 program year, the number of hospitals that would receive an increase in base operating DRG payment amount is slightly higher than the number of hospitals that would receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions would have an increase, on average, in the base operating DRG payment amount. Urban hospitals in the Middle Atlantic region would receive an average decrease in the base operating payment amount. Among rural hospitals, those in all regions would have an increase, on average, in base operating DRG payment amounts.

On average, hospitals that receive a higher percent of DSH payments would receive decreases in the base operating DRG payment amount. With respect to hospitals' Medicare utilization (MCR), those hospitals with an MCR above 65 percent would have the largest increase, on average, in base operating DRG payment amounts.

Nonteaching hospitals would have an average increase, and teaching hospitals would experience an average decrease, in the base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT PROPOSED CHANGES RESULTING FROM THE FY 2016 HOSPITAL VBP PROGRAM

	Number of hospitals	Average percentage change
By Geographic Location:		
All Hospitals	3,089	0.133
Large Urban	1,262	0.046
Other Urban	1,066	0.137
Rural Area	760	0.269
Missing*	1	1.009
Urban hospitals	*2,328*	*0.088*
0–99 beds	515	0.506
100–199 beds	735	0.025
200–299 beds	445	−0.055
300–499 beds	423	−0.075
500 or more beds	210	−0.088
Rural hospitals	*760*	*0.269*
0–49 beds	251	0.453
50–99 beds	299	0.250
100–149 beds	123	0.075
150–199 beds	49	0.044
200 or more beds	38	0.126
By Region:		
Urban By Region	2,328	0.088
New England	116	0.045
Middle Atlantic	306	−0.057
South Atlantic	389	0.038
East North Central	376	0.106
East South Central	139	0.042
West North Central	154	0.366
West South Central	332	0.178
Mountain	157	0.048
Pacific	359	0.093
Rural By Region	760	0.269
New England	20	0.384
Middle Atlantic	55	0.170
South Atlantic	123	0.330
East North Central	114	0.281
East South Central	135	0.269
West North Central	93	0.333
West South Central	140	0.162
Mountain	56	0.346
Pacific	24	0.228
By MCR Percent		
0–25	395	0.146

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT PROPOSED CHANGES RESULTING FROM THE FY 2016 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average percentage change
25–50	1,972	0.098
50–65	558	0.167
Over 65	93	0.305
Missing	70	0.506
By DSH Percent:		
0–25	1,477	0.248
25–50	1,329	0.061
50–65	138	−0.163
Over 65	144	−0.115
By Teaching Status:		
Non-Teaching	2,085	0.209
Teaching	1,003	−0.028

Actual FY 2016 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2016 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2015 program year will be used for the updated impact analysis in that final rule.

6. Effects of Proposed Changes to the HAC Reduction Program for FY 2016

In section IV.G. of the preamble of this proposed rule, we discuss the proposed changes to the HAC Reduction Program for FY 2016. We note that section 3008 of the Affordable Care Act added section 1886(p) to the Act to provide an incentive for certain hospitals to reduce the incidence of HACs. Section 1886(p) of the Act requires the Secretary to make an adjustment to payments to ''applicable hospitals'' effective beginning on October 1, 2014 and for subsequent program years. We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104). These policies describe the general framework for implementation of the HAC Reduction Program including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review. We are not proposing any changes to these policies for the implementation of the FY 2016 HAC Reduction Program.

We note that hospitals received a payment reduction for the first time in FY 2015. The table and analysis that we are presenting below are a simulation of the proposed FY 2016 HAC Reduction Program using historical data. This table and analysis will be revised with updated available data in the FY 2016 IPPS/LTCH PPS final rule. We note that, as described earlier in this proposed rule, because scores will undergo 30-day review and correction by the hospitals that will not conclude until after the publication of the final rule, we will not provide hospital-level data or a hospital-level payment impact in conjunction with the FY 2016 IPPS/LTCH PPS proposed or final rule.

For FY 2016, we note that we finalized a Total HAC Score methodology in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104) that assigns weights for Domain 1 and Domain 2 at 25 percent and 75 percent, respectively. The table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Score by hospital characteristic, based on this methodology.

To estimate the impact of the FY 2016 HAC Reduction Program, we used the following: the AHRQ Patient Safety Indicator (PSI) 90 measure results based on Medicare FFS discharges from July 2012 through June 2014 and version 4.5a of the AHRQ software. For CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), and Colon and Abdominal Hysterectomy Surgical Site Infection (SSI) measure results, the following was used: The standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 2012 and December 2013. We used the FY 2015 Final Impact File to analyze the results by hospital characteristic.

Of the 3,317 hospitals included in this analysis, 3,277 hospitals had information for geographic location, region, bed size, DSH percent, and teaching status; 3,233 had information for ownership; and 3,159 had information for Medicare days as a percent of total inpatient days (MCR percent). These differences in the number of hospitals listed for each characteristic are due to the source of the hospital characteristic data. Maryland hospitals are not included in the identification of the worst-performing quartile for the HAC Reduction Program in FY 2016 and, therefore, are not represented in the table below.

The third column in the table indicates the percent of hospitals in each category of the specified characteristic. For example, within geographic region, 40.6 percent of hospitals (or 1,329 hospitals) are characterized as large urban, 33.9 percent of hospitals (or 1,110 hospitals) are characterized as other urban, and 25.6 percent of hospitals (or 838 hospitals) are characterized as rural. The fifth column in the table indicates the proportion of hospitals for each characteristic that we estimate will be in the worst-performing quartile of Total HAC Scores and will receive a payment reduction under the FY 2016 HAC Reduction Program. For example, with regard to geographic location, we estimate 20.8 percent of hospitals (or 277 hospitals) characterized as large urban would be subject to a payment reduction; 20.1 percent of hospitals (or 223 hospitals) characterized as other urban would be subject to a payment reduction; and 15.9 percent of hospitals (or 133 hospitals) characterized as rural would be subject to a payment reduction.

With regard to geographic location of urban hospitals by bed size, 17.4 percent of hospitals (or 108 hospitals) characterized as urban hospitals with bed size of 1–99 beds would be subject to a payment adjustment; 17.5 percent of hospitals (or 129 hospitals) characterized as urban hospitals with bed size of 100–199 beds would be subject to a payment adjustment; 19.1 percent of hospitals (or 85 hospitals) characterized as urban hospitals with bed size of 200–299 beds would be subject to a payment adjustment; 22.9 percent of hospitals (or 62 hospitals) characterized as urban hospitals with bed size of 300–399 beds would be subject to a payment adjustment; 33.1 percent of hospitals (or 51 hospitals) characterized as urban hospitals with bed size of 400–499 beds would be subject to a payment adjustment; and 30.8 percent of hospitals (or 65 hospitals) characterized as urban hospitals with bed size of 500 or more beds would be subject to a payment adjustment.

With regard to geographical location of rural hospitals by bed size, 19.6 percent of hospitals (or 64 hospitals) characterized as rural hospitals with bed size of 1–49 beds would be subject to a payment adjustment; 14.0 percent of hospitals (or 42 hospitals)

characterized as rural hospitals with bed size of 50–99 beds would be subject to a payment adjustment; 9.7 percent of hospitals (or 12 hospitals) characterized as rural hospitals with bed size of 100–149 beds would be subject to a payment adjustment; 8.2 percent of hospitals (or 4 hospitals) characterized as rural hospitals with bed size of 150–199 beds would be subject to a payment adjustment; and 28.2 percent of hospitals (or 11 hospitals) characterized as rural hospitals with bed size of 200 or more beds would be subject to a payment adjustment.

With regard to region of urban hospitals, 29.6 percent of hospitals (or 34 hospitals) characterized as urban in the New England region would be subject to a payment adjustment; 27.8 percent of hospitals (or 88 hospitals) characterized as urban in the Mid-Atlantic region would be subject to a payment adjustment; 18.7 percent of hospitals (or 75 hospitals) characterized as urban in the South Atlantic region would be subject to a payment adjustment; 17.0 percent of hospitals (or 66 hospitals) characterized as urban in the East North Central region would be subject to a payment adjustment; 15.5 percent of hospitals (or 23 hospitals) characterized as urban in the East South Central region would be subject to a payment adjustment; 19.9 percent of hospitals (or 32 hospitals) characterized as urban in the West North Central region would be subject to a payment adjustment; 15.4 percent of hospitals (or 57 hospitals) characterized as urban in the West South Central region would be subject to a payment adjustment; 25.6 percent of hospitals (or 42 hospitals) characterized as urban in the Mountain region would be subject to a payment adjustment; and 22.2 percent of hospitals (or 83 hospitals) characterized as urban in the Pacific region would be subject to a payment adjustment.

With regard to region of rural hospitals, 40.0 percent of hospitals (or 8 hospitals) characterized as rural in the New England region would be subject to a payment adjustment; 16.4 percent of hospitals (or 9 hospitals) characterized as rural in the Mid-Atlantic region would be subject to a payment adjustment; 12.6 percent of hospitals (or 16 hospitals) characterized as rural in the South Atlantic region would be subject to a payment adjustment; 14.9 percent of hospitals (or 17 hospitals) characterized as rural in the East North Central region would be subject to a payment adjustment; 8.9 percent of hospitals (or 14 hospitals) characterized as rural in the East South Central region would be subject to a payment adjustment; 23.1 percent of hospitals (or 24 hospitals) characterized as rural in the West North Central region would be subject to a payment adjustment; 16.5 percent of hospitals (or 27 hospitals) characterized as rural in the West South Central region would be subject to a payment adjustment; 18.6 percent of hospitals (or 13 hospitals) characterized as rural in the Mountain region would be subject to a payment adjustment; and 19.2 percent of hospitals (or 5 hospital) characterized as rural in the Pacific region would be subject to a payment adjustment.

With regard to the DSH percent characteristic, 18.2 percent of hospitals (or 289 hospitals) characterized in the 0–24 DSH percent would be subject to a payment adjustment; 18.8 percent of hospitals (or 258 hospitals) characterized in the 25–49 DSH percent would be subject to a payment adjustment; 26.8 percent of hospitals (or 41 hospitals) characterized in the 50–64 DSH percent would be subject to a payment adjustment; and 27.4 percent of hospitals (or 45 hospitals) characterized in the 65 and over DSH percent would be subject to a payment adjustment.

With regard to the teaching status characteristic, 16.2 percent of hospitals (or 366 hospitals) characterized as nonteaching would be subject to a payment adjustment; 21.4 percent of hospitals (or 165 hospitals) characterized as fewer than 100 residents would be subject to a payment adjustment; and 42.3 percent of hospitals (or 102 hospitals) characterized as 100 or more residents would be subject to a payment adjustment.

With regard to the urban teaching and DSH characteristic, 28.4 percent of hospitals (or 235 hospitals) characterized as teaching and DSH would be subject to a payment adjustment; 18.9 percent of hospitals (or 24 hospitals) characterized as teaching and no DSH would be subject to a payment adjustment; 15.2 percent of hospitals (or 161 hospitals) characterized as no teaching and DSH would be subject to a payment adjustment; 18.7 percent of hospitals (or 80 hospitals) characterized as no teaching and no DSH would be subject to a payment adjustment; and 15.9 percent of hospitals (or 133 hospitals) characterized as nonurban would be subject to a payment adjustment.

With regard to the type of ownership characteristic, 19.8 percent of hospitals (or 371 hospitals) characterized as voluntary would be subject to a payment adjustment; 15.1 percent of hospitals (or 128 hospitals) characterized as proprietary would be subject to a payment adjustment; and 22.4 percent of hospitals (or 115 hospitals) characterized as government would be subject to a payment adjustment.

With regard to the MCR percent characteristic, 27.4 percent of hospitals (or 119 hospitals) characterized in the 0–24 MCR percent would be subject to a payment adjustment; 19.1 percent of hospitals (or 386 hospitals) characterized in the 25–49 MCR percent would be subject to a payment adjustment; 14.4 percent of hospitals (or 84 hospitals) characterized in the 50–64 MCR percent would be subject to a payment adjustment; and 7.0 percent of hospitals (or 8 hospitals) characterized in the 65 and over MCR percent would be subject to a payment adjustment.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2016 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Percent [b]	Number of hospitals in the worst-performing quartile	Percent of hospitals in the worst-performing quartile [c]
Total [d]	3,317	100	644	19.4
By Geographic Location:				
All hospitals:				
Large urban [e]	1,329	40.6	277	20.8
Other urban	1,110	33.9	223	20.1
Rural	838	25.6	133	15.9
Urban hospitals:				
1–99 beds	620	25.4	108	17.4
100–199 beds	738	30.3	129	17.5
200–299 beds	445	18.2	85	19.1
300–399 beds	271	11.1	62	22.9
400–499	154	6.3	51	33.1
500 or more beds	211	8.7	65	30.8
Rural hospitals:				
1–49 beds	326	38.9	64	19.6
50–99 beds	300	35.8	42	14.0
100–149 beds	124	14.8	12	9.7
150–199 beds	49	5.8	4	8.2

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2016 HAC REDUCTION PROGRAM—Continued

[By hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Percent [b]	Number of hospitals in the worst-performing quartile	Percent of hospitals in the worst-performing quartile [c]
200 or more beds	39	4.7	11	28.2
By Region:				
Urban by region:				
New England	115	4.7	34	29.6
Mid-Atlantic	316	13.0	88	27.8
South Atlantic	401	16.4	75	18.7
East North Central	389	15.9	66	17.0
East South Central	148	6.1	23	15.5
West North Central	161	6.6	32	19.9
West South Central	371	15.2	57	15.4
Mountain	164	6.7	42	25.6
Pacific	374	15.3	83	22.2
Rural by region:				
New England	20	2.4	8	40.0
Mid-Atlantic	55	6.6	9	16.4
South Atlantic	127	15.2	16	12.6
East North Central	114	13.6	17	14.9
East South Central	158	18.9	14	8.9
West North Central	104	12.4	24	23.1
West South Central	164	19.6	27	16.5
Mountain	70	8.4	13	18.6
Pacific	26	3.1	5	19.2
By DSH Percent [f]				
0–24	1,584	48.3	289	18.2
25–49	1,376	42.0	258	18.8
50–64	153	4.7	41	26.8
65 and over	164	5.0	45	27.4
By Teaching Status: [g]				
Non-teaching	2,265	69.1	366	16.2
Fewer than 100 residents	771	23.5	165	21.4
100 or more residents	241	7.4	102	42.3
By Urban Teaching and DSH [f g]				
Teaching and DSH	827	25.2	235	28.4
Teaching and no DSH	127	3.9	24	18.9
No teaching and DSH	1,058	32.3	161	15.2
No teaching and no DSH	427	13.0	80	18.7
Non-urban	838	25.6	133	15.9
By Type of Ownership:				
Voluntary	1,873	57.9	371	19.8
Proprietary	846	26.2	128	15.1
Government	514	15.9	115	22.4
By MCR Percent:				
0–24	435	13.8	119	27.4
25–49	2,026	64.1	386	19.1
50–64	584	18.5	84	14.4
65 and over	114	3.6	8	7.0

Source: FY 2016 HAC Reduction Program Proposed Rule Results provided by R&A contract. Scores are based on AHRQ PSI 90 data from July 2012 through June 2014 and CLABSI, CAUTI, and SSI results from January 2012 to December 2013. Hospital Characteristics are based on the FY 2015 Final Impact File last updated on September 30, 2014.

Notes:

[a] The total number of hospitals with hospital characteristic data (3,277 for geographic location, bed size, and teaching status; 3,233 for type of ownership; and 3,159 for MCR) do not add up to the total number of hospitals we estimate would be eligible for the FY 2016 HAC Reduction Program (3,317) because 40 hospitals are not included in the FY 2015 Final Impact File and not all hospitals have data for all characteristics.

[b] This column is the percent of all hospitals with each characteristic that we estimate would be eligible for the FY 2016 HAC Reduction Program and are included in the FY 2015 Final Impact File. Percentages may not sum to 100 due to rounding.

[c] This column is the percent of hospitals within each characteristic that we estimate would be in the worst-performing quartile.

[d] Total excludes the 46 Maryland hospitals.

[e] Large urban hospitals are hospitals located in large urban areas with populations over 1 million.

[f] A hospital is considered to be a DSH hospital if it has a DSH patient percentage greater than zero.

[g] A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

7. Effects of Proposed Elimination of Simplified Cost Allocation Methodology Used by Hospitals

In section IV.H. of the preamble of this proposed rule, we discuss our proposal to amend the regulations at 42 CFR 412.302(d)(4) to limit a hospital's ability to elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552 to cost reporting periods beginning before October 1, 2015. We are proposing to limit the election of the simplified cost allocation methodology because the allocation of the costs of capital-related movable equipment using this methodology yields less precise calculated CCRs. Furthermore, we believe that advances in technology have reduced the cost of recordkeeping, which has allowed hospitals to maintain accurate statistical data and afforded them the flexibility to change to a more precise allocation methodology. Although these proposed changes would impact some small rural hospitals, including CAHs, the vast majority of hospitals do not use the simplified cost allocation methodology. Based on FY 2013 data, only 9 of 1,269 CAHs and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology. In addition, when the simplified cost allocation methodology was implemented in 1996, it was expected that it also would likely result in reduced Medicare payments to hospitals. We believe that the proposed changes would not have a significant impact on the operations of a substantial number of small rural hospitals. We also do not believe that the proposed changes would affect beneficiary access to care, as affected hospitals will continue to be paid for services provided to Medicare beneficiaries.

We are inviting public comments on this analysis of impact.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.I. of the preamble of this proposed rule, for FY 2016, we discuss our implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify reimbursement for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. As discussed in section IV.I. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 11 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

We are proposing to adjust the national IPPS rates according to the methodology set forth in section IV.I.2. of the preamble of this proposed rule. We note that the phase-out of the demonstration has begun with the 7 ''pre-expansion'' participating hospitals that were selected for the demonstration during 2004 and 2008 concluding their participation during FY 2015. Therefore, we are proposing that the financial experience of these hospitals not be included in the estimated demonstration cost for FY 2016. Of the 15 hospitals that were selected in 2011 as a result of the expansion of the demonstration under the Affordable Care Act, 11 hospitals are scheduled to end their participation in the demonstration during FY 2016. Eight of these 11 hospitals are scheduled to end their participation in the demonstration prior to September 30, 2016. For each of these 8 hospitals, we are proposing to estimate the reasonable cost amount and the amount that would otherwise be paid without the demonstration for FY 2016 on a prorated basis, multiplying the estimated amounts for each hospital (as derived from ''as submitted'' cost reports for cost reporting periods ending in CY 2013) by the fraction of the number of months that it will participate in the demonstration during FY 2016 in relation to the total 12-month period. Accordingly, the proposed budget neutrality offset amount used to determine the proposed adjustment to the national IPPS rates to account for estimated demonstration costs for FY 2016 for these 15 hospitals is $26,195,949. In addition, in this proposed rule, we are proposing to subtract from the budget neutrality offset amount for FY 2016 the amount by which the budget neutrality offset amount that was finalized in the FY 2009 IPPS/LTCH PPS final rule exceeds the actual costs of the demonstration for FY 2009 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2009) ($8,457,452). Therefore, the resulting total ($17,738,497) is the amount for which a proposed adjustment to the IPPS rates for FY 2016 would be calculated.

9. Effects of the Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the Special Payment Policy

In section IV.J. of the preamble to this proposed rule, we discuss proposed changes to the list of MS–DRGs subject to the postacute care transfer policy and the DRG special payment policy. As reflected in Table 5 listed in section VI. of the Addendum to this proposed rule (which is available via the Internet on the CMS Web site), using criteria set forth in regulations at § 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special payment policies. We note that we are not proposing to make any changes in these payment policies in this FY 2016 proposed rule. We are proposing to include two proposed new MS–DRGs on the list of MS–DRGs subject to the postacute care transfer policy and the DRG special payment policy as a result of our proposals to revise the MS–DRG classifications for FY 2016. Specifically, we are proposing that two proposed new MS–DRGs would qualify for the postacute care transfer policy and the DRG special payment policy in FY 2016. Column 4 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and the relative payment weights and the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the proposed changes due to the MS–DRGs and relative payment weights account for and include changes in the status of MS–DRG postacute care transfer and special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to MS–DRG reclassification policies.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2014 update of the FY 2014 MedPAR file and the December 2014 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2014 update of the most recently available hospital cost report data (FYs 2012 and 2013) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described below.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2014 update of the FY 2014 MedPAR file, we simulated payments under the capital IPPS for FY 2015 and FY 2016 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the

proposed capital IPPS payments in FY 2016 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2015 and 2016.
- We estimate that Medicare discharges will be approximately 11.2 million in FY 2015 and 11.3 million in FY 2016.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update is 1.3 percent for FY 2016.
- In addition to the proposed FY 2016 update factor, the proposed FY 2016 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9976 and a proposed outlier adjustment factor of 0.9357. As discussed in section VI.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2016.

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2016 on total capital payments per case, using a universe of 3,366 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2014 update of the FY 2014 MedPAR file, the December 2014 update to the PSF, and the most recent cost report data from the December 2014 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2015 and estimated total payments per case for FY 2016 based on the proposed FY 2016 payment policies. Column 2 shows estimates of payments per case under our model for FY 2015. Column 3 shows estimates of payments per case under our model for FY 2016. Column 4 shows the proposed total percentage change in payments from FY 2015 to FY 2016. The proposed change represented in Column 4 includes the proposed 1.3 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2016 are expected to increase as compared to capital payments per case in FY 2015. This expected increase is due to the proposed approximately 0.8 percent increase in the capital Federal rate for FY 2016 as compared to the FY 2015 capital Federal rate and, to a lesser degree, proposed changes to the MS–DRG reclassifications and recalibrations and proposed changes in outlier payments. (For a discussion of the determination of the capital Federal rate, we refer readers to section III.A. of the Addendum to this proposed rule.) Overall, across all hospitals, the proposed changes to the GAFs are expected to slightly increase capital payments. However, regionally, the effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index) as shown in Table I in section I.G. of this Appendix.

The increase in capital payments per case due to the effects of proposed changes to the MS–DRG reclassifications and recalibrations is expected to be slightly greater for urban hospitals, as are the increases in capital payments per case due to proposed changes in outlier payments. However, most of the urban and rural areas would experience an offset to the projected increase in capital payments per case due to the effects of proposed changes to the GAFs.

The net impact of these proposed changes is an estimated 2.0 percent change in capital payments per case from FY 2015 to FY 2016 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, hospitals in all classifications (urban and rural) would experience an increase in capital IPPS payments per case in FY 2016 as compared to FY 2015. Capital IPPS payments per case for hospitals in ''large urban areas'' have an estimated increase of 2.2 percent, while hospitals in rural areas, on average, are expected to experience a 0.9 percent increase in capital payments per case from FY 2015 to FY 2016. Capital IPPS payments per case for ''other urban hospitals'' are estimated to increase 1.9 percent. The primary factor contributing to the difference in the proposed projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the proposed changes in the GAFs. Rural hospitals in all but two rural regions are projected to experience a decrease in capital payments due to the effect of proposed changes in the GAFs, while hospitals in only half of the urban regions are projected to experience a decrease in capital payments due to the effect of the proposed changes in the GAFs.

The comparisons by region show that the estimated increases in capital payments per case from FY 2015 to FY 2016 in urban areas range from a 2.7 percent increase for the Pacific urban region to a 1.5 percent increase for the East South Central and New England urban regions, and a 0.5 percent increase for Puerto Rico. For rural regions, the Pacific rural region is projected to experience the largest increase in capital IPPS payments per case of 1.8 percent; the Middle Atlantic rural region is projected to experience the smallest increase in capital IPPS payments per case of 0.3 percent; and the West South Central rural region is projected to have no change in capital payments per case in FY 2016 compared to FY 2015 payments per case. In most urban and rural regions, proposed changes in the GAFs contribute to only a small projected increase in capital payments, for example, proposed changes in the GAFs are a major factor for the West South Central rural region, which is not expected to experience any increase in capital payments per case in FY 2016 compared to FY 2015. However, the proposed changes in the GAFs have the opposite effect for the Pacific urban and rural regions where they are a primary contributor to the expected larger than average increase in capital IPPS payments per case.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2015 to FY 2016. The proposed increase in capital payments for voluntary and proprietary hospitals is estimated to be 1.9 percent. For government hospitals, the proposed increase is estimated to be 2.1 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2016. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2016, we show the proposed average capital payments per case for reclassified hospitals for FY 2016. Urban reclassified hospitals are expected experience an increase in capital payments of 2.4 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 1.9 percent. The estimated percentage increase for rural reclassified hospitals is 1.3 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 0.8 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2015 payments compared to proposed FY 2016 payments]

	Number of hospitals	Average FY 2015 payments/case	Average proposed FY 2016 payments/case	Change
By Geographic Location:				
All hospitals	3,366	873	890	2.0
Large urban areas (populations over 1 million)	1,390	965	986	2.2
Other urban areas (populations of 1 million of fewer)	1,140	836	851	1.9
Rural areas	836	592	598	0.9
Urban hospitals	2,530	906	925	2.0
0–99 beds	666	738	749	1.5
100–199 beds	777	791	806	1.8
200–299 beds	446	830	847	1.9
300–499 beds	428	921	941	2.1
500 or more beds	213	1,081	1,105	2.2
Rural hospitals	836	592	598	0.9
0–49 beds	329	491	497	1.2
50–99 beds	298	549	556	1.1
100–149 beds	121	592	597	0.8
150–199 beds	48	649	654	0.8
200 or more beds	40	708	713	0.7
By Region:				
Urban by Region	2,530	906	925	2.0
New England	120	995	1,010	1.5
Middle Atlantic	318	1,006	1,030	2.4
South Atlantic	407	804	820	2.0
East North Central	396	871	888	1.9
East South Central	150	770	782	1.5
West North Central	165	892	907	1.7
West South Central	382	823	838	1.9
Mountain	161	937	955	1.9
Pacific	380	1,151	1,182	2.7
Puerto Rico	51	399	402	0.5
Rural by Region	836	592	598	0.9
New England	22	818	822	0.6
Middle Atlantic	55	581	583	0.3
South Atlantic	128	555	563	1.4
East North Central	116	617	625	1.2
East South Central	164	539	543	0.7
West North Central	101	638	645	1.1
West South Central	165	525	525	0.0
Mountain	61	665	675	1.4
Pacific	24	772	786	1.8
By Payment Classification:				
All hospitals	3,366	873	890	2.0
Large urban areas (populations over 1 million)	1,383	966	987	2.2
Other urban areas (populations of 1 million of fewer)	1,096	840	856	1.9
Rural areas	887	605	610	0.8
Teaching Status:				
Non-teaching	2,325	741	754	1.7
Fewer than 100 Residents	794	850	867	1.9
100 or more Residents	247	1,231	1,260	2.4
Urban DSH:				
100 or more beds	1,572	929	949	2.1
Less than 100 beds	333	665	677	1.8
Rural DSH:				
Sole Community (SCH/EACH)	253	558	566	1.3
Referral Center (RRC/EACH)	220	663	667	0.7
Other Rural:				
100 or more beds	33	586	577	−1.4
Less than 100 beds	275	488	494	1.1
Urban teaching and DSH:				
Both teaching and DSH	846	1,004	1,026	2.2
Teaching and no DSH	132	915	931	1.8
No teaching and DSH	1,059	780	795	1.9
No teaching and no DSH	442	807	823	1.9
Rural Hospital Types:				
Non special status hospitals	2,701	901	920	2.1
RRC/EACH	211	728	735	1.0
SCH/EACH	327	666	674	1.3
SCH, RRC and EACH	125	725	733	1.2

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2015 payments compared to proposed FY 2016 payments]

	Number of hospitals	Average FY 2015 payments/case	Average proposed FY 2016 payments/case	Change
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2016 Reclassifications:				
All Urban Reclassified	585	926	949	2.4
All Urban Non-Reclassified	1,894	903	920	1.9
All Rural Reclassified	276	627	636	1.3
All Rural Non-Reclassified	505	544	548	0.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	48	597	586	−1.8
Type of Ownership:				
Voluntary	1,934	886	903	1.9
Proprietary	880	788	802	1.9
Government	529	918	938	2.1
Medicare Utilization as a Percent of Inpatient Days:				
0–25	713	979	1,000	2.2
25–50	2,110	874	891	1.9
50–65	332	739	752	1.7
Over 65	66	758	774	2.1

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2016. In the preamble of this proposed rule, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 418 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 326 proprietary LTCHs, and 14 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 430 LTCHs, for purposes of this impact analysis, we excluded the data of all inclusive rate providers and the LTCHs that are paid in accordance with demonstration projects, consistent with the development of the proposed FY 2016 MS–LTC–DRG relative weights (discussed in section VII.C.3.c. of the preamble of this proposed rule)). In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, including the proposed application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act (discussed in section VII.B. of the preamble of this proposed rule), the proposed 1.9 percent annual update to the LTCH PPS standard Federal payment rate in accordance with section 1886(m)(5)(C) of the Act (which is based on the full estimated increase of the proposed LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act), the proposed update to the MS–LTC–DRG classifications and relative weights for the LTCH PPS standard Federal payment rate cases, the proposed update to the wage index values and labor-related share for the LTCH PPS standard Federal payment rate cases, and the best available claims and CCR data to estimate the proposed change in payments for FY 2016.

Under the new statutory dual-rate LTCH PPS structure, there will be two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, as discussed in section VII.B. of the preamble of this proposed rule, we are proposing to provide payment for LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) based on the LTCH PPS standard Federal payment rate. In addition, consistent with the statute, we are proposing that the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, under our proposals, there would be two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that will be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. As discussed more fully in section VII.B.4.b. of the preamble of this proposed rule, the transitional payment amount for site neutral payment rate cases is a blended payment rate, which would be calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under proposed new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 418 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2016 would decrease by approximately 4.6 percent (or about $251 million). This projection takes into account estimated payments for LTCH cases that would have met the new statutory patient-level criteria and been paid the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of the discharge, and estimated payments for LTCH cases that would not have met those new statutory patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge described below.

Because the statute specifies that the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins on or after October 1, 2015, our estimate of FY 2016 LTCH PPS payments for site neutral payment rate cases includes an adjustment to account for this rolling effective date. Our proposed approach, applied to the FY 2014 data that were used for the analyses in this proposed rule, accounts for the fact that LTCHs with cost reporting periods that begin after October 1, 2015, will continue to be paid for all discharges (including those that do not meet the patient-level criteria for exclusion from the site neutral payment rate) at the LTCH PPS standard Federal payment rate until the start of their first cost reporting period beginning after October 1, 2015. Therefore, in order to estimate total LTCH PPS payments for site neutral payment rate cases in FY 2016, we first identified LTCHs with cost reporting periods that would begin in the first quarter of FY 2016 (that is, October through December 2015), and modeled those LTCHs estimated FY 2016 site neutral payment rate payments based on the proposed transitional blended payment rate.

We then modeled the estimated first quarter FY 2016 payments to LTCHs with cost reporting periods that would begin after the first quarter of FY 2016 using the LTCH PPS standard Federal payment rate. We then identified the LTCHs with cost reporting periods that would begin in each of the remaining three quarters of FY 2016, and applied an analogous analysis to estimate payments in each respective quarter of FY 2016. (For full details on our proposed method of estimating payments under our proposals for FY 2016, we refer readers to the description presented in section V.D.4. of the Addendum to this proposed rule.) We believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2016 payments.

Based on the FY 2014 LTCH cases that were used for the analyses in this proposed rule, approximately 46 percent of LTCH cases would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect in FY 2014 (that is, 46 percent of such LTCH cases would not have met the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2016 will not change significantly from the historical data. Taking into account the proposed transitional blended payment rate and other proposed policies applicable to the site neutral payment rate cases in FY 2016, and our approach to account for the rolling effective date for the new site neutral payment rate, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 14.3 percent (or about $293 million).

Approximately 54 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2016, and be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2016 would increase approximately 1.2 percent (or approximately $42 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2016 is primarily a result of the proposed 1.9 percent annual update to the LTCH PPS standard Federal payment rate for FY 2016 (discussed in section V.A. of the Addendum to this proposed rule) and an estimated decrease in HCO payments for these cases.

Based on the 418 LTCHs that were represented in the FY 2014 LTCH cases that were used for the analyses in this proposed rule, we estimate that aggregate FY 2016 LTCH PPS payments would be approximately $5.169 billion, as compared to estimated aggregate FY 2015 LTCH PPS payments of approximately $5.420 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $251 million. Because the combined distributional effects and estimated payment changes exceed $100 million, this proposed rule is a major economic rule. We note that this estimated $251 million decrease in LTCH PPS payments in FY 2016 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases) does not reflect changes in LTCH admissions or case-mix intensity, which would also affect the overall payment effects of what is proposed in this rule.

The LTCH PPS standard Federal payment rate for FY 2015 is $41,043.71. For FY 2016, we are proposing to establish a LTCH PPS standard Federal payment rate of $41,883.93, which reflects the proposed 1.9 percent annual update to the LTCH PPS standard Federal payment rate and the proposed area wage budget neutrality factor of 1.001444 to ensure that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish a LTCH PPS standard Federal payment rate of $41,061.87. This proposed reduced LTCH PPS standard Federal payment rate reflects the proposed updates described above as well as the required 2.0 percentage point reduction to the annual update for failure to submit data to the LTCH QRP. We note that the proposed factors described above to determine the FY 2016 LTCH PPS standard Federal payment rate are applied to the FY 2015 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xi) (that is, $41,034.71).

Table IV (column 6) shows that the estimated change attributable solely to the proposed annual update to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.6 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, on average, for all LTCHs. In addition to the annual update to the LTCH PPS standard Federal payment rate for FY 2016, this estimated increase in aggregate proposed LTCH PPS payments to LTCH PPS standard Federal payment rate cases of 1.6 percent shown in column 6 of Table IV also includes estimated payments for SSO cases that are paid using special methodologies that are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the penalty that is applied to the annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the proposed 1.9 percent annual update for FY 2016.

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2016 based on the most recent available data, and we are proposing to continue to use labor market areas based on the OMB CBSA delineations. In addition, we are proposing to slightly lower the labor-related share from 62.306 percent to 62.2 percent under the LTCH PPS for FY 2016, based on the most recent available data on the relative importance of the proposed labor-related share of operating and capital costs based on the FY 2009-based LTCH-specific market basket. We also are proposing to apply an area wage level budget neutrality factor of 1.001444 to ensure that the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases, which increases the proposed LTCH PPS standard Federal payment rate by approximately 0.14 percent.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases are projected to decrease from FY 2015 to FY 2016. Using the FY 2014 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2015 HCO threshold of $14,972 (as established in the FY 2015 IPPS/LTCH PPS final rule) would result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2015 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases will be approximately 8.6 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2015. Combined with our estimate that FY 2016 HCO payments for LTCH PPS standard Federal payment rate cases would be 8.0 percent of estimated total LTCH PPS standard Federal rate payments in FY 2016, this results in the estimated decrease of approximately 0.6 percent between FY 2015 and FY 2016.

In calculating these estimated HCO payments we increased estimated costs by our actuaries' projected market basket percentage increase factor. This increase in estimated costs also results in a projected increase in SSO payments in FY 2016. We estimate that these increased SSO payments in FY 2016 would increase total payments for LTCH PPS standard Federal rate payment cases by 0.2 percent. (Payments for SSO cases represent approximately 12.5 percent of the estimated total LTCH PPS payments for standard Federal payment rate cases.)

Table IV below shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2016 by comparing estimated FY 2015 LTCH PPS payments to estimated FY 2016 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2015 to FY 2016 for LTCH PPS standard Federal payment rate cases of 1.2 percent is attributable to the impacts of the proposed change to the LTCH PPS standard Federal payment rate (1.6 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (−0.6 percent), and the estimated increase in proposed payments for SSO cases (0.2 percent).

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts would result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 1.2 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2014 data for the 21 rural LTCHs (out of 418 LTCHs) that were used for the analyses in this proposed rule. We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section J.3 of this Appendix.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a new dual-rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. As discussed in section VII.B. of the preamble of this proposed rule, under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) would be paid based on the LTCH PPS standard Federal payment rate. LTCH discharges that would be paid at the site neutral payment rate would generally be paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that will be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases would be paid a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge. (For additional details on the proposed application of the site neutral payment rate beginning in FY 2016, we refer readers to section VII.B. of the preamble of this proposed rule.)

As discussed above in section I.J.1. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2016 of approximately $251 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $42 million and the projected decrease in payments to site neutral payment rate cases of approximately $293 million under the new dual-rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section VII.B.7.b. of the preamble of this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2016 LTCH PPS payments (that is, FY 2014 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV below only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section J.3 refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Below we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the new dual-rate LTCH PPS payment structure, the statute establishes two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2016 cost reporting period, discharges are paid based on the nature of the case. As described previously, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that would meet the proposed patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that would not meet the proposed patient-level criteria and would generally be paid the generally lower site neutral payment rate. For discharges occurring in cost reporting periods beginning in FY 2016 or 2017, however, the statute specifies that site neutral payment rate cases will be paid based on a transitional payment method that would be calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate.

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is set forth under § 412.515 through § 412.536. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. As explained previously, under our proposed application of the new dual-rate LTCH PPS payment structure required under section 1886(m)(6) of the Act, the LTCH PPS standard Federal payment rate would generally only be used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). Under the new statutory changes to the LTCH PPS, LTCH discharges that would not meet the statutory patient-level criteria for exclusion would be paid the site neutral payment rate, which we are proposing to calculate as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also would be able to receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2016, it is necessary to estimate payments per discharge for FY 2015 using the rates, factors, and the policies established in the FY 2015 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2016 using the rates, factors, and the policies proposed in this FY 2016 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. The resulting analyses can then be used to compare how our proposals applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, FY 2012 through FY 2013 cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our proposed policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FYs 2015 and 2016 payments on

a case-by-case basis using historical LTCH claims from the FY 2014 MedPAR files that would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for those cases. For modeling FY 2015 LTCH PPS payments, we used the FY 2015 standard Federal rate of $41,043.71, or $40,240.51 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP, which reflects the 2.0 percentage points reduction required by section 1886(m)(5)(C) of the Act. Similarly, for modeling FY 2016 LTCH PPS standard Federal rate payments, we used the proposed FY 2016 standard Federal payment rate of $41,883.93, or $41,061.87 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP, again, to reflect the 2.0 percentage points reduction required by section 1886(m)(5)(C) of the Act. In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2015 LTCH PPS payments, we used the current FY 2015 labor-related share (62.306 percent); the wage index values established in the Tables 12A through 12D listed in the Addendum to the FY 2015 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site), including the transitional blended wage index for the implementation of the CBSA delineations in FY 2015; the FY 2015 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $14,972 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2015 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2015 nonlabor-related share (37.694 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2016 LTCH PPS payments, we used the proposed FY 2016 LTCH PPS labor-related share (62.2 percent), the proposed FY 2016 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are also available via the Internet on the CMS Web site), the proposed FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $18,768 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2016 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2016 nonlabor-related share (37.8 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section J.1. of this Appendix). In modeling proposed payments for SSO and HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 5.0 percent (determined by the Office of the Actuary) to update the 2014 costs of each case.

The impacts presented below reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2015 to FY 2016 based on the proposed payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2015 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described above).
- The fifth column shows the estimated FY 2016 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described above).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and the proposed labor-related share), including the application of a proposed area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 (Column 4) to FY 2016 (Column 5) for all proposed changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2016

[Estimated FY 2015 Payments Compared to Estimated FY 2016 Payments]

LTCH classification	Number of LTCHs	Number of LTCH PPS standard federal payment rate cases	Average FY 2015 LTCH PPS payment per case	Proposed average FY 2016 LTCH PPS standard federal payment rate payment per case [1]	Proposed percent change in payments per case due to the annual update to the LTCH PPS standard federal rate [2]	Proposed percent change in payments per case due to proposed changes to the area wage level adjustment with budget neutrality [3]	Proposed percent change in payments per case from FY 2015 to FY 2016 for all proposed changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL PROVIDERS	416	73,427	$46,024	$46,564	1.6	0.0	1.2
BY LOCATION:							
RURAL	21	2,156	$39,110	$39,284	1.5	−0.8	0.4
URBAN	395	71,271	$46,233	$46,784	1.6	0.0	1.2
LARGE	197	42,434	$48,434	$49,023	1.6	0.1	1.2
OTHER	198	28,837	$42,993	$43,489	1.6	−0.2	1.2
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	13	2,057	$42,043	$43,120	1.6	0.7	2.6
OCT. 1983—SEPT. 1993	43	9,076	$51,663	$52,209	1.6	0.1	1.1
OCT. 1993—SEPT. 2002	179	32,454	$44,666	$45,290	1.7	0.0	1.4
OCTOBER 2002 and AFTER	181	29,840	$46,059	$46,469	1.6	−0.1	0.9
BY OWNERSHIP TYPE:							
VOLUNTARY	77	9,907	$46,853	$47,348	1.6	0.0	1.1
PROPRIETARY	326	62,153	$45,776	$46,324	1.6	0.0	1.2
GOVERNMENT	13	1,367	$51,255	$51,789	1.6	−0.1	1.0
BY REGION:							
NEW ENGLAND	13	2,907	$41,660	$42,687	1.5	0.7	2.5
MIDDLE ATLANTIC	28	5,296	$51,636	$51,981	1.7	−0.1	0.7
SOUTH ATLANTIC	61	12,072	$46,280	$46,832	1.6	0.1	1.2
EAST NORTH CENTRAL	69	12,164	$46,524	$47,034	1.7	0.0	1.1
EAST SOUTH CENTRAL	33	5,146	$44,648	$44,996	1.6	0.0	0.8
WEST NORTH CENTRAL	25	3,777	$46,228	$46,678	1.6	−0.2	1.0
WEST SOUTH CENTRAL	129	19,498	$40,447	$41,060	1.6	−0.1	1.5
MOUNTAIN	33	4,245	$46,867	$47,528	1.6	0.2	1.4
PACIFIC	25	8,322	$56,266	$56,714	1.6	−0.2	0.8
BY BED SIZE:							
BEDS: 0–24	27	1,517	$42,268	$42,916	1.6	0.5	1.5
BEDS: 25–49	191	24,668	$44,141	$44,640	1.6	−0.1	1.1
BEDS: 50–74	119	20,342	$46,764	$47,129	1.6	−0.3	0.8
BEDS: 75–124	46	12,998	$49,200	$49,817	1.6	0.2	1.3
BEDS: 125–199	21	7,703	$45,705	$46,370	1.6	0.1	1.5
BEDS: 200 +	12	6,199	$45,741	$46,676	1.7	0.3	2.0

[1] Estimated FY 2016 LTCH PPS payments to LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to LTCH PPS standard Federal payment rate cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 for the proposed annual update to the LTCH PPS standard Federal rate.

[3] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 to FY 2016 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2015 (shown in Column 4) to FY 2016 (shown in Column 5), including all of the proposed changes to the rates and factors applicable to LTCH PPS standard Federal payment rate cases presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the LTCH PPS standard Federal payment rate (column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments for LTCH cases that are expected to meet the LTCH PPS standard Federal payment rate criteria (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2014 LTCH cases (from 418 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are expected to increase 1.2 percent, on average, for all LTCHs from FY 2015 to FY 2016 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 1.2 percent increase in LTCH PPS payments per discharge to LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2016 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2015 LTCH PPS payments for LTCH discharges which would be LTCH PPS standard Federal payment rate cases if the new statutory dual-rate LTCH PPS payment structure had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2016 by 1.9 percent based on the latest estimate of the LTCH PPS market basket increase (2.7 percent), the proposed reduction of 0.6 percentage point for the MFP adjustment, and the 0.2 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction would be applied to the proposed annual update to the standard Federal rate. As explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the proposed payment increase due to the proposed 1.9 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.6 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2015 to FY 2016. This is because our estimate of the proposed changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that will be paid using special methodologies that are not affected by the update to the LTCH PPS standard Federal payment rate. Consequently, we estimate that proposed payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.9 percent for certain hospital categories due to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2016.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 for all hospitals is 1.2 percent. For rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.4 percent increase, while for urban LTCHs, we estimate the increase would be 1.2 percent. Both large urban and other urban LTCHs are projected to experience an increase of 1.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 44 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 1.4 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, as shown in Table IV.

Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a higher than average percent increase (2.6 percent) in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016, as shown in Table IV, which is primarily due to a projected larger than average increase in payments due to the proposed changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a 1.1 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 40 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.9 percent increase in estimated payments from FY 2015 to FY 2016.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). The majority (nearly 78 percent) of LTCHs are identified as proprietary while government-owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience an average increase in payments to LTCH PPS standard Federal payment rate cases of 1.1 percent; proprietary LTCHs are expected to experience an increase of 1.2 percent in payments to LTCH PPS standard Federal payment rate cases, while government-owned and operating LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 1.0 percent from FY 2015 to FY 2016.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2016 are projected to increase for LTCHs located in all regions in comparison to FY 2015. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases would have the largest positive impact on LTCHs in the New England region (2.5 percent as shown in Table IV), which is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the Middle Atlantic, East South Central, and Pacific regions are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. The lower than national average estimated increase in payments of 0.7 percent for the Middle Atlantic regions and 0.8 percent for the East South Central and Pacific regions is primarily due to estimated decreases in payments associated with the proposed changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. All bed size categories are projected to receive an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016. We project that large LTCHs (200+ beds) would experience a 2.0 percent increase in payments for LTCH PPS standard Federal payment rate cases, which is higher than the national average mostly due to a larger than average increase from the proposed area wage level adjustment. Similarly, we project that both small LTCHs (0–24 beds) and relatively large LTCHs (125–199 beds) would experience a 1.5 percent increase in payments for LTCH PPS standard Federal payment rate cases, which is also higher than the national average mostly due to increases in the proposed area wage level adjustment. LTCHs with 25 to 49 beds and 75 to 124 beds are expected to experience a nearly average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 (1.1 percent and 1.3 percent, respectively), while LTCHs with between 50 and 74 beds are expected to experience a smaller than average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2015 to FY 2016 (0.8 percent).

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result

in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2016 relative to FY 2015 of approximately $42 million (or approximately 1.2 percent) for the 418 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2016 relative to FY 2015 of approximately $293 million (or approximately 14.3 percent) for the 418 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to all cases in FY 2016 relative to FY 2015 of approximately $251 million (or approximately 4.6 percent) for the 418 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2018 payment determination.

In this proposed rule, we are proposing to remove nine measures from the Hospital IQR Program for the FY 2018 payment determination and subsequent years:

- STK–01 Venous Thromboembolism (VTE) Prophylaxis (NQF #0434);
- STK–06: Discharged on Statin Medication* (NQF #0439);
- STK–08: Stroke Education* (NQF endorsement removed);
- VTE–1: Venous Thromboembolism Prophylaxis* (NQF #0371);
- VTE–2: Intensive Care Unit Venous Thromboembolism Prophylaxis* (NQF #0372);
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy* (NQF #0373);
- AMI–7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival* (NQF #0164);
- IMM–1 Pneumococcal Immunization (NQF #1653); and
- SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).

(An asterisk (*) indicates that the measure is proposed for retention as an electronic clinical quality measure for the FY 2018 payment determination in section VIII.A.8. of the preamble of this proposed rule.)

The anticipated effect of removing these measures would be a reduction in the burden associated with the collection of chart-abstracted data. Due to the burden associated with the collection of chart-abstracted data, we estimate that the proposed removal of AMI–7a would result in a burden reduction of approximately 219,000 hours across all hospitals. We estimate that the proposed removal of the 6 VTE and STK chart-abstracted measures would result in a burden reduction of approximately 522,000 hours across all hospitals. The remaining two measures proposed for removal have been previously suspended from the Hospital IQR Program. Therefore, their proposed removal would not affect burden to hospitals. In total, we estimate that the removal of 6 measures would result in a total burden reduction of approximately 741,000 hours for the FY 2018 payment determination across all hospitals.

We are retaining six of the chart-abstracted measures proposed for removal as electronic clinical quality measures. We believe that retaining a variety of electronic clinical quality measures would result in increased hospital familiarity with electronic reporting. We further believe retaining some measures as electronic clinical quality measures would not affect the overall burden, as these measures were available for electronic reporting under previous requirements.

In this proposed rule, we are proposing refinements to the measure cohorts for: (1) The Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization measure (NQF #0468); and (2) the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization measure (NQF #0506). Expanding the measure cohort to include a broader population of patients adds a large number of patients, as well as additional hospitals, to the CMS 30-day Pneumonia RSMR and RSRR measures. However, this expansion would not affect the burden on hospitals or hospital performance on the Hospital IQR Program because these measures are claims-based and, therefore, require no additional effort on hospitals' part to submit the required data.

We also are proposing to add eight additional measures to the Hospital IQR Program measure set beginning with the FY 2018 payment determination and for subsequent years. Seven of these measures are claims-based, and one measure is structural. The eight proposed new measures are:

- Hospital Survey on Patient Safety Culture (structural);
- Kidney/UTI Clinical Episode-Based Payment (claims-based);
- Cellulitis Clinical Episode-Based Payment (claims-based);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment (claims-based);
- (Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment (claims-based);
- Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based);
- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and
- Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

We believe adopting the seven claims-based measures above would have no effect on hospital burden because they do not require additional effort on the part of hospitals. We further believe adopting the Hospital Survey on Patient Safety Culture measure would have a negligible effect on hospital burden, but may result in hospital staff spending time to respond to the Survey.

For the FY 2018 payment determination and subsequent years, we also are proposing to require hospitals to submit 16 measures electronically using CEHRT 2014 for the Hospital IQR Program in a manner that would permit eligible hospitals to partially align Hospital IQR Program requirements with some requirements under the Medicare EHR Incentive Program. We believe this proposal would increase the burden associated with electronic clinical quality measure reporting because electronic reporting was previously voluntary. The total burden increase is estimated to be 5 hours and 20 minutes per hospital.

We note that we are proposing to change the requirements for population and sampling such that hospitals would be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program. We believe this proposal would result in a minimal decrease in burden as hospitals would not have to report population and sample size if they electronically report any of the measures that can be reported either as an electronic clinical quality measure or via chart-abstraction.

We also note that we are proposing to modify the existing processes for validation of chart-abstracted Hospital IQR Program data to remove one stratum. This proposal would not affect hospital burden. Detailed information on the estimated burden specifically associated with information collection for the Hospital IQR Program for the FY 2018 payment determination is included in section X.B.6 of the preamble of this proposed rule.

In addition to the activities described above, participation in the Hospital IQR Program requires hospitals to participate in a number of other activities, including: (1) Reviewing reports for claims-based measure sets; (2) completing HAI validation templates for CLABSI and CAUTI; (3) completing HAI validation templates for MRSA bacteremia and CDI; and (4) completing other forms and structural measures. The cumulative effects of these activities on facility burden are expected to be substantially similar to that stated for FY 2017.

In general, however, we anticipate that, because of the new requirements we are proposing for reporting for the FY 2018 payment determination (if finalized), the number of hospitals not receiving the full annual percentage increase may be higher than average. Information is not available to determine the precise number of hospitals that would not meet the proposed requirements to receive the full annual percentage increase for the FY 2018 payment determination. Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual

percentage increase in any fiscal year. We anticipate that, because of the new requirements we are proposing for reporting for the FY 2018 payment determination (if finalized), the number of hospitals not receiving the full annual percentage increase may be higher than average. The highest number of hospitals failing to meet program requirements was approximately 200 after the introduction of new NHSN reporting requirements. If the number of hospitals failing does increase because of the new requirements, we anticipate that, over the long run, this number would decline as hospitals gain more experience with these requirements.

Finally, under OMB Control Number 0938–1022, we estimated that the total burden for the FY 2017 payment determinations was 1,781 hours per hospital and 5.9 million hours across approximately 3,300 hospitals participating in the Hospital IQR Program. We estimate here that the total burden for the FY 2018 payment determination would increase to 2,293 hours per hospital and 7.6 million hours across approximately 3,300 hospitals due to the proposals discussed above and updates to the historical data used to determine the number of cases reported and time for reporting per measure set. The table below describes the hospital burden associated with the Hospital IQR Program requirements.

BURDEN IMPACT OF HOSPITAL IQR PROGRAM REQUIREMENTS FOR FY 2018

Hospital IQR program requirement	Number of hospitals impacted	Burden per hospital for previously finalized requirements	Burden per hospital for all requirements as proposed (continuing, removed, added)	Net change in burden per hospital
Chart-abstracted and structural measures, forms	3,300	1,131 hours	906 hours	−225 hours.
Review reports for claims-based measures	3,300	4 hours	4 hours	0.
Electronic Clinical Quality Measure Reporting	Unknown	0 hours (electronic clinical quality measure reporting voluntary for FY 2017).	5 hours 20 minutes	+5 hours 20 minutes.
Validation templates	Up to 600	72 hours	107 hours	+35 hours.
Electronic Clinical Quality Measure validation test	Up to 100	16 hours	0 hours (no test this year).	−16 hours.
Validation charts photocopying	Up to 600	$8,496	$12,960	+$4,464.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for FY 2018

In section VIII.B. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act.

In section VIII.B.3. of the preamble of this proposed rule, we are proposing that PCHs will submit data on three additional measures beginning with the FY 2018 program: (1) The CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) the CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and, (3) the CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel Measure (NQF #0431). In conjunction with our proposal in section VIII.B.2. of the preamble of this proposed rule to remove the six SCIP measures from the PCHQR Program beginning with fourth quarter (Q4) 2015 discharges and for subsequent years, the PCHQR measure set would consist of 16 measures for the FY 2018 program.

The impact of the proposed new requirements for the PCHQR Program is expected to be minimal overall because all 11 PCHs are already submitting quality measure data to the CDC NHSN and are familiar with this reporting process. Beginning with Q1 2013 events, PCHs have been submitting Central Line-associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) data to the CDC NHSN (77 FR 53566). Similarly, beginning with Q1 2014 events, PCHs have been submitting Surgical Site Infections (SSI) data to the CDC NHSN (78 FR 50849). As a result, PCHs are familiar with the CDC NHSN IT infrastructure and programmatic operations. In addition to fostering transparency and facilitating public reporting, we believe our requirements uphold our goals in improving quality of care and achieving better health outcomes, which outweighs burden.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will publicly display quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, healthcare associated infection prevention programs, and research and development activities, among others.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) for FY 2018

In section VIII.C.1. of the preamble of this proposed rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) and (F) of the Act shall receive a 2 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year.

In the FY 2015 IPPS/LTCH PPS final rule (76 FR 50443 through 50445), we estimated that only a few LTCHs would not receive the full annual percentage increase in any fiscal year as a result of failure to submit data under the LTCH QRP. There are approximately 442 LTCHs currently reporting quality data to CMS. At the time that this analysis was prepared, 47, or approximately 10 percent, of these LTCHs did not receive the full annual percentage increase for the FY 2015 annual payment update determination. Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination.

We believe that a majority of LTCHs will continue to collect and submit data for the FY 2017 payment determination and subsequent years because they will continue to view the LTCH QRP as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCH QRP is the time and effort associated with data collection.

In this FY 2016 IPPS/LTCH PPS proposed rule, we are retaining 12 previously finalized measures, two of which we are proposing in order to establish their use as cross-setting measures that satisfy the required addition of quality measures under the domains of skin integrity and incidence of major falls, as mandated by the section 1899B of the Act: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We are proposing a third previously finalized measure, All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), in order to establish the newly NQF-endorsed status of this measure. Finally, we are proposing the application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; under review), which satisfies the addition of a quality measure under the third initially required domain of functional status, as mandated by section 1899B of the Act.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) we discussed burden estimates that were inclusive of the 12 previously finalized measures we are retaining in this proposed rule. We previously estimated the total cost for all 12 quality measures to be $17,410 per LTCH annually, or $7,695,423 for all LTCHs annually (79 FR 50443 through 50445); or $2,992,384 for all quality measures reported via the CDC's NHSN; and $4,703,039 for all quality measures reported to CMS using the LTCH CARE Data Set version 2.0. For a list of the 12 previously finalized measures included in the above burden estimate, we refer readers to the FY 2015 IPPS/LTCH PPS final rule.

The burden calculation discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) accounts for any burden associated with newly proposed measures in this FY 2016 IPPS/LTCH PPS proposed rule. The measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) is currently being reported by LTCHs using version 2.01 of the LTCH CARE Data Set, which has burden approval under OMB control number 0938–1163. The burden associated with the proposed application of the measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is discussed at length in the FY 2015 IPPS/LTCH PPS final rule, and is included in the above total annual burden figures in that rule, as well as listed above.

The measure All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) is calculated based on CMS FFS claims data, and therefore does not have any associated data reporting burden for LTCH providers.

The new quality measure we are proposing to include in the LTCH QRP, Cross-Setting Functional Status Process Measure: Percent of Patients or Residents with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function, is not specifically discussed in the FY 2015 IPPS/LTCH PPS final rule. However, the data elements used to report this quality measure to CMS are included in that discussion and burden estimate in that final rule, because we are proposing to use a subset of the same data elements that are used to report the previously finalized measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, which is included in that burden estimate. Therefore, the proposed addition of this quality measure to the LTCH QRP does not increase burden on LTCHs.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS: The CDC's NHSN, which is used to report all Healthcare Associated Infection (HAI) and vaccination data (used to calculate CAUTI, CLABSI, MRSA, CDI, VAE, and healthcare personnel Influenza vaccination measures); and the Quality Improvement and Evaluation System Assessment Submission and Processing (QIES–ASAP) system, which is used by LTCHs to report quality data via the LTCH CARE Data Set.

The data collection burden associated with the reporting of the quality measures (HAI and vaccination) reported via the CDC's NHSN is discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445). However, we note that these measures are stewarded by the CDC, and the reporting burden is approved under OMB control number 0920–0666.

The remaining quality measures are reported to CMS by LTCHs using the LTCH CARE Data Set (LCDS). Currently, LTCHs are using version 2.01 of the LCDS (approved under OMB control number 0938–1163) which includes data elements related to two quality measures: Percent of Patients or Residents with Pressure Ulcers that are new or Worsened (NQF #0678), and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680).

We have developed a subsequent iteration of the LCDS (version 3.0), which will also include data elements for the three quality measures we previously finalized in the FY 2015 IPPS/LTCH PPS final rule: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631—under NQF review); and Functional Status Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632—under NQF review). We refer readers to section X.B.9. of the preamble of this proposed rule for a discussion of the additional data elements in Version 3.0 of the LCDS.

Version 3.0 of the LTCH CARE Data Set will also be used to report the newly proposed measure Cross-Setting Functional Status Process Measure: Percent of Patients or Residents with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function. However, the data items that will inform this measure are a subset of the data elements currently used to report the LTCH-specific measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631—under review by NQF). Therefore this proposed measure would not add any data collection burden beyond that discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), in which NQF #2631 was finalized.

LTCH burden related to the submission of version 3.0 of the LCDS, has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445), and is included in the total annual burden noted in that rule, which is $17,410 per LTCH annually, or $7,695,423 for all LTCHs annually. We believe that this estimate remains unchanged as a result of the LTCH QRP proposals in this proposed rule.

N. Effects of Proposed Requirements Regarding Electronic Health Record (EHR) Meaningful Use Program

In section VIII.D. of the preamble of this proposed rule, we discuss proposed requirements for the EHR Incentive Program. We are proposing CQM reporting requirements, including reporting periods and submission periods, as well as CQMs required and information about CQM specifications' updates, for the Medicare EHR Incentive Program for eligible hospitals and CAHs for 2016. We note that these proposals would only apply for eligible hospitals and CAHs submitting CQMs electronically in CY 2016. Because these proposals for data collection would align with the reporting requirements in place for the Hospital IQR Program and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare EHR Incentive Program, we do not believe these proposals would have a significant impact.

II. Alternatives Considered

This proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

III. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall increase of 0.3 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that proposed operating payments will increase by approximately $278 million in FY 2016 relative to FY 2015. However, when we account for the impact of the changes in Medicare DSH payments and the impact of the new additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS

Office of the Actuary, consistent with our policy discussed in section IV.D. of the preamble of this proposed rule, we estimate that operating payments will decrease by approximately $11 million relative to FY 2015. We currently estimate that the changes in new technology add-on payments for FY 2016 will decrease spending by approximately $31 million due to the expiration of three new technology add-on payments. This estimate, combined with our estimated decrease in FY 2016 operating payment of $11 million, result in an estimated decrease of approximately $42 million for FY 2016. We estimate that hospitals will experience a 2.0 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $163 million increase in capital payments in FY 2016 compared to FY 2015. The proposed cumulative operating and capital payments would result in a net increase of approximately $121 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2016. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2016. Accordingly, based on the best available data for the 418 LTCHs in our database, we estimate that FY 2016 LTCH PPS payments will decrease approximately $251 million relative to FY 2015 as a result of the proposed payment rates and factors presented in this proposed rule.

IV. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The costs to the Federal Government associated with the policies in this proposed rule are estimated at $143 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2015 TO FY 2016

Category	Transfers
Annualized Monetized Transfers	$143 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this proposed rule under the LTCH PPS, is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2016 relative to FY 2015 of approximately −$251 million based on the data for 418 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf)*, in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 418 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

The savings to the Federal Government associated with the proposed policies for LTCHs in this proposed rule are estimated at $251 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES FROM THE FY 2015 LTCH PPS TO THE FY 2016 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	−$251 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

V. Regulatory Flexibility Act (RFA) Analysis

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 government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities. 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. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we receive and our responses will be presented in the final rule.

VI. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that 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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L.

98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

VII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately $144 million. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2016, we plan to include the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2016

A. Proposed FY 2016 Inpatient Hospital Update

As discussed in section IV.B of the preamble to this proposed rule, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a 66⅔ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.2 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2016 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero.

Based on the most recent data available for this FY 2016 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2016 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2015 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2014, which is estimated to be 2.7 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.A.1. of the preamble of this FY 2016 IPPS/LTCH PPS proposed rule, we are proposing an MFP adjustment of 0.6 percent for FY 2016. Therefore, based on IGI's first quarter 2015 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 2016	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−1.35	0.0	−1.35
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.6	−0.6	−0.6
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.9	0.55	1.225	−0.125

B. Proposed Update for SCHs for FY 2016

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2016 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). We note that the MDH program expired for discharges beginning on April 1, 2015 under current law.

As mentioned above, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the table above to the hospital-specific rate applicable to SCHs.

C. Proposed FY 2016 Puerto Rico Hospital Update

Section 401(c) of Public Laws 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.9 percent.

D. Proposed Update for Hospitals Excluded From the IPPS

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), the FY 2016 rate-of-increase percentage to be applied to the target amount for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the percentage increase in the IPPS operating market basket. For this proposed rule, the current estimate of the FY 2016 IPPS operating market basket percentage increase is 2.7 percent.

E. Proposed Update for LTCHs for FY 2016

Section 123 of Public Laws 106–113, as amended by section 307(b) of Public Laws 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS. Under section 1886(m)(6)(A) of the Act as added by section 1206(a) of Public Laws 113–67, beginning in cost reporting periods starting on or after October 1, 2015, all LTCH discharges are paid according to the site neutral payment rate unless certain criteria are met. For LTCH cases that meet the criteria for exclusion, the site neutral payment rate does not apply and payment will be made without regard to the provisions of section 1886(m)(6) of the Act. For cases that meet the criteria for exclusion from the site neutral payment rate, payment will continue to be based on the LTCH PPS standard Federal payment rate as determined in § 412.523. (For additional details on the change to LTCH PPS payments under section 1886(m)(6)(A) of the Act, specifically the establishment of the site neutral payment rate, we refer readers to section VII.B.3. of the preamble of this proposed rule.)

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2016 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.7 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In accordance with the LTCHQRP under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. The MFP adjustment described under section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.6 percent for FY 2016. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2016 be reduced by the ''other adjustment'' at section 1886(m)(4)(E) of the Act, which is 0.2 percentage point. Therefore, based on IGI's first quarter 2015 forecast of the FY 2016 LTCH PPS market basket increase, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.9 percent (that is, the current FY 2016 estimate of the market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.6 percentage point for MFP and less 0.2 percentage point). Accordingly, we are proposing to apply an update factor of 1.9 percent in determining the LTCH PPS standard Federal rate for FY 2016. For LTCHs that fail to submit quality data for FY 2016, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of -0.1 percent (that is, the proposed annual update for FY 2016 of 1.9 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of −0.1 percent in determining the LTCH PPS standard Federal rate for FY 2016.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to 3.25 percent for FY 2016. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four possible applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs. For the Puerto Rico-specific standardized amount, we are recommending an update of 1.9 percent.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.7 percent.

For FY 2016, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 1.9 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2016, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of −0.1 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2015 Report to Congress, MedPAC assessed the adequacy of current payments and costs and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates equal to 3.25 percent concurrent with changes to the outpatient prospective payment system and with initiating change to the LTCH PPS. We refer the reader to the March 2015 MedPAC report, which is available on the Web site at *http://www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2015. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. However, under current law, payment margins are projected to decline which could result in negative Medicare margins industry wide. Specifically, MedPAC noted several current law policy changes are scheduled to reduce payments in FY 2015 and FY 2016. Because of these changes and reduced payments, MedPAC asserted that an update of 3.25 percent in the base payment is warranted. MedPAC maintains that Medicare payment rates should be determined by analysis of payment adequacy rather than an across-the-board sequester reduction. Therefore, MedPAC recommended that hospitals receive base

payment rates that are 3.25 percent higher than the FY 2015 base payment rates, and there should be no sequester adjustment. However, MedPAC concluded that if the Congress increases hospital payments by reinstating expiring special payments, the full 3.25 percent update would not be warranted.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 3.25 percent, for FY 2016, as discussed above, section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the requirements for the FY 2016 applicable percentage increase. Therefore, we are proposing an applicable percentage increase for FY 2016 of 1.9 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with these statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Neosho Mucket and Rabbitsfoot; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2013–0007; 4500030114]

RIN 1018–AZ30

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Neosho Mucket and Rabbitsfoot

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat for two species of mussels, the Neosho mucket (*Lampsilis rafinesqueana*) and rabbitsfoot (*Quadrula cylindrica cylindrica*), under the Endangered Species Act of 1973, as amended (Act). In total, approximately 777 river kilometers (483 river miles) in Arkansas, Kansas, Missouri, and Oklahoma fall with the boundaries of the critical habitat designation for the Neosho mucket and approximately 2,312 river kilometers (1,437 river miles) in Alabama, Arkansas, Illinois, Indiana, Kansas, Kentucky, Mississippi, Missouri, Ohio, Oklahoma, Pennsylvania, and Tennessee, fall within the boundaries of the critical habitat designation for the rabbitsfoot. The effect of this rule is to extend the Act's protections to these mussels' critical habitats.

DATES: This rule is effective on June 1, 2015.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and the Arkansas Ecological Services Field Office's Web site at *http://www.fws.gov/arkansas-es/*. Comments and materials received, as well as some supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov*. All of the comments, materials, and documentation we considered in this rulemaking are available by appointment, during normal business hours, at: U.S. Fish and Wildlife Service, Arkansas Ecological Service Field Office, 110 South Amity Road, Suite 300, Conway, AR 72032; telephone 501–513–4470; facsimile 501–513–4480.

The coordinates, plot points, or both from which the maps are generated are included in the administrative record for this critical habitat designation and are available at *http://www.fws.gov/arkansas-es/*, at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0007, and at the Arkansas Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information we developed for this critical habitat designation will also be available at the U.S. Fish and Wildlife Service Web site and Field Office outlined above, and also may be included in the preamble, at *http://www.regulations.gov*, or both.

FOR FURTHER INFORMATION CONTACT: For general information about this rule, and information about the final designation in Arkansas, contact Melvin Tobin, Acting Field Supervisor, U.S. Fish and Wildlife Service, Arkansas Ecological Services Field Office, 110 South Amity Road, Suite 300, Conway, AR 72032; telephone 501–513–4470; facsimile 501–513–4480. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

For information about the final designation in Alabama, contact Bill Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208 Main Street, Daphne, AL 36526; telephone 251–441–5181; facsimile 251–441–6222.

For information about the final designation in Illinois, contact Richard C. Nelson, Field Supervisor, U.S. Fish and Wildlife Service, Rock Island Ecological Services Field Office, 1511 47th Avenue, Moline, IL 61265; telephone 309–757–5800; facsimile 309–757–5807.

For information about the final designation in Indiana, contact Scott Pruitt, Field Supervisor, U.S. Fish and Wildlife Service, Bloomington Ecological Services Field Office, 602 South Walker Street, Bloomington, IN 47403–2121; telephone 812–334–4261; facsimile 812–334–4273.

For information about the final designation in Kansas, contact Heather Whitlaw, Field Supervisor, U.S. Fish and Wildlife Service, Kansas Ecological Services Field Office, 2609 Anderson Avenue, Manhattan, KS 66502; telephone 785–539–3474; facsimile 785–839–8567.

For information about the final designation in Kentucky, contact Lee Andrews, Field Supervisor, U.S. Fish and Wildlife Service, Kentucky Ecological Services Field Office, 330 West Broadway, Suite 265, Frankfort, KY 40601; telephone 502–695–0468; facsimile 502–695–1024.

For information about the final designation in Mississippi, contact Stephen Ricks, Field Supervisor, U.S. Fish and Wildlife Service, Mississippi Ecological Services Field Office, 6578 Dogwood View Parkway, Suite A, Jackson, MS 39123; telephone 601–965–4900; facsimile 601–965–4340.

For information about the final designation in Missouri, contact Amy Salveter, Field Supervisor, U.S. Fish and Wildlife Service, Columbia Ecological Services Field Office, 101 Park DeVille Drive, Suite A, Columbia, MO 65203–0057; telephone 573–234–2132; facsimile 573–234–2181.

For information about the final designation in Ohio, contact Dan Everson, Field Supervisor, U.S. Fish and Wildlife Service, 4625 Morse Road, Suite 104, Columbus, OH 43230; telephone 614–416–8993; facsimile 614–416–8994.

For information about the final designation in Oklahoma, contact Jontie Aldrich, Acting Field Supervisor, U.S. Fish and Wildlife Service, Oklahoma Ecological Services Field Office, 9014 East 21st Street, Tulsa, OK 74129–1428; telephone 918–382–4500; facsimile 918–581–7467.

For information about the final designation in Pennsylvania, contact Lora Zimmerman, Field Supervisor, U.S. Fish and Wildlife Service, Pennsylvania Ecological Services Field Office, 315 South Allen Street, Suite 322, State College, PA 16801; telephone 814–234–4090; facsimile 814–234–0748.

For information about the final designation in Tennessee, contact Mary Jennings, Field Supervisor, U.S. Fish and Wildlife Service, Tennessee Ecological Services Field Office, 446 Neal Street, Cookeville, TN 38501; telephone 931–528–6481; facsimile 931–528–7075.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act of 1973, as amended (Act), when we determine that a species is an endangered or threatened species, we are required to designate critical habitat, to the maximum extent prudent and determinable. Designations of critical habitat can only be completed by issuing a rule.

On October 16, 2012, we published in the **Federal Register** a proposed rule to list the Neosho mucket and rabbitsfoot and designate critical habitat (77 FR 63440). We issued the final rule listing the Neosho mucket as endangered and the rabbitsfoot as threatened on September 17, 2013 (78 FR 57076).

The critical habitat units we are designating in this rule constitute our current best assessment of the areas that meet the definition of critical habitat for

Neosho mucket and rabbitsfoot. We are designating:

- For the Neosho mucket, in total, approximately 777 river kilometers (rkm) (483 river miles (rmi)) in 7 units in the Elk, Fall, Illinois, Neosho, Shoal, Spring, North Fork Spring, and Verdigris Rivers as critical habitat in Benton and Washington Counties, Arkansas; Allen, Cherokee, Coffey, Elk, Greenwood, Labette, Montgomery, Neosho, Wilson, and Woodson Counties, Kansas; Jasper, Lawrence, McDonald, and Newton Counties, Missouri; and Adair, Cherokee, and Delaware Counties, Oklahoma.
- For the rabbitsfoot, in total, approximately 2,312 rkm (1,437 rmi) in 31 units (3 with 2 subunits each) in the Neosho, Spring (Arkansas River system), Verdigris, Black, Buffalo, Little, Ouachita, Saline, Middle Fork Little Red, Spring (White River system), South Fork Spring, Strawberry, White, St. Francis, Big Sunflower, Big Black, Paint Rock, Duck, Tennessee, Red, Ohio, Allegheny, Green, Tippecanoe, Walhonding, Middle Branch North Fork Vermilion, and North Fork Vermilion Rivers and Bear, French, Muddy, Little Darby, and Fish Creeks as critical habitat in Colbert, Jackson, Madison, and Marshall Counties, Alabama; Arkansas, Ashley, Bradley, Clark, Cleburne, Cleveland, Drew, Fulton, Hot Spring, Independence, Izard, Jackson, Lawrence, Little River, Marion, Monroe, Newton, Ouachita, Randolph, Searcy, Sevier, Sharp, Van Buren, White, and Woodruff Counties, Arkansas; Massac, Pulaski, and Vermilion Counties, Illinois; Carroll, Pulaski, Tippecanoe, and White Counties, Indiana; Allen and Cherokee Counties, Kansas; Ballard, Edmonson, Green, Hart, Livingston, Logan, Marshall, McCracken, and Taylor Counties, Kentucky; Hinds, Sunflower, Tishomingo, and Warren Counties, Mississippi; Jasper, Madison, and Wayne Counties, Missouri; Coshocton, Madison, Union, and Williams Counties, Ohio; McCurtain and Rogers Counties, Oklahoma; Crawford, Erie, Mercer, and Venango Counties, Pennsylvania; and Hardin, Hickman, Humphreys, Marshall, Maury, Montgomery, Perry, and Robertson Counties, Tennessee.
- Compared to the proposed rule, this rule results in a net decrease of approximately 3 rkm (2 rmi) for the Neosho mucket and a net decrease of approximately 349 rkm (217 rmi) for the rabbitsfoot.

What this rule contains: This rule designates critical habitat for the Neosho mucket and rabbitsfoot.

We have prepared an economic analysis and environmental assessment for the designation of critical habitat. In accordance with Section 4(b)(2) of the Act, we prepared an analysis of the economic impacts of the critical habitat designations and related factors. We announced the availability of the draft economic analysis (DEA) and draft environmental assessment in the **Federal Register** on May 9, 2013 (78 FR 27171), allowing the public to provide comments on these documents. In response to requests we received, we reopened the comment period for the proposed critical habitat rule, DEA, and draft environmental assessment from August 27, 2013, to October 28, 2013 (78 FR 52894), and again from May 14, 2014, to July 14, 2014 (79 FR 27547). We have incorporated the comments and completed the final economic analysis (FEA) and associated summary memorandum describing our revised forecast calculations concurrently with this final determination.

Additionally, we have prepared an environmental assessment pursuant to the National Environmental Policy Act (NEPA). Based on the review and evaluation of the information contained in the environmental assessment, we determined that the designation of critical habitat for the Neosho mucket and rabbitsfoot does not constitute a major Federal action having a significant impact on the human environment under the meaning of section 102(2)(c) of NEPA.

Peer review and public comment. We sought comments from three independent specialists to ensure our designation is based on scientifically sound data and analyses. We obtained opinions from one knowledgeable individual with scientific expertise to review our technical assumptions and analysis, and to determine whether or not we had used the best available information. The peer reviewer generally concurred with our methods and conclusions and provided additional information, clarifications, and suggestions to improve this final rule. Information we received from peer review is incorporated in this final designation. We also considered all comments and information we received from the public during the comment period.

Previous Federal Actions

Please refer to the proposed listing and critical habitat rule for the Neosho mucket and rabbitsfoot published in the **Federal Register** on October 16, 2012 (77 FR 63440), for a detailed description of previous Federal actions concerning these species and protection under the Act (16 U.S.C. 1531 *et seq.*). The final rule listing the Neosho mucket as an endangered species and rabbitsfoot as a threatened species under the Act was published in the **Federal Register** on September 17, 2013 (78 FR 57076).

Summary of Comments and Recommendations

We requested written comments from the public on the proposed designation of critical habitat for the Neosho mucket and rabbitsfoot during four comment periods. The first comment period opened with the publication of the proposed rule on October 16, 2012, and closed on December 17, 2012 (77 FR 63440). Second, we requested comments on the proposed critical habitat designation and associated DEA and draft environmental assessment during a comment period that opened May 9, 2013, and closed on June 10, 2013 (78 FR 27171). Third, we re-opened the comment period for another 60 days from August 27, 2013, through October 28, 2013 (78 FR 52894). Based on continued significant interest in Arkansas regarding the proposed rule, we announced an additional reopening of the comment period for 60 days from May 14, 2014, through July 14, 2014 (79 FR 27547). We held public information meetings in Joplin, Missouri, on May 21, 2013; Greenville, Missouri, on May 23, 2013; Batesville, Arkansas, on June 4, 2014; and Benton, Arkansas, on June 5, 2014. The dates, times, and locations of these meetings were coordinated with interested stakeholders and noticed in newspapers and other media outlets. We also contacted appropriate Federal, State, and local agencies; tribes; scientific organizations; and other interested parties and invited them to comment on the proposed rule, DEA, and draft environmental assessment. In addition, we published a total of 27 legal public notices in the affected States at the beginning of the comment period for the proposed rule published on October 16, 2012.

During the first comment period, we received 10 comment letters directly addressing the proposed listing and critical habitat designation. During the second, third, and fourth comment periods, we received 11, 6, and 68 comment letters, respectively, addressing the proposed critical habitat designation, DEA, or draft environmental assessment. All substantive information provided during the comment periods has either been incorporated directly into this final determination or is addressed below. Comments are addressed in the following summary and incorporated into the final rule as appropriate.

Peer Review

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinions from three knowledgeable individuals with scientific expertise on freshwater mussel conservation and biology, with familiarity of Neosho mucket and rabbitsfoot, the geographic region and river basins in which they occur, and conservation biology principles associated with these species. We received responses from all of the peer reviewers we contacted, but only one peer reviewer commented on the proposed critical habitat designation.

We reviewed all comments we received from the peer reviewer for substantive issues and new information regarding critical habitat for the Neosho mucket and rabbitsfoot. The peer reviewer generally concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions to improve the final critical habitat rule. The peer reviewer's comments on the designation of critical habitat for these mussels are addressed in the following summary and incorporated into the final rule as appropriate.

Peer Reviewer Comments

(1) *Comment:* The peer reviewer noted the proposed critical habitat designation for rabbitsfoot references the oyster mussel (*Epioblasma capsaeformis*) as a listed species with overlapping critical habitat in the Duck River unit. The reviewer noted the oyster mussel in this river has been renamed the Duck River dartersnapper (*Epioblasma ahlstedti*) and is separate and distinct from the oyster mussel.

Our Response: We agree with the reviewer and acknowledge the oyster mussel and Duck River dartersnapper are distinct and separate species. However, the Service has not yet made a listing and critical habitat determination for the new entity, the Duck River dartersnapper. We incorporated language in this final determination to clarify the species distinction and name change, but at this time, the Duck River dartersnapper and oyster mussel are considered synonymous according to our regulations. Until such time as the regulations are revised, the critical habitat that overlaps rabbitsfoot critical habitat in the Duck River will be identified as that of the oyster mussel.

General Comments

(2) *Comment:* Multiple commenters expressed concern about interagency consultation under section 7 of the Act, particularly any differences in process between consultation on impacts to the listed species and consultation on the species' designated critical habitat. They also expressed concern about impacts on non-Federal property owners and other entities from the new restrictions resulting from the designation of critical habitat.

Our Response: Section 7(a)(2) of the Act, and its implementing regulations at 50 CFR part 402, subpart B, requires Federal agencies to consult with the Service to ensure that they are not undertaking, funding, permitting, or authorizing actions likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat. Only projects that have a Federal nexus (projects that are funded, authorized, or carried out by Federal agencies) are subject to this requirement under section 7 consultation. In fulfilling these consultation requirements, each Federal action agency and the Service must use the best scientific and commercial data available.

In occupied critical habitat, consultation for potential impacts to the species and potential impacts to critical habitat occur at the same time. The health of both mussels is closely tied to the health of their habitat. Therefore, the Service does not expect to recommend additional conservation efforts for projects to avoid adverse modification of critical habitat above and beyond what would already be required to avoid jeopardizing the continued existence of the listed species. In addition, other federally listed mussels occur in the same reaches as certain areas of designated critical habitat for Neosho mucket or rabbitsfoot; the conservation efforts already required for these listed mussels through consultation will provide the same conservation for Neosho mucket or rabbitsfoot.

As a result, we conclude that additional (incremental) project modification costs are unlikely from this designation of critical habitat. Any incremental costs, as predicted in our final economic analysis (FEA), are primarily a result of the additional requirement of considering impacts to critical habitat during these section 7 consultations. These costs are borne by the Service, the Federal action agency, and the third-party participants (generally the project proponents), including State and local governments and private parties. For a summary of the parties involved in section 7 consultations and their respective unit costs, see Exhibit 2–1 of the FEA. Chapter 3 of the FEA provides a detailed discussion of the types of third parties participating in consultations.

Federal Agency Comments

(3) *Comment:* The U.S. Army Corps of Engineers (ACOE) Pittsburgh District (COEPD) expressed concern that designating critical habitat for the rabbitsfoot may affect the COEPD's navigation and maintenance dredging activities in the Alleghany River, its operation of Alleghany Reservoir, and its regulatory program. ACOE stated that additional avoidance measures will be required to adequately protect habitat for rabbitsfoot.

Our Response: The federally endangered clubshell (*Pleurobema clava*), northern riffleshell (*Epioblasma torulosa rangiana*), rayed bean (*Villosa fabalis*), and snuffbox (*Epioblasma triquetra*) mussels occur in the same reach of the Allegheny River as rabbitsfoot. Therefore, section 7 requires consultation by Federal agencies for these listed species (see our response to Comment 2). Project modifications that minimize effects to these species would also minimize effects to rabbitsfoot. Thus, we do not expect any conservation measures or project modifications and costs for rabbitsfoot critical habitat beyond those already required for these other endangered mussels.

(4) *Comment:* The COEPD asked how tributary streams to the Allegheny River will be affected by designation of critical habitat for rabbitsfoot.

Our Response: French Creek (proposed Unit RF23; Unit RF22 in this rule) and Muddy Creek (proposed Unit RF25; Unit 24 in this rule) are the only two tributaries of the Allegheny River designated as critical habitat for rabbitsfoot. The Service will work with COEPD to determine whether any of the current, ongoing, or planned COEPD projects may have an effect on other tributaries within their district. As stated previously, the Service does not expect to recommend any project modifications in order to minimize effects to rabbitsfoot beyond those already required for other listed mussels in the Allegheny River basin.

(5) *Comment:* The ACOE Huntington District stated that the designation of critical habitat for rabbitsfoot in the Walhonding River (proposed Unit RF27) is not consistent with the definition of critical habitat (that lakes and impoundments are not included). They stated that 40 percent of the Walhonding River upstream of Mohawk Dam in Ohio is impounded for flood control.

Our Response: Mohawk Dam is a dry dam, meaning during normal flows,

water passes through the dam unimpeded and there are no permanent pools of water (areas of inundation) upstream resulting from the structure. During high flow events, the dam temporarily reduces flows downstream of the structure to maintain flows within the river banks. Hoggarth (1995–1996, pp. 163–164) found a stable and diverse mussel assemblage, including adult and juvenile rabbitsfoot, upstream of Mohawk Dam. Because Mohawk Dam does not inundate riverine habitat by forming a lake or reservoir and a diverse and abundant mussel assemblage inhabits upstream reaches behind the dam, we believe the habitat there contains the primary constituent elements for rabbitsfoot critical habitat (see *Primary Constituent Elements for Neosho Mucket and Rabbitsfoot,* below).

Section 3.3.1 of the FEA has been amended to add information about the presence of the dam in the study area of proposed Unit RF27; however, the Service does not expect to recommend additional conservation efforts for the dam, above and beyond what would be required to protect against jeopardy of the species, to protect against adverse modification of critical habitat.

(6) *Comment:* The ACOE Little Rock District stated that the designation will result in increased costs for energy development and that the estimated cost of timing restrictions and limiting project scope are too low, as projects may be delayed or denied due to permitting and modification issues.

Our Response: The discussion of potential baseline impacts in the FEA has been updated to reflect additional information provided by the ACOE regarding impacts to energy development associated with avoidance and delays related to the presence of the species. Exhibit 4–2 of the FEA (''Ranges of Costs of Common Conservation Efforts for Mussel Species'') notes that the cost of conservation efforts may be higher than the estimates shown. A key conclusion of the analysis is that the listing of the species may lead to many conservation efforts (such as those presented in Exhibit 4–2) that would not have been required previously. However, as outlined in our response to Comment 2, designation of critical habitat is not anticipated to generate additional conservation measures for these two mussels beyond those generated by the species' listing.

State Agency Comments

Section 4(i) of the Act states, ''the Secretary shall submit to the State agency a written justification for [her] failure to adopt regulations consistent with the agency's comments or petition.'' The designation of critical habitat for Neosho mucket includes streams in Arkansas, Kansas, Missouri, and Oklahoma, and for rabbitsfoot includes streams in Alabama, Arkansas, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Ohio, Oklahoma, Pennsylvania, and Tennessee. We received comments from the States of Illinois, Kansas, Pennsylvania, Ohio, and Oklahoma regarding the proposal and address them below.

(7) *Comment:* The Pennsylvania Fish and Boat Commission (PFBC) supported the designation of critical habitat for rabbitsfoot. PFBC recommended extending the critical habitat designation for rabbitsfoot upstream from Kidds Mill Road to Pymatuning Dam on the Shenango River. Western Pennsylvania Conservancy (WPC) submitted a public comment with the same recommendation. PFBC provided a report by Bursey (1987) documenting the presence of rabbitsfoot at Porter Road, 8.5 rkm (5.3 rmi) upstream of Kidds Mill Road. PFBC stated that without critical habitat designation in this location, any newly discovered rabbitsfoot populations in this river reach would not be protected by the Act.

Our Response: We appreciate PFBC's support and look forward to continuing work with the PFBC and WPC to recover rabbitsfoot. Considering the information in Bursey (1987), we agree the extent of critical habitat designation in the Shenango River should be extended 8.8 rkm (5.4 rmi) upstream to Porter Road. This modification is reflected in this final determination. As described under *Criteria Used to Identify Critical Habitat,* we reviewed available information pertaining to the habitat requirements of rabbitsfoot. In accordance with the Act and its implementing regulation at 50 CFR 424.12(e), we considered whether designating additional areas—outside those currently occupied as well as those occupied at the time of listing—are necessary to ensure the conservation of the species. However, we respectfully disagree that there is sufficient scientific information from which to conclude that the reach from Pymatuning Dam to Porter Road is occupied by rabbitsfoot. While this reach appears to contain sufficient physical or biological features to support the life history of mussels, possibly including rabbitsfoot, we determined that designating unoccupied critical habitat for rabbitsfoot was not essential for the conservation of the species in this reach due to the altered natural stream hydrology and geomorphology. Unoccupied areas exhibit limited habitat availability, degraded habitat, or low potential value for management, and there are no historical records of occurrence within the stream reach for rabbitsfoot (see also *Criteria Used to Identify Critical Habitat*).

This does not mean, however, that this reach will be without protection if the rabbitsfoot is later found to occupy that reach. The protections of the Act brought about by the species' listing are in effect wherever the species is found. In addition, the reach upstream of Porter Road will continue to be protected through the conservation actions implemented for the other listed mussels (*e.g.,* clubshell) that currently occur in that area.

(8) *Comment:* PFBC suggested that by restricting critical habitat to occupied areas, the Service appears to be unintentionally inhibiting recovery of rabbitsfoot, as habitat loss outside of critical habitat areas cannot be avoided under a section 7 jeopardy analysis.

Our Response: It is correct that section 7 consultation would not be triggered for potential rabbitsfoot habitat that is not occupied by the species or designated as critical habitat (although some areas may be occupied by other listed species and/or critical habitat for other listed species that would trigger section 7 consultations on Federal actions). However, we disagree that recovery of either species will be inhibited because we are not designating unoccupied habitat. We have found that unoccupied stream reaches are not essential for the conservation of either species for one or more of the following reasons:

(a) Unoccupied habitats are isolated from occupied habitats due to reservoir construction and dam operations;

(b) Unoccupied areas exhibit limited habitat availability, degraded habitat, or low potential value for management;

(c) Collection records for both species indicate that these species have been extirpated from unoccupied areas for several decades or more, and, in some cases, reintroduction efforts have not been successful at re-establishing populations; or

(d) There are no historical records of occurrence within the stream reach for Neosho mucket, rabbitsfoot, or both.

While we recognize the importance of unoccupied habitat to recovery of listed species, in this case unoccupied habitat does not at this time provide habitat for reintroduction or reduce the level of stochastic and human-induced threats (see *Criteria Used to Identify Critical Habitat* for more detailed information).

(9) *Comment:* The Ohio Department of Transportation (ODOT) inquired about costs for highway departments and other public infrastructure entities and whether normal consultation time would increase due to the designation of critical habitat. ODOT believes the estimated economic impact of $1.4 million to the transportation and utility sectors over the next 20 years is an underestimate. This conclusion is based on the assumption that no instream work will be allowed for any project over or near critical habitat. ODOT provides an example of replacing a multiple span bridge with a single span structure increases cost by an average of 260 percent, or from $2.2 million to $5.6 million, exceeding the Service's estimate of economic impacts. The agency also expressed the belief that replacement or maintenance costs to improve or maintain 23 bridge structures over designated critical habitat areas will increase and the economic impact to ODOT alone will exceed the estimated $1.4 million forecast in the economic analysis for transportation and utility activities without considering increased costs associated with coordination, survey, reporting, mitigation, and monitoring.

Our Response: Future section 7 consultations concerning transportation and utilities are expected to occur in 35 critical habitat units, including the Walhonding River and Little Darby and Fish Creeks (proposed Units RF27, RF28, and RF30; Units RF26, RF27, and RF29 in the final rule) in Ohio. Collectively, transportation and utilities consultations in these three critical habitat units are forecast to cost $15,000 over the next 20 years or $980 annually (one percent of total transportation and utilities costs). For comparison, the total transportation and utilities cost for all critical habitat units are forecast to cost $1,400,000 over the next 20 years or $93,000 annually (Exhibit 3–9 in the FEA). The designation of critical habitat will not preclude the construction of instream bridge support structures or maintenance to existing piers.

The designation of critical habitat does not change the time frames required to complete consultation under section 7 of the Act and its implementing regulations at 50 CFR part 402, subpart B. As previously stated, conservation measures required to avoid jeopardizing the continued existence of the species are expected to be similar to those required to avoid adversely modifying critical habitat (that is, we foresee no conservation actions specifically due to critical habitat). We do not expect the designation of critical habitat to lengthen the consultation process. Thus, the best available economic data do not support ODOT's assertion.

(10) *Comment:* The ODOT inquired about how the Service ensures consistent consultation on critical habitat throughout the range of rabbitsfoot. ODOT concluded that the term ''adverse modification'' is vague and interpretations, policies, and level of effort could vary among Service offices.

Our Response: In 1986, the Service and the National Marine Fisheries Service (collectively referred to as the Services) established a definition for ''destruction or adverse modification'' (50 CFR 402.02) that was later found to be invalid by the U.S. Court of Appeals for the Fifth (2001) and Ninth (2004) Circuits. The Services each issued guidance to discontinue the use of the 1986 adverse modification regulation. Specifically, in evaluating an action's effects on critical habitat as part of interagency consultation, the Services began applying the definition of ''conservation'' as set out in the Act, which defines conservation (and conserve and conserving) to mean ''to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no long necessary'' (16 U.S.C. 1532(3)). Further, after examining the baseline and effects of the action, the Services began analyzing whether the implementation of the Federal action under consultation, together with any cumulative effects, would result in the critical habitat remaining ''functional'' (or retain the current ability for the primary constituent elements to be functionally established) to serve the intended conservation role for the species.

Section 7(a)(2) of the Act defines the consultation process, which is further developed in regulations set forth at 50 CFR part 402 and in the Service's section 7 handbook (guidance). The handbook ensures consistent implementation of consultation procedures by Service field offices responsible for carrying out section 7 activities throughout the range of rabbitsfoot. Furthermore, the Service and the Federal action agency are required to use the best available science in conducting the consultations (see our response to Comment 2).

On May 12, 2014, we published a proposed rule in the **Federal Register** (79 FR 27060) to adopt the following definition of destruction or adverse modification: ''Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the conservation value of critical habitat for listed species. Such alterations may include, but are not limited to, effects that preclude or significantly delay the development of physical or biological features that support the life-history needs of the species for recovery.'' On June 26, 2014 (79 FR 36284) we extended the public comment period on the proposal to October 9, 2014. We have not yet published a final rule for this action, but expect to do so in the spring of 2015.

(11) *Comment:* The ODOT requested an exclusion from critical habitat designation for portions of the river underneath and directly adjacent to roadway bridges in the Walhonding River and Little Darby and Fish Creeks. ODOT concluded that since bridge structures already exist and areas under the bridge are subject to regular maintenance activities that section 7 consultation for other listed mussels in these streams would be adequate to protect rabbitsfoot while streamlining consultation.

Our Response: Under section 4(b)(2) of the Act and its implementing regulations at 50 CFR 424.19, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise her discretion to exclude the area only if such exclusion would not result in the extinction of the species.

This area is not subject to exclusion based on impacts to national security or other relevant impacts, such as the presence of a conservation plan (for example, a habitat conservation plan (HCP)), status as a tribal land, or an existing partnership. In evaluating whether it should be excluded due to economic impacts, we concluded that no change in economic activity levels or the management of economic activities is expected to result from the critical habitat designation (see our response to Comment 2). Some additional costs reflect additional administrative effort as part of future section 7 consultations in order to consider the potential for activities to result in adverse modification of critical habitat. Section 7 consultation is required in occupied habitat with or without a critical habitat

designation. We acknowledge it is unlikely additional conservation measures beyond those identified to avoid jeopardy for the species would be required to avoid adverse modification. Accordingly, the Secretary is not exerting her discretion to exclude any areas in the Walhonding River and Little Darby and Fish Creeks from the designation based on economic impact, national security impact, or other relevant impacts.

(12) *Comment:* The Oklahoma Department of Wildlife Conservation (ODWC) stated that it does not support designation of critical habitat for Neosho mucket and rabbitsfoot. ODWC questioned potential benefits of critical habitat designation cited in the proposed rule (77 FR 63472), which ODWC stated are not compelling arguments in favor of designation. ODWC concluded:

(a) The presence of Neosho mucket or rabbitsfoot in a stream segment already is a trigger for section 7 consultation and the designation of critical habitat does not change this requirement;

(b) The focusing of conservation activities on the most essential features and area for each mussel species should be addressed through development and implementation of a recovery plan, and the designation of critical habitat is not essential to this prioritization process and can be articulated just as effectively in the recovery plan;

(c) The educational benefits derived from critical habitat can be conveyed through Federal, State, and private entities more effectively with an informative, detailed, and publicly accessible Web site; and

(d) It is not clear how designation of critical habitat prevents ''people from causing inadvertent harm to the species'' as the designation only applies to Federal actions and not those of the general public.

ODWC further concluded, based on these four arguments, that there is no unique added value to the designation of critical habitat.

Our Response: Section 4(a)(3)(A) of the Act requires that, to the maximum extent prudent and determinable, we designate critical habitat at the time a species is determined to be endangered or threatened. Our regulations at 50 CFR 424.12(a)(1) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species. The Service determined that there is no threat of take attributed to collection or vandalism under Factor B for either species, and identification and mapping of critical is not expected to initiate any such threat. We also believe that designating critical habitat will be beneficial to the species, as described in the proposed rule (77 FR 63440, p. 63472) (see also our response to Comment 52, below). We address ODWC's specific conclusions below.

(a) We acknowledge that presence of Neosho mucket or rabbitsfoot is a trigger for section 7 consultation with or without the designation of occupied critical habitat. We also acknowledge occupied areas outside the final critical habitat designation will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act, regulatory protections afforded by the section 7(a)(2) jeopardy standard, and the prohibitions of section 9 of the Act. However, if designated critical habitat should become unoccupied at some point in the future, the designation of critical habitat ensures regulatory protections afforded by section 7(a)(2).

(b) We acknowledge that critical habitat designation is not essential to establish recovery criteria and prioritize recovery actions during development and implementation of recovery plans. However, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat), which can be very beneficial both in focusing conservation efforts on specific activities, areas, or features and in establishing future recovery efforts. Designation can often help to focus recovery efforts and ensure these features, areas, and activities receive priority during section 7 consultations and the planning efforts of both the Service and its partners.

(c) We agree that the Internet and social media are effective venues to convey the benefits of designating critical habitat. We also agree there are many misperceptions by entities and individuals regarding designation of critical habitat. The Service maintains a publicly accessible Internet site, social media, and other educational materials related to critical habitat and the Act, in general, to inform the public and abate concerns. In outlining benefits of designating critical habitat for Neosho mucket and rabbitsfoot, our intent was not to imply that designation of critical habitat is only an educational tool for the recovery of Neosho mucket and rabbitsfoot. To the contrary, critical habitat is a tool within the Act which identifies areas essential to the conservation of endangered and threatened species and that may require special management considerations. Through identification of physical or biological features essential to the conservation of Neosho mucket and rabbitsfoot, critical habitat informs agencies, entities, and individuals about habitats and specific features of these habitats essential to the conservation of Neosho mucket and rabbitsfoot and helps focus efforts. Accordingly, even though designation is not the sole educational tool in the recovery process, it may still provide educational benefits.

(d) Federal agencies must consult with the Service to ensure that any action authorized, funded, or carried out will not destroy or adversely modify critical habitat for listed species. This rule identifies the primary constituent elements of the physical or biological features essential to the conservation of Neosho mucket and rabbitsfoot. These primary constituent elements will help Federal agencies (and those for which they are providing funding, providing authorization, or completing activities) in planning or evaluating projects. In addition, it may be beneficial to those who wish to conserve this species to know which areas have been determined to be essential to the conservation of the species through this designation. The maps in the designation spatially depict the areas we have identified as critical habitat, assisting with these efforts.

(13) *Comment:* ODWC stated that the Service (a) did not identify and quantify the relative importance of potential threats in each critical habitat unit, and (b) cannot determine whether Federal actions are important to the recovery of Neosho mucket and rabbitsfoot. ODWC further concluded that if Federal actions are not relevant then designation of critical habitat has no recovery value.

Our Response: In each unit description in the proposed designation, the Service identified physical or biological features that may require special management considerations or protections to address threats such as land use conversion; alteration of water chemistry and water and sediment quality; changes in stream bed material composition and quality from activities that release sediments and nutrients into the water, such as urban development and associated construction projects; livestock grazing; and releases from municipal effluents. In addition, in the Effects of Critical Habitat Designation, *Section 7 Consultation* and *Application of the ''Adverse Modification'' Standard* sections in the proposed designation (77

FR 63440), we discuss the Federal process concerning section 7 consultations and review of projects for adverse modification of designated critical habitat. We provide a description of the actions and activities that may result in adverse effects to occupied Neosho mucket and rabbitsfoot critical habitat. This is not an exhaustive list, and we note that the activities listed may be able to be modified by measures which would sufficiently offset the potential adverse effects so that the value of the habitat for its intended conservation function is not appreciably reduced. The occurrence of the actions we described will not always result in adverse modification of critical habitat if the available compensation can reduce the effects of these actions on the habitat.

These types of activities would require section 7 consultation only in cases where there is Federal involvement (see response to Comment 2). The FEA examined the Service's section 7 consultation record as a means to project future consultations. The FEA also accounts for projected increases in section 7 consultations, by activity category, based on communication with Service field offices and Federal agencies. Additional supporting information and documentation for the FEA is contained within our administrative record. The ACOE, Bureau of Land Management, U.S. Department of Energy, Federal Energy Regulatory Commission, U.S. Department of Transportation (DOT), U.S. Department of Agriculture (USDA) Forest Service, Environmental Protection Agency (EPA), and Tennessee Valley Authority are Federal agencies who may fund, permit, or conduct actions that may potentially affect designated critical habitat for Neosho mucket or rabbitsfoot and are expected to consult with the Service under section 7 of the Act. Recovery of these mussels will not be attained without the valuable contribution of our Federal partners, in accordance with section 7(a)(1) of the Act, as well as our State and nongovernmental partners.

(14) *Comment:* The ODWC recommended modification to Unit RF2 (Verdigris River) for rabbitsfoot. ODWC indicated that the critical habitat unit includes a portion of the Verdigris River downstream of Oklahoma Highway 266, which has been substantially modified by dredging and channel modification to create the upper end of the McClellan-Kerr Arkansas River Navigation System.

Our Response: In response to this comment, we have re-evaluated Unit RF2, and, based on the best available scientific information, we are modifying it in this final rule. For further information, see Summary of Changes from Proposed Rule, below.

(15) *Comment:* The ODWC questioned the biological benefit of including Unit NM1 for Neosho mucket due to existing State water quality standards. ODWC also suggested that the designation of critical habitat may hinder recreational activity in the Illinois River.

Our Response: Please refer to our responses for Comments 12 and 13. Since recreational activities on the Illinois River are not regulated by a Federal agency, we do not anticipate any effects to recreational activities due to the designation of critical habitat in Unit NM1.

(16) *Comment:* The Pennsylvania Department of Transportation (PDOT) opposed the designation of critical habitat for the rabbitsfoot due to the financial hardship it believes the designation will bring to Pennsylvania taxpayers. PDOT concluded it would not be a prudent expense of transportation dollars to engage in all the coordination and expense associated with the critical habitat designation.

Our Response: All PDOT activities authorized or funded, in whole or part, by the Federal Highway Administration (FHA) or permitted by a Federal agency such as the ACOE (such as, placement of bridge piers in a navigable stream) are required to adhere to section 7(a)(2) of the Act (see our response to Comment 2). PDOT projects that have no Federal nexus are not subject to section 7 consultation. However, as previously stated, four other federally endangered mussels occur in the same reaches of the Allegheny and Shenango Rivers and French and Muddy Creeks as the rabbitsfoot. Although no critical habitat has been designated for these mussels, we believe that project modifications that have been implemented to minimize effects to these listed mussel species are the same types of measures that would be implemented to minimize effects to rabbitsfoot and its critical habitat. Therefore, we expect the additional cost to taxpayers to be minimal.

(17) *Comment:* The PDOT stated there will be additional costs associated with section 7 consultation with FHA due to the requirement to prepare a biological assessment in designated critical habitat regardless of species presence. PDOT requested evaluation of all financial impacts to the agency associated with designating critical habitat. PDOT also suggested adverse modification has not occurred previously at completed bridge projects as evidenced by the Service's willingness to utilize these sites for reintroduction of endangered mussels.

Our Response: FHA is required under section 7(a)(2) of the Act to evaluate beneficial and adverse effects associated with their actions in areas containing listed species. While the Service agrees some completed bridge project sites may serve as suitable sites for mussel augmentation and reintroduction, potential effects of future bridge projects to listed species and their critical habitat will vary depending on a variety of factors, including, but not limited to, the location and type of structure being proposed, as well as the extent to which rabbitsfoot occurs in the project area. Under section 7(a)(2) of the Act and its implementing regulations at 50 CFR part 402, subpart B, Federal agencies are not required to prepare biological assessments for actions that they determine will have no effect, or that may affect but are not likely to adversely affect, a species and its designated critical habitat. Therefore, if a bridge project is deemed not likely to adversely affect this species or other listed species or their critical habitat, no biological assessment would be required by the agency.

One of the main conclusions of the FEA is that the Service does not expect critical habitat designation to result in project modification costs beyond what would be requested to avoid jeopardy to the species. As a result, we expect incremental economic impacts of considering critical habitat as part of the forecast section 7 consultations will be limited to additional administrative costs to the Service, Federal agencies, and third parties. Future section 7 consultations concerning transportation and utilities are expected to occur in 34 critical habitat units, including French Creek, the Allegheny River, and Muddy Creek (Units RF22, RF23, and RF24 in this rule) that occur in Pennsylvania. Collectively, transportation and utilities consultations in these three critical habitat units are forecast to cost $196,000 over the next 20 years or $12,500 annually. For comparison, the total transportation and utilities cost for all critical habitat units are forecast to cost $1,400,000 over the next 20 years or $93,000 annually (Exhibit 3–9 in the FEA; IEc 2014a, p. 1). As outlined in the FEA, these costs are the incremental costs of the critical habitat designation (that is, those costs, such as expenditures related to consultation, which can be attributed solely to critical habitat).

(18) *Comment:* PDOT asked the Service ''that if the Rabbitsfoot Mussel is listed and critical habitats are designated, that there is solid scientific

evidence that the species for which the critical habitat is being designated is present and/or uses the habitat.'' PDOT asserted that it committed significant monetary resources in the past to mitigate effects to endangered and threatened species in areas with no evidence of species presence.

Our Response: The Act and its implementing regulations require the Service to use the best available scientific and commercial data during consultation (see response to Comment 2). The Service will continue to work with PDOT and other partners to ensure procedures to document presence or absence of the mussels is scientifically supported and to avoid and minimize effects to the rabbitsfoot in areas where this and other listed species are present and critical habitat is designated.

(19) *Comment:* PDOT requested minor road work (such as rehabilitation or resurfacing) and bridge work (such as replacement and repair) on existing roads be exempt from formal coordination (consultation), including areas 100 feet (ft) upstream and downstream of the project foot print.

Our Response: Only PDOT projects that have a Federal nexus are subject to consultation (see our response to Comment 2). There is no *de minimis* exception from the consultation requirement. However, to streamline the consultation process, a Federal agency's determination of ''no effect'' or ''no adverse modification'' does not require concurrence by the Service.

(20) *Comment:* PDOT expressed concern with its ability to quickly issue hauling permits for oversize and overweight loads and to restrict routing for materials such as fracking brine. The need to restrict routing for a subset of haulers such as hazardous material haulers would preclude PDOT's ability to electronically permit and route these haulers, resulting in extensive time delays and subsequently a need for a significant increase in manpower. PDOT concluded that manual permit review to assure limited section 9 liability represents significant economic burden to both the State of Pennsylvania (due to increases in manpower) and to many other industries (due to permit delays).

PDOT also identified the DOT's Federal Motor Carrier Safety Administration and Pipeline and Hazardous Material Safety Administration as the regulatory agencies with oversight for transportation of hazardous materials on main traffic routes. PDOT concluded that a section 7 consultation is required for each load in response to the designation of critical habitat and each tanker truck is subject to those consultation procedures or detour routes around critical habitat (for example, to avoid crossing designated critical habitat in French Creek).

Our Response: The Service appreciates PDOT's input. We respectfully disagree that the designation of critical habitat for rabbitsfoot would increase PDOT's section 9 liability and create or increase an economic burden on the State of Pennsylvania and industries transporting hazardous materials. A key conclusion of the FEA for rabbitsfoot critical habitat designation is that the Service does not expect critical habitat designation to generate additional requests for project modification in any of the critical habitat units, including the Allegheny and Shenango Rivers and French and Muddy Creeks. Our conclusion is based on the FEA and that the creeks and rivers where rabbitsfoot occurs are already inhabited by other federally listed mussels. Project modifications that minimize effects to other listed mussel species within these reaches also would minimize effects to rabbitsfoot (see our response to Comment 2).

(21) *Comment:* PDOT indicated it has pre- and post-Marcellus and Utica shale drilling truck accident reports that may be useful in identifying whether increased oil and gas exploration has or has not translated to an increased threat of crashes that may release contaminants.

Our Response: The Service appreciates PDOT's cooperation to further identify potential threats to rabbitsfoot and designated critical habitat. Your comments have been forwarded to our Pennsylvania Ecological Services Field Office so that they may review the information and, if appropriate, work cooperatively with PDOT to minimize any potential threats to rabbitsfoot and its designated critical habitat and other listed mussels from contamination that may result from these accidents.

(22) *Comment:* PDOT stated that the information and data it provided refines the Service's analysis regarding the proposed designation of critical habitat for rabbitsfoot in proposed Units RF23, RF24, RF25, and RF32 and provided evidence that diminishes, to a significant extent, the threat from chemical contamination as a result of spills at bridge crossings over critical habitat. PDOT requested a detailed list of hazardous materials that pose a threat of adverse modification in order to plan and prepare for actions PDOT must take to reduce their potential liability under section 9 of the Act.

Our Response: Due to the vast number of hazardous materials hauled on the nation's roads and limited toxicity data available for different life stages of freshwater mussels and their potential sensitivity to many of these compounds and effects to their habitat, the Service is unable to provide a comprehensive list of hazardous materials that may affect rabbitsfoot designated critical habitat. However, please refer to the Chemical Contaminants section of the proposed listing and designation of critical habitat rule (77 FR 63440) for further detail on compounds known to adversely affect freshwater mussels and their habitats.

(23) *Comment:* ODOT and PDOT expressed concern that the DEA underestimated impacts to the transportation sector associated with the proposed designation. They asserted that the DEA does not account for the additional consultation, coordination, surveying, reporting, assessment, mitigation, and monitoring costs that will result from the rule. According to one comment, there are 23 existing structures crossing critical habitat in Ohio that will be affected by the rule due to project modifications that will discontinue in-water work. Another comment asserted that permits for roadwork in Pennsylvania will be interrupted as a result of the rule, and that this will result in time delays and traffic diversions.

Our Response: Section 3.3.6 of the FEA provides information on the likely incremental impacts of the designation to transportation and utility-related activities. The analysis forecasts future section 7 consultations on these activities using both historical consultation data and information from the Service's field offices that have jurisdiction in the study area regarding likely future consultations. As the commenters did not provide specific information regarding the number or rate of future consultations in the study area (including Ohio) over the next 20 years, the analysis relies on the estimates provided in section 3.3.6 of the FEA. Specifically, the FEA estimates that over the next 20 years, approximately 13.3 consultations are likely to occur for transportation projects in proposed critical habitat units RF27 and RF28, which are located in Ohio, in addition to approximately 3.3 consultations in proposed critical habitat unit RF30, which is located in Indiana and Ohio.

The designation of critical habitat is not anticipated to generate additional conservation measures for the two mussels beyond those that would be generated by the species being listed.

Regardless of whether critical habitat is designated, the time period for consultation does not change. Therefore, the designation is unlikely to result in incremental project delays due to the consultation process. As a result, we expect the quantified direct incremental impacts of the designation will be limited to additional administrative costs to the Service, Federal agencies, and third parties of considering critical habitat as part of future section 7 consultations (see our response to Comment 2).

(24) *Comment:* The Kansas Department of Wildlife, Parks and Tourism (KDWPT) expressed concern regarding the proposed designation of critical habitat for Neosho mucket in the Cottonwood River (Unit NM8). KDWPT provided data from 2013 surveys of two Neosho mucket reintroduction sites. Only one live Neosho mucket was located from the original reintroduction effort. KDWPT contended that this river reach does not support a self-sustaining population and that there are no data available to suggest reintroduction efforts have been successful; therefore, this habitat should not be considered occupied.

Our Response: We agree that the Cottonwood River should not be considered occupied, and we are not designating critical habitat for Neosho mucket in the Cottonwood River. We have clarified our definition of occupied for the Neosho mucket (see Summary of Changes from Proposed Rule).

(25) *Comment:* KDWPT suggested that the Cottonwood River population of Neosho mucket be considered an experimental population and propagated individuals be exempted from take under the Act. KDWPT also suggested that safe harbor agreements should be made available to any landowner agreeing to release Neosho mucket individuals in the Cottonwood River.

Our Response: We are not designating critical habitat for Neosho mucket in the Cottonwood River (proposed Unit NM8), Chase County, Kansas. Recent KDWPT data from 2013 (Tabor 2013, pers. comm.) do not support that released individual mussels into the Cottonwood River were able to survive and become established (thriving and sufficiently viable to suggest continuation or permanence without human intervention), and the future success of the reintroduction efforts are unknown at this time (see Summary of Changes from Proposed Rule, below).

The Secretary may authorize the establishment of an experimental population (including offspring arising solely therefrom) by regulation under section 10(j) of the Act if the location of that population is wholly separate geographically from nonexperimental populations of the same species. However, the Cottonwood River is not outside the current range of Neosho mucket, so such a regulation is not appropriate. If any of the released Neosho mucket individuals are found to have survived, they are protected by the provisions of the Act as an endangered species.

If determined to be appropriate for the landowner and conservation of the mussel, the Service will work with interested property owners to develop a safe harbor agreement and to apply for an enhancement of survival permit pursuant to section 10(a)(1)(A) of the Act. The Service will also assist property owners in identifying actions they can voluntarily undertake or forego to benefit species covered by the safe harbor agreement and permit.

Public Comments

(26) *Comment:* Several commenters expressed concern that the designation of critical habitat in Arkansas and Kansas gives the Service authority to restrict activities on privately owned land. The commenters specifically expressed concern regarding landowner water development projects, development or modification of livestock and irrigation water rights, normal aquaculture, farming and ranching activities, timber harvests, housing development projects, and development of mineral rights. They wanted to know whether these activities would trigger section 7 consultation and, if so, what the costs would be to private landowners for these consultations.

Our Response: The designation of critical habitat will not increase government regulation of private land. Private activities are not subject to the Act's section 7 consultation requirements unless the activities are authorized, funded, or carried out by a Federal agency. Most normal operations for rearing of livestock or fish, or for other land uses common in Arkansas and Kansas, do not require Federal permits or funding and are not carried out by a Federal agency. Therefore, we do not anticipate this designation will impose any additional direct regulatory burdens to private landowners in Arkansas and Kansas (see our response to Comment 2).

(27) *Comment:* One commenter requested that the Service designate critical habitat only in stream reaches with recent live specimen collections and that the designation extend no more than 3 miles upstream and downstream of collection sites. Similarly, other commenters suggested that the Service should limit the designation to areas that are or have historically been inhabited by the species and that the designation should not include the entire geographical region where a species can or may reside.

Our Response: We are designating as critical habitat areas that we have determined to be occupied at the time of listing and contain sufficient elements of physical or biological features to support life-history processes essential to the conservation of the Neosho mucket and rabbitsfoot. River habitats are highly dependent upon upstream and downstream channel habitat conditions for their maintenance. Therefore, where one occurrence record was known from a river reach, we considered the entire reach between the uppermost and lowermost locations of the mussel as occupied habitat, except in lakes and reservoirs. The nearest stream confluence or highway crossing to known localities was used to delineate the upstream and downstream extent of critical habitat. For the Neosho mucket, we have defined occupied habitat as those stream reaches known to be currently extant. For the rabbitsfoot, we have defined occupied habitat as those stream reaches that contain sizeable and small populations as defined by Butler (2005, pp. 88–89), and the marginal populations of Fish Creek and Red River that are the last extant populations in their respective basins (Great Lakes and Cumberland) and Allegheny River as a metapopulation (interconnected populations where there is gene flow). All other areas where populations are classified as marginal are not considered as occupied habitat (see *Criteria Used to Identify Critical Habitat,* below).

(28) *Comment:* One commenter stated a belief that the protections afforded Neosho mucket and rabbitsfoot under Kansas Nongame and Endangered Species Conservation Act (K.S.A. 32–957 through 32–963, 32–1009 through 32–1003) preclude the need to designate critical habitat for these mussels under the Act.

Our Response: The Act requires that critical habitat be designated to the maximum extent prudent and determinable for any species that is determined to be an endangered or threatened species under the Act. We acknowledge Kansas State law affords State level protections similar to those afforded by the Act, but there are differences. For example, Kansas State law does not require Federal action agencies to consult with the Service.

Further, Federal listing and designation of critical habitat affords opportunity for funding of recovery actions from Federal sources, and may include cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations.

(29) *Comment:* One commenter asserted there is no information, other than personal communication from the KDWPT, to support the presence of a stable, reproductive Neosho mucket population in the Cottonwood River, Kansas. The commenter contended the 1.6-rmi (2.6-rkm) reach of proposed critical habitat in the Cottonwood River is not occupied by Neosho mucket or is only occupied due to reintroduction and, therefore, should not be designated as critical habitat.

Our Response: We are not designating critical habitat for the Neosho mucket in the Cottonwood River (see also our response to Comment 24, above, and Summary of Changes from Proposed Rule, below).

(30) *Comment:* One commenter stated our estimate of $4.4 million for informal and formal section 7 consultations is high, and questioned how these consultations can generate this cost.

Our Response: The final total estimated economic impact of the designation related to consultation under the Act is $4.4 million over the 20-year period of analysis, or $290,000 on an annualized basis. These figures represent the estimated costs of consultation associated with eight categories of economic activity across the 12 States where critical habitat was proposed. Chapter 3 of the FEA provides detailed information regarding the portion of total cost associated with each category of activity and how many consultation actions are projected to occur over the 20-year period.

(31) *Comment:* Two commenters from Kansas and Missouri stated that the Service did little, if any, outreach to the agricultural community.

Our Response: The Service published legal notices during the first comment period in the *Southeastern Missourian* and *Joplin Globe* in Missouri, and *The Morning Sun* (Pittsburgh, Kansas), *Wichita Eagle,* and *Topeka Capitol Journal* in Kansas. The Service sent news releases to 17 additional Missouri and 18 additional Kansas newspapers with readership in the areas affected by the proposed rule, including farmers. Advance notification of the proposed rule and the document making available the draft economic analysis and extending the proposal's comment period was provided to the Kansas Forestry Commission and Missouri Conservation Commission—Forest Management.

The Service's Missouri field office held two public informational meetings in the area affected by this rule during the second comment period. The first meeting was held in Joplin, Missouri, on May 21, 2013, and the second meeting was held in Greenville, Missouri, on May 23, 2013. Information pertaining to both meetings was disseminated through typical media outlets in the region where the meetings were held, which is predominately agricultural.

At the request of the Kansas Farm Bureau, the Service's Kansas field office scheduled public informational meetings for October 9 and 10, 2013, in Parsons and Strong City, Kansas, respectively, during the third comment period. These meetings were cancelled due to a lapse in appropriations and partial government shutdown. The Service's Kansas field office attempted to reschedule the meetings with the Kansas Farm Bureau during the week of October 22, 2013, but was unable to reschedule the meetings prior to the comment period closing. As an alternative, the Service responded via email on October 22, 2013, to a list of Kansas Farm Bureau questions related to the proposed rule and draft economic analysis.

(32) *Comment:* One commenter expressed concern that the designation of critical habitat in Unit RF4a (Ouachita River) will interfere with many of Camp Ozark's river activities, including expansion in coming years. The commenter asserted the camp is a significant local economic driver, and the inability to both use the river for recreation and to pursue development plans will stymie its ability to provide jobs and wealth to the local economy.

Our Response: The originally proposed RF4b has been separated into two units (RF4a and RF4b) in this final designation. The Service has removed the originally proposed critical habitat Unit RF4a from the final designation based on recent survey efforts suggesting the rabbitsfoot population in this area should be classified as marginal based on Butler's (2005) classification (see Summary of Changes from Proposed Rule, below). As a result, the area the commenter expressed concerns about is not included in the final designation of critical habitat.

(33) *Comment:* One commenter stated that the designation of critical habitat will significantly increase the number of consultations required for permitted and non-permitted activities.

Our Response: As other listed species already occur in all designated critical habitat units for Neosho mucket and rabbitsfoot, we do not expect the number of consultations to increase due to this designation.

(34) *Comment:* One group of commenters stated that the Service fails to meet the Act's requirements for lawful designation of critical habitat in two respects: (a) By designating areas occupied by the rabbitsfoot in Arkansas as critical habitat absent an appropriate determination that such areas include features essential to the conservation of the species and which require special management considerations or protection, and (b) by designating areas unoccupied by rabbitsfoot in Arkansas as critical habitat absent an appropriate determination those areas are essential for the conservation of the species.

Our Response: In accordance with 50 CFR 424.12(d), the Service concluded designating critical habitat in river reaches between, or in close proximity to, the uppermost and lowermost occupied areas represent an inclusive area essential to the conservation of Neosho mucket and rabbitsfoot. In accordance with 50 CFR 424.12(b), the Service determined all or some primary constituent elements were present in each unit as evidenced by occupied space (that is, stable habitat) for individual growth, feeding, and reproduction, presence of gravid females, availability of fish hosts, and water quality. While all water quality needs may not be completely understood, we estimate some numeric standards have been adopted under the Clean Water Act (33 U.S.C. 1251 *et seq.*) that represent levels essential to the conservation of these mussels (such as dissolved oxygen, ammonia, pH, metals) (see *Physical or Biological Features*). In this final determination and in accordance with 50 CFR 424.12(b), we have identified nine categories of primary threats affecting Neosho mucket and rabbitsfoot habitat that may necessitate special management or protection (see *Special Management Considerations or Protection*). We did not designate as critical habitat any areas that are unoccupied by either species.

(35) *Comment:* One group of commenters stated that the Service's record for the rule does not include sufficient information for the Service to determine critical habitat features essential to the conservation of the species based on descriptions of the physical or biological features, which state ''little is known of the specific habitat requirements for the Neosho mucket and rabbitsfoot'' and ''the ranges of many water quality parameters that define suitable habitat conditions for Neosho mucket and rabbitsfoot have not

been investigated or are poorly understood.'' Accordingly, the commenters expressed the belief that the critical habitat units are overly broad and unnecessary for preservation and propagation of these mussels.

Our Response: Generally, the Neosho mucket is found embedded in stable substrates associated with shallow riffles (areas where shallow, generally less than 1 meter (m) (3.3 ft) in depth, turbulent water passes through and over stones or gravel of somewhat similar size) and runs (intermediate areas between pools and riffles with moderate current) with gravel and sand substrate and moderate to swift currents (Oesch 1984, p. 221; Harris 1998, p. 5; Obermeyer 2000, pp. 15–16). However, in Shoal Creek and the Illinois River, the Neosho mucket prefers near-shore areas or areas out of the main current (Harris 1998, p. 5). The rabbitsfoot usually occurs in shallow areas along the bank and adjacent runs and riffles with gravel and sand substrates where the water velocity is reduced, but it also may occur in deep runs (Parmalee and Bogan 1998, pp. 211–212). Unlike the Neosho mucket (Barnhart 2003, p. 17), the rabbitsfoot seldom burrows in the substrate, but lies on its side (Watters 1988, p. 13; Fobian 2007, p. 24). Neosho mucket and rabbitsfoot, similar to other mussels, are dependent on areas with flow refuges where shear stress (the stream's ability to entrain and transport bed material created by the flow acting on the bed material) is low and sediments remain stable during flood events (Layzer and Madison 1995, p. 341; Strayer 1999, pp. 468 and 472; Hastie *et al.* 2001, pp. 111–114). Habitat conditions described above provide space, cover, shelter, and sites for breeding, reproduction, and growth of offspring for the Neosho mucket and rabbitsfoot; are essential to their conservation; and may require special management considerations or protection. These habitat conditions have been accurately captured in the physical or biological features that we have identified to be essential to the conservation of the species. Based on the best available scientific information, we conclude the designation of critical habitat for Neosho mucket and rabbitsfoot meets the criteria set forth in 50 CFR 424.12.

(36) *Comment:* One group of commenters suggested that the Service should limit critical habitat designations for rabbitsfoot in Arkansas to areas where successful host species and rabbitsfoot coexist.

Our Response: Based on the best available information, suitable fish hosts for the rabbitsfoot occur in all areas that we are designating as critical habitat. The Arkansas Game and Fish Commission (AGFC) fish database (2014) includes numerous records for rabbitsfoot fish hosts in the critical habitat units designated in Arkansas. Our administrative record documents the coexistence of rabbitsfoot and its fish hosts in these critical habitat units.

(37) *Comment:* One group of commenters suggested that the Service should remove streams impacted and/or controlled by hypolimnetic (lower thermally stratified portion of a lake) or other cold water releases (such as Mammoth Spring in Arkansas) because those streams are not preferred habitat for rabbitsfoot. Specifically, they referenced the Spring River (proposed Unit RF12) from Hardy downstream to Ravenden, Arkansas, and Ouachita River (proposed Unit RF4b) from Interstate 30 downstream to the Little Missouri River confluence. They stated that the rabbitsfoot cannot survive in these two cold water reaches.

Our Response: Our decision record documents the presence of a diverse and abundant mussel assemblage in the Spring River from Hardy, Arkansas, downstream to Ravenden, Arkansas (Rust 1993, Appendix 1.2 and 1.4; Harris *et al.* 2007; AGFC Mussel Database 2014; various museum records). The Ouachita River mussel and fish fauna from Remmel Dam downstream to Interstate 30 is affected by cold water releases (Harris 1999, p. 4–2). Mussel species richness and abundance increases downstream of Interstate 30 (Harris 1999, p. 3–8). Harris (1999, p. 4–2) reported double-digit species richness and higher relative abundance of mussels downstream of the Tenmile Creek confluence compared to sites upstream. Live rabbitsfoot occur in the Spring River between Hardy and Ravenden, Arkansas, and in the Ouachita River downstream of Tenmile Creek to the confluence of the Caddo River (Harris *et al.* 2007, pp. 14–16; AGFC Mussel Database 2014; Harris 1999, p. 3–8). Therefore, the best available scientific information supports that mussels, including rabbitsfoot, can survive in these reaches.

(38) *Comment:* One group of commenters recommended modifications to six critical habitat units for rabbitsfoot. They asserted that the critical habitat units should be restricted to stream reaches where live rabbitsfoot individuals are known to occur. The units are as follows:

(a) Ouachita River (proposed Unit RF4a): Remove entire designation because occurrence of rabbitsfoot is only reported from Arkansas Highway 379 and 298.

(b) Ouachita River (proposed Unit RF4b): Restrict designation to the confluence of Little Missouri River downstream to U.S. Highway 79.

(c) Saline River (proposed Unit RF5): Restrict designation to 2 miles upstream of Arkansas Highway 15 to the Snake Creek confluence north of the Felsenthal National Wildlife Refuge boundary.

(d) Black River (proposed Unit RF9): Restrict designation to Pocahontas, Arkansas, downstream to Black Rock, Arkansas.

(e) Spring River (proposed Unit RF10): Restrict designation to Ravenden, Arkansas, downstream to confluence with Black River. They also believe water temperatures from Hardy to Ravenden, Arkansas, do not support propagation of rabbitsfoot and, thus, are not essential to the conservation of the species.

(f) South Fork Spring River (proposed Unit RF11): Remove entire designation based on the lack of documentation of live rabbitsfoot despite multiple surveys.

Our Response: We have re-evaluated the critical habitat units in question and, based on the best available scientific information, we are removing or modifying the following units in this final rule. For further information, see Summary of Changes from Proposed Rule, below.

(a) Ouachita River (proposed Unit RF4a): We agree, in part, with the commenters and in this final designation have removed the originally proposed Unit RF4a.

(b) Ouachita River (Unit RF4b): We agree, in part, with the commenters and have revised proposed Unit RF4b into two units. The Ouachita River from Arkadelphia downstream to the Little Missouri River confluence has not been comprehensively surveyed for mussels. While the absence of rabbitsfoot from this reach is likely a result of no survey data and not actual absence, the best available scientific information supports designating critical habitat in two Ouachita River units, revised Unit RF4a and revised Unit RF4b (see Summary of Changes from Proposed Rule, below).

(c) Saline River (Unit RF5): We agree, in part, with the commenters and have modified Unit RF5 in this final designation so that the upstream boundary is at the Frazier Creek confluence near Mt. Elba, Arkansas, and the downstream boundary is at the Mill Creek confluence near Stillions, Arkansas.

(d) Black River (Unit RF9): We agree, in part, with the commenters and have modified Unit RF9 in this final

designation so that the downstream boundary is at the Flat Creek confluence downstream of Powhatan, Arkansas.

(e) Spring River (Unit RF10): The best available scientific information supports the designation with a slight adjustment to the upstream boundary of Unit RF10 downstream approximately 3.72 rkm (6 rmi) to the Ott Creek confluence. We have made this change in this final designation.

(f) South Fork Spring River (proposed Unit RF11): The best available scientific information supports categorizing the South Fork Spring River rabbitsfoot population as marginal. Therefore, the Service has removed proposed Unit RF11 (the South Fork Spring River) from this final designation. (Note that units have been renumbered for this final rule and final Unit RF11 is not the same location as proposed Unit RF11).

(39) *Comment:* One group of commenters stated that the Service failed to acknowledge protections afforded to proposed Units RF10 and RF4a under Arkansas Pollution Control and Ecology Commission (APCEC) Regulation 2 (waters designated as Extraordinary Resource Waters (ERW) and Ecologically Sensitive Waterbodies (ESW)), which they stated provide sufficient protection to preserve the physical or biological features essential to the conservation of rabbitsfoot.

Our Response: The Service acknowledges there are some protections afforded to ERW and ESW under APCEC's Regulation 2, which was developed pursuant to the Arkansas Water and Air Pollution Control Act and the Clean Water Act (CWA). Significant physical alterations of habitat are not allowed unless: (a) The proposed physical alteration of habitat will not impair water quality, natural flow regime, and the habitat of fish, shellfish, or aquatic life; and (b) there is no feasible alternative to the proposed project. Regulation 2 also allows the short-term activity authorization for a variety of activities that are permitted to exceed water quality standards provided there is no permanent or long-term impairment. However, despite provisions in Regulation 2 that explicitly prohibit short-term activity authorization for activities that result in adverse effects to federally endangered and threatened species or their critical habitat, short-term activity authorizations in ERW and ESW watersheds have been linked to documented take of endangered species (see *U.S.* v. *Hawk Field Services, LLC* 2011). Furthermore, Regulation 2 allows for the removal of an ERW or ESW designation for the purpose of constructing a reservoir to provide domestic drinking water, if it can be demonstrated: (a) The sole purpose is to provide domestic drinking water supply; and (b) there is no feasible alternative to constructing a reservoir to meet the domestic water needs of the citizens of Arkansas. Given that a goal of the CWA is to establish water quality standards that protect shellfish and given documented declines of these mussel species still continue due to poor water quality and other factors, we take a conservative approach in favor of the species and conclude that Regulation 2 has been insufficient to significantly reduce or remove threats to the Neosho mucket and rabbitsfoot in Units RF4a and RF10.

(40) *Comment:* One group of commenters commissioned its own study of the economic impacts of the critical habitat designation. Their study compared their results to the Service's DEA and concluded that the DEA ''vastly understates'' costs of the regulatory action because it does not take into account direct and indirect costs to businesses, State and local governments, and other private property owners resulting from section 7 consultation requirements. Furthermore, these impacts would lead to additional damages to the regional economy in the form of lost tax revenue, increased unemployment claims, damage from unrepaired roads and bridges, increases in transportation costs, and tax increases. Specifically, the evaluation estimated, based on a sample of affected projects, the total cost to affected Arkansas counties would exceed $19 million, approximately 5 times the cost of $4.4 million estimated in the DEA for the entire 12-State region of the designation.

Our Response: The commenter's evaluation describes the economic impacts that would occur if a variety of hypothetical scenarios were to result from critical habitat designation (for example, if visitation at Camp Ozark declined by 25 percent; visitation at the Pond Creek National Wildlife Refuge decreased by 20 percent; an oil well is not drilled; a poultry farm is closed; the construction of a planned county-road bridge over the Osage River is delayed; or city or county discharges under the National Pollution Discharge Elimination System (NPDES) are restricted). However, the evaluation does not provide evidence to suggest such restrictions will actually occur as a result of the critical habitat designation.

The Service considered whether restrictions are likely to result from the designation of critical habitat and found this to be unlikely. Specifically, the Service prepared a memorandum describing the likely outcome of future section 7 consultations (see Appendix D of the FEA). The Service is designating critical habitat in river segments that are occupied by the mussels. Section 7 consultation requirements take effect once the mussels are listed under the Act, even if critical habitat is not designated (see response to Comment 2). Thus, the incremental costs of additional regulation designating critical habitat are limited to the administrative costs to the Service, the Federal action agencies, and third parties involved in consultations. The FEA's estimate of $4.4 million (present value impacts assuming a 7 percent discount rate) results from this additional administrative burden.

(41) *Comment:* Multiple commenters stated that the DEA underestimates the impacts of the proposed critical habitat designation because it utilizes an incremental approach that ''only estimates the likely costs of agencies consulting with each other'' and does not consider the actual opportunity costs to businesses, State and local governments, and other private property owners related to the required consultations.

Our Response: The Service's focus on the incremental impacts of the critical habitat rule is consistent with the U.S. Office of Management and Budget's (OMB's) guidelines for best practices concerning the conduct of economic analysis of Federal regulations. As described in section 2.1 of the FEA, OMB guidelines direct Federal agencies to measure the costs of a regulatory action against a baseline, which it defines as the ''best assessment of the way the world would look absent the proposed action.'' The baseline utilized in the FEA is the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat *absent* the designation of critical habitat. The baseline includes protections afforded the species under the Act, as well as under other Federal, State, and local laws and guidelines.

In recognition of the divergent opinions of the courts and to address the Presidential memorandum dated February 28, 2012, the Service promulgated final regulations specifying that it is appropriate for the Secretary to consider impacts of a critical habitat designation on an incremental basis (78 FR 53058, August 28, 2013). This rule discusses the impact analysis for proposed critical habitat through completion of an ''incremental analysis.'' This method of determining

the probable impacts of the designation seeks to identify and focus solely on the impacts over and above those resulting from existing protections.

Accordingly, the FEA employs ''without critical habitat'' (baseline) and ''with critical habitat'' (incremental) scenarios. The analysis qualitatively describes how baseline conservation efforts for the two mussels may be implemented across the proposed designation, and, where possible, provides examples of the potential magnitude of costs of these baseline conservation efforts (Chapter 4). The FEA focuses, however, on the incremental analysis, describing and monetizing the incremental impacts due specifically to the designation of critical habitat for the species (Chapter 3). Sections 2.2 and 2.3 of the FEA describe in detail how the analysis defines and identifies incremental effects of the proposed designation.

The incremental approach employed by the Service in its analyses of proposed critical habitat designations does not necessarily limit impacts to administrative costs of consultation. In some cases, designation of critical habitat does result in new project modifications that need to be implemented to avoid possible adverse modification of the habitat. The costs of these project modifications would then be counted in the incremental analysis, regardless of who incurs the cost. In the case of the Neosho mucket and rabbitsfoot, all of the designated critical habitat is occupied by the species, and therefore any project modifications will be required even absent critical habitat (in the baseline) to avoid possibly jeopardizing the species' existence (see response to Comment 2).

(42) *Comment:* Multiple commenters expressed concern that the proposed critical habitat designation will have an economic impact on Arkansas counties, cities, communities, businesses, and industry sectors through effects on employment, tax revenues, business and industrial operations, and overall quality of life. Commenters suggested that these impacts will occur as a result of new critical habitat-related restrictions, prohibitions, delays, cancellations of activities, and/or additional requirements for conservation and consultation.

Our Response: The commenters do not provide information regarding how or why they believe critical habitat will result in new restrictions, prohibitions, delays, cancellations, or conservation requirements. Within the FEA, the Service specifically considered whether additional or different conservation measures would be needed to avoid destruction or adverse modification of critical habitat above and beyond those measures needed to avoid jeopardizing the continued existence of the species, and found this to be unlikely (see our response to Comment 2). Because all of the units are occupied by at least one of the mussel species, any measures needed to protect habitat would be requested by the Service, even if critical habitat was not designated, to avoid jeopardizing the continued existence of the species.

(43) *Comment:* Multiple commenters expressed concern that the DEA does not address impacts to private landowners (such as farmers and ranchers), and in particular, those impacts associated with property value or third party lawsuits resulting from critical habitat designation. One commenter expressed concern that no small landowners were contacted in accordance with the provisions of the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*).

Our Response: Incremental impacts of the designation are expected to be limited to additional administrative costs to the Service, Federal agencies, and third parties of considering critical habitat as part of future section 7 consultations (see our response to Comment 2). The FEA incorporates potential impacts to private landowners as third parties in forecasted consultations on water quality; timber, agriculture, and grazing; and development activities. In addition, Appendix A of the FEA includes an analysis of the distributional impacts of the proposed critical habitat designation on small entities. As described in Appendix A, the only costs expected to be borne by third parties as a result of the proposed designation are portions of the total cost of forecasted section 7 consultations. These costs are relatively minor, ranging from $260 to $2,080 per consultation.

Section 2.3.2 of the FEA discusses how the designation of critical habitat may, under certain circumstances, result in indirect impacts such as time delays, regulatory uncertainty, and stigma effects (such as property value impacts). The Service does not expect indirect impacts to result from critical habitat designation for the two mussels. However, as a result of the concern expressed in these comments, we have added new language to the FEA concerning to the potential for indirect costs associated with third party lawsuits or property value impacts. Because the nature, timing, and likelihood of future litigation or property value impacts are highly uncertain, the FEA does not quantify these impacts but instead describes them qualitatively and notes that these are uncertainties in the analysis.

(44) *Comment:* One commenter asserted that the DEA is flawed because it limits the physical scope of its enquiry to the riparian watersheds and census tracts included in those watersheds. The commenter argued that standard practice for an economic impact analysis has been to use county boundaries or a defined local market area as the basis for any comprehensive evaluation of costs and benefits. The use of such narrow boundaries is an attempt to limit the estimated effects by omitting consideration of the interconnectedness of modern economies.

Our Response: The commenter is correct that the DEA defines its ''study area'' as including the watersheds encompassing proposed critical habitat (either the fourth level (8-digit) or sixth level (12-digit) Hydrologic Unit Code (HUC) watersheds defined by the U.S. Geological Survey (USGS)). The study area is used to identify projects (such as oil wells, roads, bridges, etc.) that could have a hydrologic connection to critical habitat. For example, these projects may be sufficiently close to a critical habitat river segment that runoff from the construction site would increase sediment loads to the river, potentially affecting the mussels. If such a hydrologic connection exists, these projects are more likely to require consultation. Defining the study area more broadly would result in the inclusion of projects with no hydrologic connection to critical habitat, and thus no reason for consultation.

Importantly, while the identification of projects requiring consultation is limited to the study area, the consideration of economic impacts that might result if these projects are modified is not limited to this geographic area. However, in the case of Neosho mucket and rabbitsfoot, incremental project modifications are unlikely. Incremental costs are limited to administrative costs, which would be incurred by the agencies or private entities pursuing the projects, regardless of where those entities are headquartered.

(45) *Comment:* One commenter provided an analysis of the economic impacts of the proposed critical habitat designation based on hypothetical project modifications using IMPLAN (an input-output modeling system) multipliers. Such an analysis measures the change in economic output resulting from a policy change. The authors argued that such multiplier analysis is the appropriate framework for answering impact analysis questions,

noting the DOT recommends this approach for construction planning.

Our Response: The commenter is correct that economic impact analyses generally rely on input-output or multiplier analysis using tools such as IMPLAN. Examples of such analyses include estimates of the changes in economic output generated by the construction of a new stadium or the loss of a manufacturing facility.

In contrast, the method of economic analysis of proposed Federal regulations is subject to the direction provided by Executive Order 12866 and associated guidance provided by OMB in Circular A–4. As described in Circular A–4, ''opportunity cost'' is the appropriate concept for valuing benefits and costs of regulatory actions. Costs are incurred when resources are used for one purpose and hence cannot be used for another purpose. The opportunity cost is the value of the benefit that could have been provided by devoting the resources to their best alternative use. Estimates of the change in opportunity cost are sometimes referred to as economic efficiency effects or changes in social welfare.

For example, assume section 7 consultations are required prior to drilling at oil and gas sites potentially affecting the mussels. If delays caused by section 7 consultation cause oil and gas operators to forego the activity without pursuing production at substitute sites, net change in oil and gas production at a national level would represent the opportunity cost of the regulation. If operators pursue production at substitute sites, resulting in no net change in production but redistributing activity away from sites near the mussels, then the marginal cost of reduced profitability associated with the next best alternative location represents the opportunity cost. In either case, the resources used to produce the oil and gas (for example, materials and labor necessary to drill for and transport the oil and gas) are not lost to society. Rather, these resources are still available for other productive uses. As a result, estimates of changes in efficiency effects, or social welfare, are fundamentally different than the estimate of the distributional effects using tools like IMPLAN, and the results are not directly comparable.

Given that the designation of critical habitat for the mussels is unlikely to result in additional project modifications beyond those related to the listing of these species, the types of distributional effects measured using IMPLAN multipliers are likely to be minimal. The opportunity cost of the regulation is limited to the resources (primarily labor) needed to address the administrative requirements of the section 7 process. Thus, the DEA appropriately captured the incremental opportunity costs of the proposed regulation.

(46) *Comment:* One commenter noted that the DEA predicts an increase in future section 7 consultations on Natural Resources Conservation Service (NRCS) Farm Bill activities in Arkansas. The commenter expressed concern because these consultations are new, and the Service has no way to predict the incremental costs to private landowners associated with new conditions (such as a 180-foot buffer along stream, discharge zones, and karst features and methods to prevent soil erosion and runoff) that will be recommended during section 7 consultation on Farm Bill-related activities.

Our Response: Section 3.3.3 of the DEA includes the likely increase in section 7 consultations in Arkansas due to new NRCS Farm Bill program work under the Agricultural Act of 2014 (H.R. 2642, Pub. L. 113–79, which is also known as the 2014 Farm Bill), an act that authorizes nutrition and agriculture programs in the United States for 2014 through 2018, and this section of the DEA provides an estimate of the administrative costs associated with the forecasted consultations. Additionally, the discussion provides information on the likely incremental impacts of the proposed critical habitat designation on timber, agriculture, and grazing activities. As described in section 2.3.2 of the DEA, the designation of critical habitat is not anticipated to generate additional conservation measures for the two mussels beyond those that would be generated by the listing.

We note that the conditions identified by the commenter from the DEA as ''specific conservation recommendations identified by the Service'' (*i.e.,* a minimum 180-foot buffer and methods to prevent soil erosion and runoff) are mischaracterized in the economic analysis as having been made by the Service, which is incorrect. We have included an Addendum to the FEA (IEc 2014b) to correct information regarding the programmatic consultation with NRCS. It is important to note, however, that although the information was not correctly presented in the economic analysis, it had no bearing on the results of the incremental effects analysis, as that information was incorporated in the baseline.

(47) *Comment:* One commenter stated that the costs presented in the DEA are based on ''an unrealistic discount rate of seven percent'' and costs should be presented instead using a discount rate of 5 percent or less.

Our Response: The DEA demonstrated the sensitivity of the results of the analysis to the choice of discount rate by presenting costs using discounts rates of both 7 and 3 percent. Specifically, results estimated using both rates are presented in the Executive Summary (see Exhibit ES–3). For presentation purposes, the remainder of the report presents detailed cost estimates using a 7 percent discount rate; however, Appendix B replicates all detailed tables using a 3 percent discount rate for comparison.

The choice of discount rates is consistent with OMB's Circular A–4, which states: ''As a default position, OMB Circular A–4 states a real discount rate of seven percent should be used as a base-case for regulatory analysis. The seven percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (for example, through higher consumer prices for goods and services), a lower discount rate is appropriate. For regulatory analysis, you should provide estimates of net benefits using both three percent and seven percent.'' The rate of 5 percent recommended by the commenter is captured in this range.

(48) *Comment:* One commenter asserted the RFA analysis does not consider whether or not the proposed critical habitat designation would have a substantial impact on local government jurisdictions because, as stated in the DEA, ''potential financial impacts to local government agencies and private landowners are not estimated as a proportion of annual revenues due to lack of data.''

Our Response: The purpose of the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*) analysis, provided in Appendix A of the DEA, is to assess whether or not the proposed critical habitat designation will have a significant economic impact on a substantial number of small entities. As described in section A.1, the analysis provides information regarding the potential number of third parties participating in consultations on an annual basis in order to ensure a robust examination of the effects of the proposed rule. In addition, the analysis provides information to assist the Service in determining whether these entities are likely to be ''small'' and whether the number of potentially affected small entities is ''substantial.''

Importantly, the impacts of the rule must be both significant and substantial to prevent certification of the rule under the RFA and to require the preparation of an initial regulatory flexibility analysis.

As shown in Exhibit A–2 of the DEA, the proportion of small entities in the study area that may be affected in one year by the proposed designation ranges from 0.1 percent to 3.1 percent, which is not considered to be a substantial number. Despite this conclusion, the analysis also provides information on whether the economic impact on these entities is likely to be significant. Specifically, the analysis estimates the likely annualized impact per entity as a proportion of estimated annual revenue. Due to lack of data on the annual revenues of each entity that may be involved in section 7 consultations across the designation, we perform a ''threshold analysis''; that is, we determine that for impacts to exceed one percent of an entity's annual revenues, those annual revenues would have to be less than $47,000. We assume this is very unlikely to be the case for local government agencies in the study area. For example, one of the least populous counties in the study area in Arkansas is Calhoun County, whose total revenues for 2011 were reported at $8,863,000 (Center for Governmental Research Inc., 2013: *http://www.govistics.com/AR/CALHOUN*).

(49) *Comment:* One commenter stated that for private timber, agricultural, and grazing entities, the RFA analysis relies on the flawed assumptions in chapter 3 of the DEA. The Service concludes there will be no significant impact to small entities when the DEA clearly states the Service has no data with which to predict future incremental costs to such private landowners because there is no history of consultation between the Service and NRCS.

Our Response: In Appendix A of the DEA, we note that we are unable to estimate potential financial impacts to local government agencies and private landowners as a proportion of annual revenues due to a lack of data. However, for any entity with greater than $47,000 in annual revenue, the financial burden of undertaking a project requiring consultation on the mussels would constitute less than one percent of annual revenue because the designation of critical habitat is not anticipated to generate additional conservation measures for the two mussels beyond those that would be generated by the species being listed. Less than one percent of annual revenue would not be considered a significant impact. Therefore, we have determined there would not be a significant impact to a substantial number of small entities.

(50) *Comment:* One commenter provided information about NPDES permits for direct and indirect discharges into rivers containing proposed critical habitat. The commenter asserted that ''serious economic and fiscal impacts will accompany any water-system adjustments that would have to be instituted to divert or avoid discharges into the host rivers.'' In addition, the commenter stated that the NPDES permits will ''be subjected to an increased level of regulation, including potential need for formal and/or informal consultation with [the Service].''

Our Response: The commenter does not provide any information regarding the likelihood or nature of ''water-system adjustments'' resulting from critical habitat designation that would aid in providing greater clarification to address the concern. As outlined in our response to Comment 2 and elsewhere in this document, the designation of critical habitat is not anticipated to generate additional conservation measures for the two mussels beyond those that would be generated by the species being listed. In addition, section 3.3.2 of the DEA provided an estimated number of future water quality-related section 7 consultations, including those on NPDES permit programs. The DEA forecast costs related to water quality activities for all units in which future section 7 consultations concerning water quality management activities are expected to occur.

(51) *Comment:* One commenter stated that although the DEA does address benefits of designating critical habitat, the analysis should account for benefits to other species from the designation of critical habitat for the mussels. Studies have shown these protections promote stream health by preventing erosion, filtering runoff, and providing shade and microhabitats. Other benefits include areas for scientific study and aesthetic value to residents.

Our Response: The primary goal of critical habitat designation for the mussels is to support their long-term conservation. Theoretically, conservation and recovery of the species may result in benefits, including use benefits (wildlife-viewing), non-use benefits (existence values), and ancillary ecosystem service benefits (such as public safety benefits of reduced wildfire risks). Section 5.3 of the DEA contained a discussion of potential ancillary benefits of mussel conservation, including improved water quality and aesthetic benefits.

(52) *Comment:* One commenter asked why the critical habitat designation is necessary when no additional conservation measures are required beyond those associated with the listing.

Our Response: The Act requires that critical habitat be designated to the maximum extent prudent and determinable for any species that is determined to be an endangered or threatened species under the Act. In the October 16, 2012, proposed rule to list these species and designate critical habitat (77 FR 63440), we identified ''the potential benefits'' of designating critical habitat to ''include: (1) Triggering consultation under section 7 of the Act in new areas for actions in which there may be a Federal nexus where it would not otherwise occur because, for example, it is or has become unoccupied or the occupancy is in question; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or private entities; and (4) preventing people from causing inadvertent harm to the species'' (see *Prudency Determination,* 77 FR 63472).

(53) *Comment:* Several commenters contended that the designation of critical habitat in Arkansas is an attempt by the Service or Federal government to ''take'' privately owned property.

Our Response: The designation of critical habitat does not authorize the Service or Federal government to purchase, condemn, take through eminent domain, or otherwise confiscate private property through the use of legislation, regulation, or other legal means. In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for Neosho mucket and rabbitsfoot in a takings implications assessment. As discussed above, the designation of critical habitat affects only Federal actions. Although private parties that receive Federal funding, assistance, or require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests on the Federal agency.

(54) *Comment:* Multiple commenters requested that the Service conduct a ''complete impact study'' to include all property owners and businesses.

Our Response: Based on a review and evaluation of the information contained in the environmental assessment, we

determined the designation of critical habitat for the Neosho mucket and rabbitsfoot does not constitute a major Federal action significantly affecting the quality of the human environment under the meaning of section 102(2)(c) of NEPA. Accordingly, an environmental impact statement is not required. See our responses to Comments 41 and 42 regarding economic impacts to private landowners and businesses.

(55) *Comment:* One commenter stated that the designation of critical habitat in Arkansas will close rivers to fishing.

Our Response: As discussed above, designating critical habitat has no impact on landowner or citizen activities that do not require Federal funding or permits.

(56) *Comment:* One commenter expressed concern that oral comments were not recorded during public meetings held in Arkansas. Furthermore, the commenter requested policy changes to require public meetings be recorded and entered into the public record.

Our Response: The commenter appears to be confusing the requirements for a ''public hearing'' with those for the ''public information meeting'' that was actually held. A public hearing, which may be requested on any proposed rule within 45 days after the opening of the comment period, includes oral testimony from participants which is recorded by a court reporter and entered into the public record. With regard to the proposed critical habitat designation for the two mussels, no public hearings were requested during any of the four open comment periods. Instead, the Service was asked to reopen the comment periods to allow additional time for interested parties to review the proposed rule, DEA, and draft environmental assessment. The Service agreed to hold public information meetings during the open comment periods to facilitate a better understanding of the proposed action. In a public information meeting, which is a less formal process than a public hearing, there is no requirement for recording oral testimony. However, the Service voluntarily provided comment cards that participants could fill out during the meetings and submit as formal comments to be entered into the record. These comments have been uploaded onto *http://www.regulations.gov* along with all other comments we received during the comment periods.

(57) *Comment:* One commenter stated predation by raccoon, otter, beaver, and other predators is a greater threat to Neosho mucket and rabbitsfoot than habitat loss or degradation.

Our Response: The Service determined predation was not a significant threat to the overall status of Neosho mucket and rabbitsfoot. A more detailed discussion of this threat is presented in the final listing rule under Summary of Factors Affecting the Species (78 FR 57076, September 17, 2013).

(58) *Comment:* One commenter expressed concern about additional restrictions on the aquaculture industry in Arkansas, specifically on water withdraw or diversion, pond cleanout, pond effluent discharge, and inspection requirements, due to the designation of critical habitat.

Our Response: As discussed above, designating critical habitat has no impact on landowner activities that do not require Federal funding and permits. For aquaculture activities that require a Federal permit or assistance, the Service may recommend conservation actions in a section 7 consultation for the affected species that protect not only the species, but also its habitats, regardless of whether or not there is designated critical habitat. Currently, such conservation measures to protect the species and their habitats are in place for other listed mussel species that occur within the Arkansas critical habitat units such that no additional conservation measures or regulatory restrictions are expected to result from this critical habitat designation.

(59) *Comment:* One commenter stated that the Service should release data used to determine critical habitat for Neosho mucket and rabbitsfoot.

Our Response: All of the comments, materials, and documentation we considered in this rulemaking are available at the Arkansas Ecological Services Field Office (see **ADDRESSES**, above). Comments and materials received, as well as some supporting documentation we used in preparing this rule, are also available for public inspection at *http://www.regulations.gov*.

(60) *Comment:* Several commenters expressed concern about fluoride as a chemical contaminant affecting Neosho mucket and rabbitsfoot.

Our Response: While all the water quality needs for these two mussels may not be completely understood, we estimate some numeric standards have been adopted under the CWA that represent levels essential to conservation of these mussels (such as dissolved oxygen, ammonia, pH, metals) (see *Physical or Biological Features*). In a North Carolina study, effective concentrations for growth effects were found to be 17 and 8 times as high as the State's and EPA's water quality criteria for fluoride, respectively (Keller and Augspurger 2005 *in* Farris and Van Hassel 2007, p. 162). Fluoride, at concentrations typical of most streams meeting state and EPA water quality criteria, is not toxic to glochidia (freshwater mussel larvae) and juveniles of Unionidae mussels such as the Neosho mucket and rabbitsfoot. In this final designation, and in accordance with 50 CFR 424.12(b), we have identified nine categories of primary threats affecting Neosho mucket and rabbitsfoot habitat that may necessitate special management or protection (see *Special Management Considerations or Protection*—Chemical Contaminants).

(61) *Comment:* Multiple commenters expressed concern regarding ''sue and settle'' agreements between Federal agencies and nongovernmental organizations. They contend this process is a binding out-of-court settlement that prohibits farmers, small businesses, and private property owners from participating in discussions and providing meaningful input prior to the publication of a proposed rule.

Our Response: The multiyear listing workplan under which this critical habitat rule was proposed was developed through settlement agreements with Wild Earth Guardians and the Center for Biological Diversity to resolve multidistrict litigation. It established deadlines for completing listing determinations for each candidate species, including the Neosho mucket (first included in the 2001 CNOR; 66 FR 54808, October 30, 2001) and rabbitsfoot (first included in the 2009 CNOR; 74 FR 57804, November 9, 2009). The Service published a final listing rule for these mussels on September 17, 2013 (78 FR 57076), in accordance with these deadlines. Section 4(a)(3)(A) of the Act requires that we designate critical habitat, when prudent and determinable, concurrently with making a determination to list a species as endangered or threatened. Therefore, in making this final designation at this time, the Service is adhering to the requirements of the listing workplan and settlement agreement and the Act.

(62) *Comment:* One commenter contended that the greatest threat to the Neosho mucket and rabbitsfoot is White River (Arkansas) minimum flows regulated by the ACOE.

Our Response: Neosho mucket does not occur in the White River. The construction of a series of six flood control reservoirs on the upper White River in the 1940s and 1950s, including

Bull Shoals and Norfork Lakes, led to the extirpation of rabbitsfoot from a large section of the White River upstream of Batesville, Arkansas. White River minimum flows provide adequate low flow releases from Bull Shoals and Norfork Lakes dams to enhance trout habitat and survival in cold tailwater reaches of the White River located upstream of Unit RF8a. There is no evidence to support minimum flows contributing to declines in rabbitsfoot. Minimum flows may be beneficial to the species by providing higher and more consistent flow during low flow periods when mussels may become stranded and be subjected to desiccation (drying).

Summary of Changes From Proposed Rule

The information below is provided as a result of the peer and public review process. In this final designation, we have made changes to maps, units, and the rule itself. A change in mapping methodology resulted in a revision to the total number of river kilometers (river miles) for the designation of rabbitsfoot critical habitat. The beginning and ending points of the proposed critical habitat designation, as well as the unit descriptions (as described in the proposed critical habitat rule) will remain the same except where modified for other reasons.

(1) We have made changes to Unit RF7 to correct an oversight in mapping methodology, specifically in methods used for estimating the unit length. The new method uses a better technique for following the curve and meander of the river channel, which results in an additional 1.5 rkm (0.9 rmi) designated as critical habitat for the rabbitsfoot. In addition, this correction resulted in a corresponding increase to the private ownership lands (expressed as river km/mi) adjacent to Unit RF7.

(2) We are not designating critical habitat for Neosho mucket in the Cottonwood River (Unit NM8), Chase County, Kansas, as originally proposed. Recent KDWPT data from 2013 (Tabor 2013, pers. comm.) do not indicate that released individual mussels into the Cottonwood River were able to survive and become established, and the future success of the reintroduction efforts are unknown at this time. We have clarified our definition of extant Neosho mucket populations in this final designation to address reintroduced populations and selection criteria for critical habitat for this mussel (see the *Criteria Used to Identify Critical Habitat*).

(3) We are not designating critical habitat for rabbitsfoot in the Ouachita River (Unit RF4a), Montgomery County, Arkansas, as originally proposed. Rabbitsfoot was collected live at two sites in 1988 (AGFC Mussel Database 2014). However, an AGFC and Service comprehensive survey in 2007 failed to find any live rabbitsfoot in this reach. In 2013, AGFC resurveyed the two 1988 sites and failed to locate any live or fresh dead (shells still have flesh attached to the valves, retain a luster to their nacre (pearly, innermost layer of the shell), and their periostracum (outermost layer of the shell) is not peeling, indicating relatively recent death (within months)) rabbitsfoot (Harris 2013, pers. comm.). Based on recent survey efforts, the rabbitsfoot population in the Ouachita River upstream of Lake Ouachita should be classified as marginal based on Butler's (2005) classification.

(4) We are not designating critical habitat for rabbitsfoot in the South Fork Spring River (Unit RF11), Fulton County, Arkansas, as originally proposed. Butler (2005, pp. 75–76) categorized the South Fork Spring River as a small population based on a 2002 collection of seven fresh dead specimens upstream of Arkansas Highway 289. Harris *et al.* (2007, p. 22) collected the only live rabbitsfoot from this same reach in 2006. The best available scientific information supports categorizing the South Fork Spring River rabbitsfoot population as marginal based on Butler's (2005) classification.

(5) We have modified or revised six critical habitat units for rabbitsfoot (originally proposed Units RF2, RF4b, RF5, RF9, RF10, and RF32) due to new biological information.

- Verdigris River (Unit RF2): We have revised the downstream extent of Unit RF2. A portion of the Verdigris River from near the Bird Creek confluence downstream to Interstate 44 has been altered by the upper extent of the McClellan-Kerr Arkansas River Navigation System and continues to be dredged. There are no rabbitsfoot records from this reach. Therefore, the Service has modified Unit RF2 in this final designation so that the downstream boundary is at Oklahoma Highway 266 northwest of Catoosa, Oklahoma. This change represents a net reduction of 7.6 rkm (4.7 rmi) from the originally proposed Unit RF2.
- Ouachita River (Unit RF4b): We have divided Unit RF4b into two units (Units RF4a and RF4b in this rule). Harris (1999, pp. 3–8 and 3–9) collected live rabbitsfoot at three sites located from near the confluence of Tenmile Creek downstream to the Caddo River confluence. However, the Ouachita River from Caddo River confluence downstream to the Little Missouri River confluence has not been comprehensively surveyed for mussels. While the absence of rabbitsfoot from this reach is likely a result of no survey data and not actual absence, the best available scientific information supports designating critical habitat in two Ouachita River subunits due to the distance between the reaches known to be occupied. Therefore, the Service has created Unit RF4a to be from the Tenmile Creek confluence downstream to the Caddo River confluence (22.7 rkm (14.1 rmi)), and Unit RF4b to be from the Little Missouri River confluence downstream to U.S. Highway 79 near Camden, Arkansas (revised Unit RF4b; 43 rkm (26.7 rmi)). Together, the new Units RF4a and RF4b represent a net reduction of 92.2 rkm (57.3 rmi) from the originally proposed Unit RF4b.
- Saline River (Unit RF5): We have revised the upstream and downstream extent of Unit RF5. Collections by several surveyors since 2002 support the presence of a small population of rabbitsfoot in the Saline River from the Frazier Creek confluence near Mount Elba, Arkansas, to the Mill Creek confluence near Stillions, Arkansas (Service, unpublished data, 2013). One live specimen was collected in Grant County in 1993 (Illinois Natural History Survey Mollusk Collection 14549). One live specimen also was collected at U.S. Highway 167 in 2006 (AGFC Mussel Database 2014), but this record and the 1993 Grant County record are disjunct (approximately 48.3 rkm (30 rmi)) from the aforementioned reach downstream of Mount Elba. Historically, rabbitsfoot was reported from sites at Benton, Arkansas, and Jenkins Ferry State Park (University of Michigan Museum of Zoology 67254, 75750). Based on the best available scientific information, the Service has revised the upstream and downstream extent of Unit RF5 in this final designation due to the lack of live records downstream of the Mill Creek confluence near Stillions, Arkansas, and sporadic disjunct records upstream of the core population. This change represents a net reduction of 168.9 rkm (105.0 rmi) from the originally proposed Unit RF5.
- Black River (Unit RF9): We have revised the downstream boundary of Unit RF9. Rust (1993 *in* AGFC Mussel Database 2014) collected one live rabbitsfoot approximately 0.78 rkm (1.25 rmi) downstream of Powhatan, Arkansas. One live rabbitsfoot was collected near Powhatan in 1984 (AGFC Mussel Database 2014). There are no records from the Flat Creek confluence with the Black River downstream to the Strawberry River confluence with the Black River. Therefore, the Service has

modified Unit RF9 in this final designation so that the downstream boundary is at the Flat Creek confluence with the Black River downstream of Powhatan, Arkansas. This change represents a net reduction of 41.0 rkm (25.5 rmi) from the originally proposed Unit RF9.

• Spring River (Unit RF10): We have changed the upstream boundary of the originally proposed Unit RF10. Harris *et al.* (2007, pp. 14–16) collected three live rabbitsfoot in 2005 from a site approximately 1.55 rkm (2.5 rmi) upstream of Williford, Arkansas (or Arkansas Highway 58). They also reported numerous rabbitsfoot from muskrat middens in the reach from Williford to Ravenden Springs, Arkansas. One live specimen was collected in 1983, near the confluence of Ott Creek (AGFC Mussel Database 2014). The AGFC Mussel Database (2014) also contains a 1983 record from near the Pierce Creek confluence located upstream of Ott Creek near Hardy, Arkansas. The Spring River downstream of Hardy, Arkansas, supports a diverse and abundant mussel community as evidenced in our records. Thus, the best available scientific information supports the designation with a slight adjustment (net reduction) to the upstream extent of Unit RF10 downstream by approximately 11.3 rkm (7.0 rmi) to the Ott Creek confluence. Therefore, the Service has revised the upstream boundary of the originally proposed Unit RF10 in this final designation.

• Shenango River (Unit RF32): We have changed the upstream boundary of the originally proposed Unit RF32. Considering new information in Bursey (1987), the best available scientific information supports extending the extent of the originally proposed Unit RF32 (now Unit RF31 in this final designation) upstream 8.6 rkm (5.3 rmi).

The new unit descriptions are provided below in Final Critical Habitat Designation. Because of the removal of the originally proposed Unit RF11, originally numbered Units RF12 to RF32 have been renumbered Units RF11 to RF31. In addition, these revisions resulted in a net decrease of designated critical habitat for the Neosho mucket of approximately 3 rkm (2 rmi) and a net decrease of critical habitat for the rabbitsfoot of 349 rkm (217 rmi). The majority of the changes from the proposed rule are to units occurring in Arkansas, with a net reduction of approximately 350 rkm (218 rmi; a 27 percent decrease). There was only one increase in critical habitat length (originally proposed Unit RF32, now Unit RF31, in this final designation).

(6) The critical habitat in the originally proposed Unit RF19 (now Unit RF18 in this final designation) for rabbitsfoot in the Duck River overlaps with the oyster mussel (*Epioblasma capsaeformis*) critical habitat. In the Duck River, the oyster mussel has been renamed the Duck River dartersnapper (*Epioblasma ahlstedti*) and is separate and distinct from the oyster mussel. We agree that the oyster mussel and Duck River dartersnapper are distinct and separate species. However, the Service has not yet made a listing and critical habitat determination for the new entity, the Duck River dartersnapper. We incorporated language in this final rule to clarify the species distinction and name change, but at this time, the Duck River dartersnapper and oyster mussel are considered synonymous according to our regulations.

(7) In the proposed rule, we inadvertently left out the description of a physical or biological feature for both species that addresses habitats protected from disturbance or representative of the historical, geographic, and ecological distributions of the species. We have added the description into this final rule (see *Physical or Biological Features,* below).

(8) In the proposed rule, Primary Constituent Element 4 for both species stated that fish hosts for each mussel were ''currently unknown'' and provided a statement regarding natural fish assemblages ''until appropriate host fish can be identified.'' While we do not currently know all fish species that may act as hosts for one or both of the glochidia of these mussels, this final rule identifies those fish species we believe are or may be host species (see *Primary Constituent Elements for Neosho Mucket and Rabbitsfoot* in this rule and *General Biology* in the proposed rule (77 FR 63442)).

(9) In the proposed rule, we incorrectly labeled the Pond Creek National Wildlife Refuge (NWR) as Cossatot NWR. This has been corrected in this final rule.

(10) Several Counties were inadvertently left out of the Executive Summary of the proposed rule; we added them in this final designation.

(11) In the proposed rule, we incorrectly named Mammoth Cave National Park North Entrance Road as Maple Springs Ranger Station Road in the unit description for Unit RF21. The correct road name is used in this final rule.

Summary of the Species' Status

Please refer to the proposed listing and critical habitat rule (77 FR 63440; October 16, 2012) and final listing rule (78 FR 57076, September 17, 2013) for the Neosho mucket and rabbitsfoot for a summary of species information. Additional information on the associated draft economic analysis and draft environmental assessment for the proposed rule was published in the **Federal Register** on May 9, 2013 (78 FR 27171).

For more information on relative abundance and trends of extant populations of Neosho mucket and rabbitsfoot by river basin please refer to the *Taxonomy, Life History, and Distribution* section of the proposed rule published in the **Federal Register** on October 16, 2012 (77 FR 63440).

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge,

wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are those specific elements of the physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential for the conservation of the species and may be included in the critical habitat designation. We designate critical habitat in areas outside the geographical area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to insure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) section 9 of the Act's prohibitions on taking any individual of the species, including taking caused by actions that affect habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species.

We derive the specific physical or biological features essential to Neosho mucket and rabbitsfoot from studies of these species' habitat, ecology, and life history as described in the Critical Habitat section of the proposed rule to designate critical habitat published in the **Federal Register** on October 16, 2012 (77 FR 63440), and in the information presented below. Additional information can be found in the final listing rule published in the **Federal Register** on September 17, 2013 (78 FR 57076). We have determined that Neosho mucket and rabbitsfoot require the following physical or biological features:

Space for Individual and Population Growth and for Normal Behavior

The Neosho mucket is historically associated with the Illinois, Neosho, and Verdigris Rivers and their larger tributaries (Arkansas River basin). Generally, the Neosho mucket is found embedded in stable substrates associated with shallow riffles (areas

where shallow, generally less than 1 m (3.3 ft) in depth, turbulent water passes through and over stones or gravel of somewhat similar size) and runs (intermediate areas between pools and riffles with moderate current) with gravel and sand substrate and moderate to swift currents (Oesch 1984, p. 221; Harris 1998, p. 5; Obermeyer 2000, pp. 15–16). However, in Shoal Creek and the Illinois River, the Neosho mucket prefers near-shore areas or areas out of the main current (Harris 1998, p. 5). These habitats are formed and maintained by water quantity, channel slope, and normal sediment input to the system.

The rabbitsfoot is historically associated with small- to medium-sized streams and some larger rivers in the Lower Great Lakes and Lower Mississippi River sub-basins and Ohio, Cumberland, Tennessee, White, Arkansas, and Red River basins. The rabbitsfoot usually occurs in shallow areas along the bank and adjacent runs and riffles with gravel and sand substrates where the water velocity is reduced, but it also may occur in deep runs (Parmalee and Bogan 1998, pp. 211–212). Unlike the Neosho mucket (Barnhart 2003, p. 17), the rabbitsfoot seldom burrows in the substrate, but lies on its side (Watters 1988, p. 13; Fobian 2007, p. 24).

Neosho mucket and rabbitsfoot, similar to other mussels, are dependent on areas with flow refuges where shear stress (the stream's ability to entrain and transport bed material created by the flow acting on the bed material) is low and sediments remain stable during flood events (Layzer and Madison 1995, p. 341; Strayer 1999, pp. 468 and 472; Hastie *et al.* 2001, pp. 111–114). Flow refuges conceivably allow relatively immobile mussels such as the Neosho mucket and rabbitsfoot to remain in the same general location throughout their entire lives. These patches of stable habitat may be highly important for the rabbitsfoot since it typically does not burrow, making it more susceptible to displacement into unsuitable habitat. However, flow refuges are not created equally and there are likely other habitat variables that are important, but poorly understood (Roberts 2008, pers. comm.).

Natural river and creek channel stability are achieved by allowing the river or creek to develop a stable dimension, pattern, and profile, such that, over time, channel features are maintained and the river or creek system neither aggrades nor degrades. Channel instability occurs when the scouring (flushing) process leads to degradation or excessive sediment deposition results in aggradation. Stable rivers and creeks consistently transport their sediment load, both in size and type, associated with local deposition and scour (Rosgen 1996, pp. 1–3).

Habitat conditions described above provide space, cover, shelter, and sites for breeding, reproduction, and growth of offspring for the Neosho mucket and rabbitsfoot. These habitats are formed and maintained by water quantity, channel features (dimension, pattern, and profile), and sediment input to the system through periodic flooding, which maintains connectivity and interaction with the flood plain, and are dynamic. Changes in one or more of these parameters can result in channel degradation or aggradation, with serious effects to mussels. Therefore, we identify adequate water quantity, stream channel stability, and floodplain connectivity to be physical or biological features for Neosho mucket and rabbitsfoot that are essential in accommodating feeding, breeding, growth, and other normal behaviors of these species and in promoting gene flow within each species' populations and movement of their fish hosts.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

The Neosho mucket and rabbitsfoot are riverine-adapted species that depend upon adequate water flow and are not found in ponds or lakes. Continuously flowing water is a habitat feature associated with all surviving populations of these species. Flowing water maintains the river and creek bottoms and flow refuge habitats in riffles and runs where these species are found, transports food items to the sedentary juvenile and adult life stages, removes wastes, and provides oxygen for respiration of the Neosho mucket and rabbitsfoot. A natural flow regime that includes periodic flooding and maintains connectivity and interaction with the floodplain is critical for the exchange of nutrients, movement of and spawning activities for potential fish hosts, and maintenance of flow refuges in riffle and run habitats.

Mussels, such as the Neosho mucket and rabbitsfoot, filter algae, detritus, microscopic animals, and bacteria from the water column (Fuller 1974, p. 221; Silverman *et al.* 1997, pp. 1862–1865; Nichols and Garling 2000, pp. 874–876; Strayer *et al.* 2004 pp. 430–431). Encysted (attached) glochidia are nourished by their fish hosts and feed for a period of one week to several months. Nutrient uptake by glochidia is not well understood, but probably occurs through the microvillae (fingerlike outward projections of a cell's surface) of the mantle (the part of the outer layer of skin (epidermis) of a mollusk that secretes the shell) (Watters 2007, p. 55). For the first several months, juvenile mussels partially employ pedal (foot) feeding, extracting bacteria, algae, and detritus from the sediment, although they also may filter interstitial (pore) water (Yeager *et al.* 1994, pp. 217–221). However, their gills are rudimentary and generally incapable of filtering particles (Watters 2007, p. 56). Adult mussels also can obtain their food by deposit feeding, siphoning in food from the sediment and its interstitial (pore) water and pedal feeding directly from the sediment (Yeager *et al.* 1994, pp. 217–221; Vaughn and Hakenkamp 2001, pp. 1432–1438). Food availability and quality for the Neosho mucket and rabbitsfoot in their habitats are affected by habitat stability, floodplain connectivity, flow, and water and sediment quality.

The ranges of many water quality parameters that define suitable habitat conditions for the Neosho mucket and rabbitsfoot have not been investigated or are poorly understood. The pathways of exposure to a variety of environmental pollutants for all four mussel life stages (free and encysted glochidia, juveniles, and adults) and differences in exposure and sensitivity were previously discussed in the proposed rule (77 FR 63440, see Factor A). Environmental contamination is a causal (contributing) factor in the decline of mussel populations. We estimate most numeric standards for pollutants and water quality parameters (for example, dissolved oxygen, pH, heavy metals) adopted by States under the CWA represent levels essential to the conservation of these mussels. However, some regulatory mechanisms may not adequately protect mollusks in some reaches (77 FR 63440, see Factor D). Other factors that can potentially alter water quality are droughts and periods of low flow, nonpoint-source runoff from adjacent land surfaces (excessive amounts of sediments, nutrients, and pesticides), point-source discharges from municipal and industrial wastewater treatment facilities (excessive amounts of ammonia, chlorine, and metals), and random spills or unregulated discharge events. This could be particularly harmful during drought conditions when flows are depressed and pollutants are more concentrated.

As relatively sedentary animals, mussels must tolerate the full range of environmental stressors that occur within the streams where they persist. Both the amount (flow) and the physical

and chemical conditions (sediment and water quality) where these species currently exist vary widely according to season, precipitation events, and seasonal human activities within the various watersheds. Conditions across their historical ranges vary even more due to geology, geography, and differences in human population densities and land uses. In general, these species survive in areas where the severity, frequency, duration, and seasonality of water flow is adequate to maintain stable flow refuges in riffle and run habitats (sufficient flow to remove fine particles and sediments without causing degradation), and where sediment and water quality is adequate for year-round survival (moderate to high levels of dissolved oxygen; low to moderate exposure to environmental pollutants such as nutrients, dissolved metals, and pharmaceuticals; and relatively unpolluted water and sediments). Adequate water flow, water quality, and sediment quality (as defined above) is essential for normal behavior, growth, and viability during all life stages of the Neosho mucket and rabbitsfoot and their potential larva fish hosts. Therefore, based on the information above, we identify water flow, water quality, and sediment quality to be physical or biological features for both these species.

Sites for Breeding, Reproduction, or Rearing

Mussels require a fish host for transformation of larval mussels (glochidia) to juvenile mussels (Williams *et al.* 2008, p. 68); therefore, presence of the appropriate fish host(s) is essential to the conservation of the Neosho mucket and rabbitsfoot (77 FR 63440, see *Taxonomy, Life History, and Distribution*). Neosho mucket and rabbitsfoot juveniles require stable habitats with adequate water quantity and quality as previously described for growth and survival. Excessive sediments or dense growth of filamentous algae can expose juvenile mussels to entrainment or predation and be detrimental to the survival of juvenile mussels (Hartfield and Hartfield 1996, pp. 372–374). Geomorphic instability can result in the loss of interstitial habitats and juvenile mussels due to scouring or deposition (Hartfield 1993, pp. 372–373). Water quality, sediment quality, stable habitat, health of fish hosts, and diet (of all life stages) all influence survival of each life stage and subsequent reproduction and recruitment (Cope *et al.* 2008, p. 452).

Connections between the rivers and adjacent flood plains occur periodically during wet years and provide habitat for spawning and foraging fish hosts that require flood plain habitats for successful reproduction and recruitment to adulthood. Barko *et al.* (2006, pp. 252–256) found that several fish host or potential host species benefited from exploiting the resources of flood plain habitats that were not typically available for use during normal hydrology years. Furthermore, Kwak (1988, pp. 243–247) and Slipke *et al.* (2005, p. 289) indicated that periodic inundation of floodplain habitats increased successful fish reproduction, which leads to increased availability of native host fishes for mussel reproduction. However, Rypel *et al.* (2009, p. 502) indicated that mussels tended to exhibit minimal growth during high flow years. Therefore, optimal flooding of these habitats would not be too frequent and should occur at similar frequencies to that of the natural hydrologic regime of the rivers and creeks inhabited by the Neosho mucket and rabbitsfoot. Based on the information above, we identify water quality, sediment quality, stable habitat, health of fish hosts, diet (of all life stages), and periodic flooding of floodplain habitat to be physical or biological features for these species.

Primary Constituent Elements for Neosho Mucket and Rabbitsfoot

Under the Act and its implementing regulations, we are required to identify the physical or biological features essential to the conservation of Neosho mucket and rabbitsfoot in areas occupied at the time of listing, focusing on the features' primary constituent elements. Primary constituent elements are those specific elements of the physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

Based on the above needs and our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the primary constituent elements specific to the Neosho mucket and rabbitsfoot are:

(1) Geomorphically stable river channels and banks (channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as stable riffles, sometimes with runs, and mid-channel island habitats that provide flow refuges consisting of gravel and sand substrates with low to moderate amounts of fine sediment and attached filamentous algae).

(2) A hydrologic flow regime (the severity, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species are found and to maintain connectivity of rivers with the floodplain, allowing the exchange of nutrients and sediment for maintenance of the mussel's and fish host's habitat, food availability, spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats.

(3) Water and sediment quality (including, but not limited to, conductivity, hardness, turbidity, temperature, pH, ammonia, heavy metals, and chemical constituents) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

(4) The occurrence of natural fish assemblages, reflected by fish species richness, relative abundance, and community composition, for each inhabited river or creek that will serve as an indication of appropriate presence and abundance of fish hosts necessary for recruitment of the Neosho mucket and rabbitsfoot. Suitable fish hosts for Neosho mucket glochidia include smallmouth bass (*Micropterus dolomieu*), largemouth bass (*Micropterus salmoides*), and spotted bass (*Micropterus punctulatus*). Suitable fish host for rabbitsfoot may include, but are not limited to, blacktail shiner (*Cyprinella venusta*) from the Black and Little River and cardinal shiner (*Luxilus cardinalis*), red shiner (*C. lutrensis*), spotfin shiner (*C. spiloptera*), bluntface shiner (*C. camura*), rainbow darter (*Etheostoma caeruleum*), rosyface shiner (*Notropis rubellus*), striped shiner (*L. chrysocephalus*), and emerald shiner (*N. atherinoides*).

(5) Competitive or predaceous invasive (nonnative) species in quantities low enough to have minimal effect on survival of freshwater mussels.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographic area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection.

For Neosho mucket and rabbitsfoot, we have grouped the primary threats affecting their habitat, thus potentially the need to implement special management or protection, into nine categories.

(1) Impoundments (primary constituent elements 1–4). Dams eliminate and alter river flow within impounded areas, trap silt leading to increased sediment deposition, alter water quality, change hydrology and channel geomorphology, decrease habitat heterogeneity, affect normal flood patterns, and block upstream and downstream movement of mussels and fish (Layzer *et al.* 1993, pp. 68–69; Neves *et al.* 1997, pp. 63–64; Watters 2000, pp. 261–264). Within impounded waters, decline of mussels has been attributed to direct loss of supporting habitat, sedimentation, decreased dissolved oxygen, temperature levels, and alteration in resident fish populations (Neves *et al.* 1997, pp. 63–64; Pringle *et al.* 2000, pp. 810–815; Watters 2000, pp. 261–264). Downstream of dams, mussel declines are associated with changes and fluctuation in flow regime, channel scouring and bank erosion, reduced dissolved oxygen levels and water temperatures, and changes in resident fish assemblages (Williams *et al.* 1992, p. 7; Layzer *et al.* 1993, p. 69; Neves *et al.* 1997, pp. 63–64; Watters 2000, pp. 265–266; Pringle *et al.* 2000, pp. 810–815). Dams that are low to the water surface, or have water passing over them (small low head or mill dams) can have some of these same effects on mussels and their fish hosts, particularly reducing species richness and evenness and blocking fish host movements (Watters 2000, pp. 261–264; Dean *et al.* 2002, pp. 235–238). Examples of special management actions that would minimize or ameliorate these threats include: (a) Modified reservoir releases from dams to improve water quality and habitat conditions in many tailwaters, and (b) modified dam operations (for example, TVA's Tims Ford Dam on the Elk River, where water temperature is monitored and dam operation is adjusted to support endangered mussels downstream) and water quality and biological monitoring.

(2) Channelization (primary constituent elements 1–4). Dredging and channelization activities have profoundly altered riverine habitats nationwide. Hartfield (1993, pp. 131–139), Neves *et al.* (1997, pp. 71–72), and Watters (2000, pp. 268–269) reviewed the specific upstream and downstream effects of channelization on freshwater mussels. Channelization affects a stream physically (accelerates erosion, increases sediment bed load, reduces water depth, decreases habitat diversity, creates geomorphic (natural channel dimensions) instability, and eliminates riparian canopy) and biologically (decreases fish and mussel diversity, changes species composition and abundance, decreases biomass, and reduces growth rates) (Hartfield 1993, pp. 131–139). Channel modification for navigation has been shown to increase flood heights (Belt 1975, p. 684), partly as a result of an increase in stream bed slope (Hubbard *et al.* 1993, p. 137). Flood events are exacerbated, conveying large quantities of sediment, potentially with adsorbed contaminants, into streams. Channel maintenance often results in increased turbidity and sedimentation that often smothers mussels (Stansbery 1970, p. 10). Examples of special management actions that would minimize or ameliorate these threats include: (a) Determining distribution and abundance of mussels, (b) developing dredging protocols and mussel identification booklets to help minimize effects (for example, ACOE–Memphis District in the White River avoids dredging known mussel beds), and (c) funding research on geomorphological requirements of mussels to better inform management decisions.

(3) Sedimentation (primary constituent elements 3–4). Excessive sediments are believed to negatively impact riverine mussel populations requiring clean, stable streams (Ellis 1936, pp. 39–40; Brim-Box and Mossa 1999, p. 99). Adverse effects resulting from sediments have been noted for many components of aquatic communities. Potential sediment sources within a watershed include virtually all activities that disturb the land surface. Most localities occupied by the Neosho mucket and rabbitsfoot, including viable populations, are currently being affected to varying degrees by sedimentation. Specific biological effects include reduced feeding and respiratory efficiency from clogged gills, disrupted metabolic processes, reduced growth rates, limited burrowing activity, physical smothering, and disrupted host fish attraction mechanisms (Ellis 1936, pp. 39–40; Marking and Bills 1979, p. 210; Vannote and Minshall 1982, pp. 4105–4106; Waters 1995, pp. 173–175; Hartfield and Hartfield 1996, p. 373). Examples of special management actions that would minimize or ameliorate these threats include: (a) Restoration and protection of riparian corridors, (b) implementation of best management practices to minimize erosion (such as State and industry practices for forestry activities), (c) stream bank restoration projects, and (d) private landowner programs to promote watershed and soil conservation.

(4) Chemical Contaminants (primary constituent elements 3–4). Chemical contaminants are ubiquitous in the environment and are considered a major contributor to the decline of mussel species (Richter *et al.* 1997, p. 1081; Strayer *et al.* 2004, p. 436; Wang *et al.* 2007, p. 2029; Cope *et al.* 2008, p. 451). Chemicals enter the environment through point- and nonpoint-source discharges including spills, industrial and municipal effluents, and residential and agricultural runoff. These sources contribute organic compounds, heavy metals, nutrients, pesticides, and a wide variety of newly emerging contaminants such as pharmaceuticals to the aquatic environment. As a result, water and sediment quality can be degraded to the extent that results in adverse effects to mussel populations. Examples of special management actions that would minimize or ameliorate these threats include: (a) Revising water quality standards (such as EPA's new ammonia aquatic life criteria), (b) implementing storm water best management practices, (c) promoting green areas along riparian corridors in rapidly developing urban areas (such as the Illinois River), (d) upgrading industrial and municipal treatment facilities to improve water quality in effluents, and (e) participating in private landowner programs to promote watershed conservation (such as USDA Farm Bill programs).

(5) Mining (primary constituent elements 1–4). Gravel, coal, and metal mining are activities negatively affecting water quality in Neosho mucket and rabbitsfoot habitat. Instream and alluvial gravel mining has been implicated in the destruction of mussel populations (Hartfield 1993, pp. 136–138; Brim-Box and Mossa 1999, pp. 103–104). Negative effects associated with gravel mining include stream channel modifications (altered habitat, disrupted flow patterns, sediment transport), water quality modifications (increased turbidity, reduced light penetration, increased temperature), macroinvertebrate population changes (elimination), and changes in fish populations, resulting from adverse effects to spawning and nursery habitat and food web disruptions (Kanehl and Lyons 1992, pp. 4–10). Coal mining activities, resulting in heavy metal-rich drainage, and associated sedimentation has adversely affected many drainages with rabbitsfoot populations (Ortmann 1909 *in* Butler 2005, p. 102; Gordon 1991, pp. 4 and 5; Layzer and Anderson 1992 *in* Butler 2005, p. 102). Numerous mussel toxicants, such as polycyclic aromatic hydrocarbons and heavy metals (copper, manganese, and zinc) from coal mining,

contaminate sediments when released into streams (Ahlstedt and Tuberville 1997, p. 75). Acid mine runoff may have local effects on mussel recruitment and may lead to mortality due to improper shell development or erosion (Huebner and Pynnonen 1990, pp. 2350–2353). Examples of special management actions that would minimize or ameliorate these threats include: (a) Remediating soils contaminated with heavy metals (such as Tri-State Mining Area's reclamation of contaminated areas to improve water quality), and (b) partnering with industry to identify mussel locations to avoid during instream and alluvial sand and gravel mining operations.

(6) Oil and Natural Gas Development (primary constituent elements 1–4). Exploration and extraction of these energy resources can result in increased siltation, a changed hydrograph (graph showing changes in the discharge of a river over a period of time), and altered water quantity and quality even at considerable distances from the mine or well field because effects are carried downstream from the original source. Examples of special management actions that would minimize or ameliorate these threats include: (a) Developing and implementing best management practices for oil and natural gas development activities (such as Fayetteville Shale located in the upper Little Red River watershed), (b) partnering with industry and nongovernmental organizations to restore mussel habitat (such as Southwestern Energy's ECH_20 (Energy Conserving Water) and the Archey Fork Little Red River Restoration Project), (c) creating conservation memoranda of agreement with industry to conserve mussel habitat (such as Crestwood Midstream in the upper Little Red River watershed), and (d) developing ecologically sustainable flow requirements for mussels.

(7) Invasive, nonindigenous species (primary constituent element 5). Invasive, nonindigenous species, such as zebra mussel, black carp, and Asian clam, have potentially adversely affected populations of the Neosho mucket and rabbitsfoot and their fish hosts, and these effects are expected to persist into the future. Examples of special management actions that would minimize or ameliorate these threats include: (a) Implementation of nonregulatory conservation measures to control Asian carp and other invasive, nonindigenous species, and (b) continued State engagement in efforts to minimize effects of Asian carp (such as eradication) on native fish resources.

(8) Temperature (primary constituent elements 3–4). Natural temperature regimes can be altered by impoundments, tailwater releases from dams, industrial and municipal effluents, and changes in riparian habitat. Low temperatures can significantly delay or prevent metamorphosis in mussels (Watters and O'Dee 1999, pp. 454–455). Cold water effluent below dams may negatively impact populations; rabbitsfoot were less abundant and in poor condition below a cold water outflow on the Little River, compared to two other sites upstream (Galbraith and Vaughn 2011, p. 198). Low water temperatures caused by dam releases also may disrupt seasonal patterns in reproduction (Galbraith and Vaughn 2009, pp. 43–44).

High temperatures can reduce dissolved oxygen concentrations in the water, which slows growth, reduces glycogen stores, impairs respiration, and may inhibit reproduction (Fuller 1974, pp. 240–241). Water temperature increases have been documented to shorten the period of glochidial encystment, reduce righting speed (various reflexes that tend to bring the body into normal position in space and resist forces acting to displace it out of normal position), and slow burrowing and movement responses (Bartsch *et al.* 2000, p. 237; Watters *et al.* 2001, p. 546; Schwalb and Pusch 2007, pp. 264–265). Several studies have documented the influence of temperature on the timing aspects of mussel reproduction (van Snik *et al.* 2002, p. 156; Allen *et al.* 2007, p. 85; Steingraeber *et al.* 2007, pp. 303–309). Peak glochidial releases are associated with water temperature thresholds that can be thermal minimums or maximums, depending on the species (Watters and O'Dee 2000, p. 136). Examples of special management actions that would minimize or ameliorate these threats include: (a) Increase cold water temperature to optimal range for mussels by modification to tailwater releases, (b) improve industrial and municipal water treatment, and (c) protect and restore riparian habitat.

(9) Climate change (primary constituent elements 2–4). As temperature increases due to climate change throughout the range of Neosho mucket and rabbitsfoot, both species may experience population declines as warmer rivers become more suitable for thermally tolerant species. Overall, the distribution of fish species is expected to change, including range shifts and local extirpations (Ficke *et al.* 2005, pp. 67–69; 2007, pp. 603–605). Because freshwater mussels are entirely dependent upon a fish host for successful reproduction and dispersal, any changes in local fish populations would also affect freshwater mussel populations. Examples of special management actions that would minimize or ameliorate these threats include: (a) Reduce habitat fragmentation; (b) maintain ecosystem function and resiliency; (c) develop and implement strategies to help our native fish, wildlife, and habitats adapt to a changing climate; and (d) reduce non-climate stressors.

The reduction of these threats will require the implementation of special management considerations or protections within each of the critical habitat areas identified in this rule. All critical habitat requires active management to address some or all of the ongoing threats listed. Some of these activities include, but are not limited to, those previously discussed in the Summary of Factors Affecting the Species section in the final listing rule (78 FR 57076, September 17, 2013).

In summary, we find the areas we are designating as critical habitat were occupied at the time of listing and contain the features essential to the conservation of the Neosho mucket and rabbitsfoot, and these features may require special management considerations or protection. Special management considerations or protection may be required to eliminate, or to reduce to negligible levels, the threats affecting each unit and to preserve and maintain the essential physical or biological features the critical habitat units provide to the Neosho mucket and rabbitsfoot. A more detailed discussion of these threats is presented in the final listing rule under Summary of Factors Affecting the Species (78 FR 57076, September 17, 2013). Additional discussions of threats facing individual sites are provided in the individual unit descriptions.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify occupied areas at the time of listing that contain the features essential to the conservation of the species. As discussed above, we are designating critical habitat areas that we have determined to be occupied at the time of listing in 2013 and that contain sufficient elements of physical or biological features to support life-

history processes essential to the conservation of the Neosho mucket and the rabbitsfoot. If after identifying areas occupied by the species at the time of listing, we determine that those areas are inadequate to ensure conservation of the species, in accordance with the Act and our implementing regulations at 50 CFR 424.12(e), we then consider whether designating additional areas—outside those occupied at the time of listing—are essential for the conservation of the species. In this rule, we are not designating any areas outside the geographic area occupied by the species at the time of listing because occupied areas are sufficient for the conservation of the species.

In this rule, we have defined occupied habitat for the Neosho mucket as those stream reaches known to be currently extant. Extant Neosho mucket populations are naturally occurring populations represented by live or fresh dead specimens collected since 1985. For the rabbitsfoot, we have defined occupied habitat as those stream reaches that are sizeable and small populations as defined by Butler (2005, pp. 88–89), and the marginal populations of Fish Creek and Red River that are the last extant populations in their respective basins (Great Lakes and Cumberland) and Allegheny River, a metapopulation (interconnected populations where there is gene flow). All other populations classified as marginal are not considered as occupied habitat.

No unoccupied stream, as defined in the proposed critical habitat rule (77 FR 63440, October 16, 2012), is being designated as critical habitat for Neosho mucket or rabbitsfoot. We find that unoccupied stream reaches are not essential for the conservation of either species for one or more of the following reasons:

(1) Unoccupied habitats are isolated from occupied habitats due to reservoir construction and dam operations (dam water releases have altered natural stream hydrology, geomorphology, water temperature, and native mollusk and fish communities);

(2) Unoccupied areas exhibit limited habitat availability, degraded habitat, or low potential value for management (Muskingum, Elk, Scioto, Little Miami, Licking, East Fork White, Cumberland, Holston, Clinch, Sequatchie, and Buffalo (Duck River system) Rivers);

(3) Collection records for both species indicate that these species have been extirpated from unoccupied areas for several decades or more and, in some cases (such as Cottonwood River), reintroduction efforts have not been successful at re-establishing populations; or

(4) There are no historical records of occurrence within the stream reach for Neosho mucket, rabbitsfoot, or both.

(5) While we recognize the importance of unoccupied habitat to recovery of listed species, in this case, unoccupied habitat does not provide habitat for reintroduction at this time and does not reduce the level of stochastic and human-induced threats for the following reasons:

(a) Unoccupied habitat does not currently contain sufficient physical or biological features or have the ability to be restored to support life-history functions of the Neosho mucket and rabbitsfoot (such characteristics as geomorphically stable channels, perennial water flows, adequate water quality, and appropriate benthic substrates);

(b) Unoccupied habitat does not support the once diverse mollusk communities, including the presence of closely related species requiring physical or biological features similar to the Neosho mucket and rabbitsfoot; or

(c) Unoccupied habitat is not adjacent to currently occupied areas where there is potential for natural dispersal and reoccupation by the Neosho mucket and rabbitsfoot.

Based on the above analysis, a total of 38 units, all of which were occupied at the time of listing, are being designated based on sufficient elements of physical or biological features being present to support Neosho mucket (7 units) and rabbitsfoot (31 units) life-history processes. Some units contain all of the identified elements of physical or biological features and support multiple life-history processes. Some units contain only some elements of the physical or biological features necessary to support the Neosho mucket's or rabbitsfoot's particular use of that habitat.

When determining critical habitat boundaries within this final rule, we made every effort to avoid including developed areas such as dams, piers, and bridges, and other structures because such areas usually lack physical or biological features for the species. Areas designated as critical habitat for the Neosho mucket and rabbitsfoot include only stream channels within the ordinary high-water line and do not contain manmade structures (such as dams, piers and docks, bridges, or other similar structures), or areas inundated by lakes and reservoirs. The ordinary high-water line defines the stream channel and is the point on the stream bank where water is continuous and leaves some evidence, such as erosion or aquatic vegetation. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of structures or other developed areas. Any such areas inadvertently left inside critical habitat boundaries shown on the maps of this final rule have been excluded by text in the final rule and are not designated as critical habitat. Therefore, a Federal action involving these areas would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document in the rule portion. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates, plot points, or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0007 on our Internet site *http://www.fws.gov/arkansas-es/*, and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT,** above).

Three critical habitat units for the Neosho mucket and rabbitsfoot are currently designated as critical habitat for the oyster mussel (*Epioblasma capsaeformis;* now recognized by the scientific community as the Duck River dartersnapper (*Epioblasma ahlstedti*) in the Duck River) and Cumberlandian combshell (*Epioblasma brevidens*) encompassing the Duck River, Tennessee (74 rkm (46 rmi)) and Bear Creek, Alabama and Mississippi (40 rkm (25 rmi)) (50 CFR 17.95(f)), and for the yellowcheek darter (*Etheostoma moorei*) in the Middle Fork Little Red River, Arkansas (23.2 rkm (14.5 rmi)) (50 CFR 17.95(e)). The existing critical habitat for the oyster mussel and Cumberlandian combshell completely overlaps the originally proposed Unit RF16 (Bear Creek, now Unit RF15), but the exact unit descriptions (length) differ due to mapping refinement since the earlier designation. In addition, five critical habitat units being designated for the Neosho mucket and rabbitsfoot are currently designated by the State of Kansas as critical habitat for both species in the Fall, Spring, Neosho, and Verdigris Rivers and for Neosho mucket in Shoal Creek (K.S.A. 32–959; Table 1) and are afforded similar State-level protections as those provided under the Act.

Final Critical Habitat Designation

TABLE 1—CRITICAL HABITAT AREAS FOR THE NEOSHO MUCKET AND RABBITSFOOT THAT ARE CURRENTLY DESIGNATED AS CRITICAL HABITAT FOR OTHER FEDERALLY AND STATE LISTED SPECIES

Unit (unit #)	Species present in unit	Federal reference	State reference	Length of overlap in rkm (rmi)
Shoal Creek (NM3)	Neosho mucket, fluted shell, Ouachita kidneyshell, Western fanshell, redspot chub.		K.S.A. 32–959	9.7 (6.0)
Spring River (NM4 and RF1)	Neosho mucket, rabbitsfoot, elktoe, ellipse shell, Neosho madtom, fluted shell, Ouachita kidneyshell, Western fanshell, redspot chub.		K.S.A. 32–959	11.6 (7.2)
Fall River (NM6)	Neosho mucket, Western fanshell		K.S.A. 32–959	90.4 (56.2)
Verdigris River (NM6 and RF2).	Neosho mucket, rabbitsfoot, Ouachita kidneyshell, western fanshell, butterfly.		K.S.A. 32–959	80.6 (50.1)
Neosho River (NM7 and RF3)	Neosho mucket, rabbitsfoot, butterfly, Neosho madtom, Ouachita kidneyshell, western fanshell.		K.S.A. 32–959	245.9 (152.8)
Middle Fork Little Red River (RF7).	Yellowcheek darter	50 CFR 17.95(e)		23.3 (14.5)
Bear Creek (RF15)	Oyster mussel (Duck River dartersnapper), Cumberlandian combshell.	50 CFR 17.95(f)		49.7 (30.9)
Duck River (RF18)	Oyster mussel (Duck River dartersnapper), Cumberlandian combshell.	50 CFR 17.95(f)		74.0 (46.0)
Total				585.2 (363.7)

We are designating seven units, totaling approximately 777 rkm (483 rmi), in four States (Arkansas, Kansas, Missouri, and Oklahoma) as critical habitat for the Neosho mucket (Table 2). We are designating 31 units (3 with subunits), totaling approximately 2,312 rkm (1,437 rmi), in 12 States (Alabama, Arkansas, Illinois, Indiana, Kansas, Kentucky, Mississippi, Missouri, Ohio, Oklahoma, Pennsylvania, and Tennessee) as critical habitat for the rabbitsfoot (Table 2). Four of the 31 units (Units NM4, NM7, RF1, and RF3) are occupied by both Neosho mucket and rabbitsfoot.

Public lands adjacent to Neosho mucket and rabbitsfoot critical habitat units consist of approximately 469 rkm (291 rmi) of riparian lands in the following units:

- Unit NM1: Ozark National Forest, 20.4 rkm (12.7 rmi); ACOE's Lake Tenkiller Project, 9.0 rkm (5.6 rmi); and Sparrowhawk Wildlife Management Area (WMA), 2.2 rkm (1.4 rmi);
- Units NM4 and RF1: Spring River Wildlife Area, 1.4 rkm (0.9 rmi);
- Unit RF2: ACOE's Oologah Lake Project, 0.6 rkm (0.4 rmi);
- Unit NM7: Neosho Wildlife Area, 6.1 rkm (3.8 rmi);
- Unit RF6: Little River NWR, 37.6 rkm (23.5 rmi); Ouachita National Forest, 16.1 rkm (10.0 rmi); and Pond Creek NWR, 11.4 rkm (7.2 rmi);
- Unit RF8a: Jacksonport State Park, 2.9 rkm (1.8 rmi) and Henry Gray–Hurricane Lake WMA, 7.9 rkm (4.9 rmi);
- Unit RF8b: White River NWR, 57.9 rkm (36.0 rmi);
- Unit RF10: Harold Alexander WMA, 1.1 rkm (0.7 rmi);
- Unit RF12: Buffalo National River, 113.6 rkm (70.6 rmi);
- Unit RF13: Sam A. Baker State Park, 1.0 rkm (0.6 rmi) and ACOE's Wappapello Lake Project, 25.3 rkm (15.7 rmi);
- Unit RF15: Tishomingo State Park, 6.1 rkm (3.8 rmi); NPS Natchez Trace Parkway, 4.5 rkm (2.8 rmi); and TVA Pickwick Lake Project, 7.4 rkm (4.6 rmi);
- Unit RF17: Fern Cave NWR, 0.5 rkm (0.3 rmi);
- Unit RF18: Yanahli WMA, 38.9 rkm (24.3 rmi) and Santa Fe County Park, 1.4 rkm (0.9 rmi);
- Unit RF19a: Shiloh National Military Park, 2.6 rkm (1.6 rmi);
- Unit RF19b: Kentucky Dam Village State Resort Park, 0.6 rkm (0.4 rmi) and unnamed TVA land downstream of Kentucky Lake Dam, 2.4 rkm (1.5 rmi);
- Unit RF20: Massac Forest Nature Preserve, 2.2 rkm (1.4 rmi); West Kentucky WMA, 5.6 rkm (3.5 rmi); Ballard WMA, 2.6 rkm (1.6 rmi); and Chestnut Hills Nature Preserve, 2.4 rkm (1.5 rmi);
- Unit RF21: Mammoth Cave National Park, 17.0 rkm (10.6 rmi);
- Unit RF22: Pennsylvania State Game Land, 277, 2.9 rkm (1.8 rmi) and Pennsylvania State Game Land 85, 0.6 rkm (0.4 rmi);
- Unit RF23: Clear Creek State Forest, 9.9 rkm (6.2 rmi);
- Unit RF24: Erie NWR, 16.2 rkm (10.1 rmi);
- Unit RF25: Prophetstown State Park, 2.1 rkm (1.3 rmi);
- Unit RF26: Muskingum Watershed Conservancy Land, 5.0 rkm (3.1 rmi);
- Unit RF27: Little Darby State Scenic Waterway–River Lands, 8.7 rkm (5.4 rmi);
- Unit RF29: Fish Creek Wildlife Area, 1.6 rkm (1.0 rmi); and
- Unit RF31: ACOE's Shenango River Lake Project, 8.8 rkm (5.5 rmi).

TABLE 2—APPROXIMATE RIVER DISTANCES CURRENTLY OCCUPIED BY NEOSHO MUCKET AND RABBITSFOOT

Species	Approximate river distances currently occupied by the species	
	River km	River miles
Neosho mucket	776.5	482.5
Rabbitsfoot	2,312.1	1,436.7
Total	3,088.6	1,919.2
Species, Stream (Unit), and State	**Currently occupied**	
Neosho mucket:		
Unit NM1, Illinois River AR, OK	146.1	90.8
Unit NM2, Elk River, MO, OK	20.3	12.6
Unit NM3, Shoal Creek, KS, MO	75.8	47.1
Unit NM4, Spring River, KS, MO	102.3	63.6
Unit NM5, North Fork Spring River, MO	16.4	10.2
Unit NM6, Fall and Verdigris Rivers, KS	171.1	106.3
Unit NM7, Neosho River, KS	244.5	151.9
Total	776.5	482.5
Rabbitsfoot:		
Unit RF1, Spring River, MO, KS	56.5	35.1
Unit RF2, Verdigris River, OK	38.0	23.6
Unit RF3, Neosho River, KS	26.6	16.5
Unit RF4a, Ouachita River, AR	22.7	14.1
Unit RF4b, Ouachita River, AR	43.0	26.7
Unit RF5, Saline River, AR	119.4	74.2
Unit RF6, Little River, OK, AR	139.7	86.8
Unit RF7, Middle Fork Little Red River, AR	24.8	15.4
Unit RF8a, White River, AR	188.3	117.0
Unit RF8b, White River, AR	68.9	42.8
Unit RF9, Black River, AR	51.2	31.8
Unit RF10, Spring River, AR	51.5	32.0
Unit RF11, Strawberry River, AR	123.8	76.9
Unit RF12, Buffalo River, AR	113.6	70.6
Unit RF13, St. Francis River, MO	64.3	40.0
Unit RF14, Big Sunflower River, MS	51.5	32.0
Unit RF15, Bear Creek, AL, MS	49.7	30.9
Unit RF16, Big Black River, MS	43.3	26.9
Unit RF17, Paint Rock River, AL	81.0	50.3
Unit RF18, Duck River, TN	235.3	146.2
Unit RF19a, Tennessee River, TN	26.7	16.6
Unit RF19b, Tennessee River, KY	35.6	22.1
Unit RF20, Ohio River, KY, IL	45.9	28.5
Unit RF21, Green River, KY	175.6	109.1
Unit RF22, French Creek, PA	120.4	74.8
Unit RF23, Allegheny River, PA	57.3	35.6
Unit RF24, Muddy Creek, PA	20.1	12.5
Unit RF25, Tippecanoe River, IN	75.6	47.0
Unit RF26, Walhonding River, OH	17.5	10.9
Unit RF27, Little Darby Creek, OH	33.3	20.7
Unit RF28, North Fork Vermilion River and Middle Branch North Fork Vermilion River, IL	28.5	17.7
Unit RF29, Fish Creek, OH	7.7	4.8
Unit RF30, Red River, KY, TN	50.2	31.2
Unit RF31, Shenango River, PA	24.8	15.4
Total	2,312.1	1,436.7

These critical habitat units include the river channels within the ordinary high-water line. As defined at 33 CFR 329.11, the ordinary high-water mark on nontidal rivers is the line on the shore established by the fluctuations of water and indicated by physical characteristics, such as a clear, natural line impressed on the bank; shelving; changes in the character of soil; destruction of terrestrial vegetation; the presence of litter and debris; or other appropriate means that consider the characteristics of the surrounding areas. States were granted ownership of lands beneath navigable waters up to the ordinary high-water line upon achieving Statehood (*Pollard* v. *Hagan,* 44 U.S. (3 How.) 212 (1845)). Prior to Statehood, the American colonies may have made grants to private parties that included lands below the ordinary high-water mark of some navigable waters that are included in this final rule. However, most, if not all, lands beneath the navigable waters included in this final rule are owned by the States. Although areas designated as critical habitat for the Neosho mucket and rabbitsfoot include only stream channels within the

ordinary high-water line, riparian lands along the waters adjacent to, but not included in, the critical habitat units are either in private ownership, or owned by municipalities, States, or Federal entities. Table 3 summarizes primary adjacent riparian landowners in each of the Neosho mucket and rabbitsfoot critical habitat units by private, State, Tribal (jurisdictional, not ownership), or Federal ownership. One Neosho mucket and two rabbitsfoot critical habitat units, respectively, are located within Tribal jurisdictional areas: Unit NM1 (Illinois River, Oklahoma; 103.0 rkm (64.0 rmi)), Unit RF2 (Verdigris River, Oklahoma; 38.0 rkm (23.6 rmi)), and Unit RF6 (Little River, Oklahoma; 41.4 rkm (25.7 rmi)).

TABLE 3—OWNERSHIP OF RIPARIAN LANDS ADJACENT TO—BUT NOT INCLUDED IN—THE CRITICAL HABITAT UNITS FOR NEOSHO MUCKET AND RABBITSFOOT

Critical habitat units	Adjacent federal rkm (rmi)	Adjacent state & local government rkm (rmi)	Adjacent private rkm (rmi)	Adjacent tribal * (subset of Private) rkm (rmi)
Neosho Mucket				
Unit NM1: Illinois River	29.4 (18.3)	2.3 (1.4)	114.4 (71.1)	103.0 (64.0)
Unit NM2: Elk River	0	0	20.3 (12.6)	0
Unit NM3: Shoal Creek	0	0	75.8 (47.1)	0
Unit NM4: Spring River	0	1.4 (0.9)	100.9 (62.7)	0
Unit NM5: North Fork Spring River	0	0	16.4 (10.2)	0
Unit NM6: Fall and Verdigris Rivers	0	0	171.1 (106.3)	0
Unit NM7: Neosho River	0	6.1 (3.8)	238.3 (148.1)	0
Total	29.4 (18.3)	9.8 (6.1)	737.3 (458.1)	103.0 (64.0)
Rabbitsfoot				
Unit RF1: Spring River	0	1.4 (0.9)	55.0 (34.2)	0
Unit RF2: Verdigris River	0.6 (0.4)	0	37.3 (23.2)	37.3 (23.2)
Unit RF3: Neosho River	0	0	26.6 (16.5)	0
Unit RF4a: Ouachita River	0	0	22.7 (14.1)	0
Unit RF4b: Ouachita River	0	0	43.0 (26.7)	0
Unit RF5: Saline River	0	0	119.4 (74.2)	0
Unit RF6: Little River	63.9 (39.7)	0	75.8 (47.1)	41.4 (25.7)
Unit RF7: Middle Fork Little Red River	0	0	24.8 (15.4)	0
Unit RF8a: White River	0	10.8 (6.7)	177.5 (110.3)	0
Unit RF8b: White River	57.9 (36.0)	0	10.9 (6.8)	0
Unit RF9: Black River	0	0	51.2 (31.8)	0
Unit RF10: Spring River	0	1.1 (0.7)	50.4 (31.3)	0
Unit RF11: Strawberry River	0	0	123.8 (76.9)	0
Unit RF12: Buffalo River	113.6 (70.6)	0	0	0
Unit RF13: St. Francis River	25.2 (15.7)	1.0 (0.6)	38.1 (23.7)	0
Unit RF14: Big Sunflower River	0	0	51.5 (32.0)	0
Unit RF15: Bear Creek	11.9 (7.4)	6.1 (3.8)	31.7 (19.7)	0
Unit RF16: Big Black River	0	0	43.3 (26.9)	0
Unit RF17: Paint Rock River	0.5 (0.3)	0	80.5 (50.0)	0
Unit RF18: Duck River	0	40.5 (25.2)	194.7 (121.0)	0
Unit RF19a: Tennessee River	2.6 (1.6)	0	24.1 (15.0)	0
Unit RF19b: Tennessee River	2.4 (1.5)	0.6 (0.4)	32.5 (20.2)	0
Unit RF20: Ohio River	0	12.9 (8.0)	33.0 (20.5)	0
Unit RF21: Green River	17.0 (10.6)	0	158.5 (98.5)	0
Unit RF22: French Creek	0	3.5 (2.2)	116.8 (72.6)	0
Unit RF23: Allegheny River	0	10.0 (6.2)	47.3 (29.4)	0
Unit RF24: Muddy Creek	16.3 (10.1)	0	3.9 (2.4)	0
Unit RF25: Tippecanoe River	0	2.1 (1.3)	73.5 (45.7)	0
Unit RF26: Walhonding River	0	5.0 (3.1)	12.6 (7.8)	0
Unit RF27: Little Darby Creek	0	8.7 (5.4)	24.6 (15.3)	0
Unit RF28: North Fork Vermilion River and Middle Branch North Fork Vermilion River	0	0	28.5 (17.7)	0
Unit RF29: Fish Creek	0	1.6 (1.0)	6.1 (3.8)	0
Unit RF30: Red River	0	0	50.2 (31.2)	0
Unit RF31: Shenango River	8.8 (5.5)	0	15.9 (9.9)	0
Total	320.7 (199.4)	105.3 (65.5)	1,885.8	82.7 (48.9)
Total for both species	350.1 (217.7)	115.1 (71.6)	(1,171.8) 2,623.1 (1,629.9)	185.7 (112.9)

Note: Distances may not sum due to rounding.

* Tribal Jurisdictional Area only, does not represent riparian land ownership by any tribe and is a subset of the private lands category.

We present brief descriptions of all units, including the upstream and downstream boundaries of each stream reach, and reasons why they meet the definition of critical habitat for the Neosho mucket and rabbitsfoot.

Neosho Mucket

Unit NM1: Illinois River—Benton and Washington Counties, Arkansas; and Adair, Cherokee, and Delaware Counties, Oklahoma

Unit NM1 includes 146.1 rkm (90.8 rmi) of the Illinois River from the Muddy Fork Illinois River confluence with the Illinois River south of Savoy, Washington County, Arkansas, downstream to the Baron Creek confluence southeast of Tahlequah, Cherokee County, Oklahoma. This unit contains all or some components of all four physical or biological features and contains primary constituent elements 2, 3, 4, and 5. The physical or biological features in this unit may require special management considerations or protection to address changes in stream channel stability associated with urban development and clearing of riparian areas due to land use conversion in the watershed; alteration of water chemistry or water and sediment quality; and changes in stream bed material composition and quality from activities that would release sediments or nutrients into the water, such as urban development and associated construction projects, livestock grazing, confined animal operations, and timber harvesting. The majority of the riparian lands adjacent to, but not included in, this unit are in private ownership or private lands under tribal jurisdiction (Table 3).

Unit NM2: Elk River—McDonald County, Missouri; and Delaware County, Oklahoma

Unit NM2 includes a total of 20.3 rkm (12.6 rmi) of the Elk River from Missouri Highway 59 at Noel, McDonald County, Missouri, to the confluence of Buffalo Creek immediately downstream of the Oklahoma and Missouri State line, Delaware County, Oklahoma. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The primary biological or physical features in this unit may require special management considerations or protection to address changes in the existing flow regime due to such activities as impoundment, water diversion, or water withdrawal; alteration of water chemistry or water quality; and changes in stream bed material composition and sediment quality from activities that would release sediments or nutrients into the water, such as urban development and associated construction projects, livestock grazing, confined animal operations (turkey and chicken), timber harvesting, and mining. All the riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit NM3: Shoal Creek—Cherokee County, Kansas; and Newton County, Missouri

Unit NM3 includes approximately 75.8 rkm (47.1 rmi) of Shoal Creek from Missouri Highway W near Ritchey, Newton County, Missouri, to Empire Lake where inundation begins in Cherokee County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes to the same activities as discussed in Unit NM2, above, and releases of chemical contaminants from industrial and municipal effluents (77 FR 63440, see Factor A). All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit NM4: Spring River—Jasper and Lawrence Counties, Missouri; and Cherokee County, Kansas

Unit NM4 includes 102.3 rkm (63.6 rmi) of the Spring River from Missouri Highway 97 north of Stotts City, Lawrence County, Missouri, downstream to the confluence of Turkey Creek north of Empire, Cherokee County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes to the same activities as discussed in Unit NM2, above, and releases of chemical contaminants from industrial and municipal effluents. Almost all (99 percent) of the riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit NM5: North Fork Spring River—Jasper County, Missouri

Unit NM5 includes 16.4 rkm (10.2 rmi) of the North Fork Spring River from the confluence of Buck Branch southwest of Jasper, Missouri, downstream to its confluence with the Spring River near Purcell, Jasper County, Missouri. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes to the same activities as discussed in Unit NM2, above. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit NM6: Fall River—Elk, Greenwood, and Wilson Counties, Kansas; Verdigris River—Montgomery and Wilson Counties, Kansas

Unit NM6 includes a total of 171.1 rkm (106.3 rmi), including 90.4 rkm (56.2 rmi) of the Fall River from Fall River Lake dam northwest of Fall River, Greenwood County, Kansas, downstream to its confluence with the Verdigris River near Neodesha, Wilson County, Kansas. Unit NM6 also includes 80.6 rkm (50.1 rmi) of the Verdigris River from Kansas Highway 39 near Benedict, Wilson County, Kansas downstream to the Elk River confluence near Independence, Montgomery County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes to the same activities as discussed in Unit NM2, above. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit NM7: Neosho River—Allen, Cherokee, Coffey, Labette, Neosho, and Woodson Counties, Kansas

Unit NM7 includes 244.5 rkm (151.9 rmi) of the Neosho River from Kansas Highway 58 west of LeRoy, Coffey County, Kansas, downstream to the Kansas and Oklahoma State line, Cherokee County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes to the same activities as discussed in Unit NM2, above, and releases of chemical contaminants from industrial and municipal effluents and tail water releases downstream of John Redmond Reservoir. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Rabbitsfoot

The physical or biological features in units RF1 through RF31 may require special management considerations to address changes in the existing flow regime due to such activities as impoundment, water diversion, or water withdrawal; alteration of water chemistry or water quality; and changes in stream bed material composition and sediment quality from activities that would release sediments or nutrients into the water, such as urban development and associated construction projects, livestock grazing, confined animal operations (turkey and chicken), timber harvesting, and mining, and releases of chemical contaminants from industrial and municipal effluents. Where there are other activities in individual units requiring special management considerations, they are set forth in the individual unit descriptions.

Unit RF1: Spring River—Jasper County, Missouri; and Cherokee County, Kansas

Unit RF1 includes 56.5 rkm (35.1 rmi) of the Spring River from Missouri Highway 96 at Carthage, Jasper County, Missouri, downstream to the confluence of Turkey Creek north of Empire, Cherokee County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection described above. The majority of the riparian lands adjacent to, but not included in, this unit are in private ownership or private lands under tribal jurisdiction (Table 3).

Unit RF2: Verdigris River—Rogers County, Oklahoma

Unit RF2 includes 38.0 rkm (23.6 rmi) of the Verdigris River from Oologah Lake dam north of Claremore, Oklahoma, downstream to Oklahoma Highway 266 northwest of Catoosa, Rogers County, Oklahoma. This unit contains all or some components of all four physical or biological features and in part, contains primary constituent elements 3, 4, and 5. It is possible that primary constituent elements 1 and 2 are limiting factors for rabbitsfoot distribution and abundance from Oologah Lake dam downstream to the confluence of the Caney River; thus we are unable to determine at this time whether this reach contains primary constituent elements 1 and 2. The physical or biological features in this unit may require special management considerations or protection as described above and changes in the existing flow regime due to such activities as impoundment, tail water releases from Oologah Lake dam, and channelization associated with the McClellan-Kerr Arkansas River Navigation System. The majority of the riparian lands adjacent to, but not included in, this unit are in private ownership or private lands under tribal jurisdiction (Table 3).

Unit RF3: Neosho River—Allen County, Kansas

Unit RF3 includes 26.6 rkm (16.5 rmi) of the Neosho River from the Deer Creek confluence northwest of Iola, Kansas, downstream to the confluence of Owl Creek southwest of Humboldt, Allen County, Kansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above except for releases of chemical contaminants from industrial and municipal effluents. Approximately 97 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and the remaining lands in State or local ownership (Table 3).

Unit RF4a: Ouachita River—Clark and Hot Spring Counties, Arkansas

Unit RF4a includes 22.7 rkm (14.1 rmi) of the Ouachita River from the Tenmile Creek confluence north of Donaldson downstream to the Caddo River confluence near Caddo Valley, Hot Spring and Clark Counties, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Approximately 82 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and the remaining 18 percent are in Federal ownership (Table 3).

Unit RF4b: Ouachita River—Ouachita County, Arkansas

Unit RF4b includes 43.0 rkm (26.7 rmi) of the Ouachita River from the Little Missouri River confluence downstream to U.S. Highway 79 at Camden, Ouachita County, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. All the riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF5: Saline River—Ashley, Bradley, Cleveland, and Drew Counties, Arkansas

Unit RF5 includes 119.4 rkm (74.2 rmi) of the Saline River from Frazier Creek confluence near Mount Elba, Cleveland County, Arkansas, to the Mill Creek confluence near Stillions, Ashley and Bradley Counties, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. All the riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF6: Little River—McCurtain County, Oklahoma; and Little River and Sevier Counties, Arkansas

Unit RF6 includes 139.7 rkm (86.8 rmi) of the Little River from the Glover River confluence northwest of Idabel, McCurtain County, Oklahoma, downstream to U.S. Highway 71 north of Wilton, Little River and Sevier Counties, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Riparian lands adjacent to, but not included in, this unit are in private ownership (42 percent), Federal (35 percent), and private land under tribal jurisdiction (23 percent) (Table 3).

Unit RF7: Middle Fork Little Red River—Cleburne and Van Buren Counties, Arkansas

Unit RF7 includes 24.8 rkm (15.4 rmi) of the Middle Fork Little Red River from the confluence of Little Tick Creek north of Shirley, Arkansas, downstream to Greers Ferry Reservoir (where inundation begins), Van Buren County, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and natural gas development and hillside rock harvesting. All riparian lands adjacent

to, but not included in, this unit are in private ownership (Table 3).

Unit RF8a: White River—Independence, Jackson, White, and Woodruff Counties, Arkansas

Unit RF8a includes 188.3 rkm (117.0 rmi) of the White River from the Batesville Dam at Batesville, Independence County, Arkansas, downstream to the Little Red River confluence north of Georgetown, White, and Woodruff Counties, Arkansas. This unit contains all or some components of all four physical or biological features and contains primary constituent elements 2, 3, 4, and 5. The ACOE maintains a navigation channel, which involves routine dredging and snag removal, from Newport, Arkansas, to its confluence with the Mississippi River. The physical or biological features in this unit may require special management considerations or protection described above except for releases of chemical contaminants from industrial and municipal effluents and including tail water releases from a series of reservoirs on the upper White River; row crop agriculture; increasing demand for instream sand from the White River upstream of Newport, Arkansas, to support natural gas development needs; natural gas development; and channelization. Riparian lands adjacent to, but not included in, this unit are in private ownership (94 percent) and State and local ownership (6 percent) (Table 3).

Unit RF8b: White River—Arkansas and Monroe Counties, Arkansas

There are no records of rabbitsfoot from the 160-rkm (100-rmi) reach separating Unit RF8a from Unit RF8b (Butler 2005, p. 66). Unit RF8b includes 68.9 rkm (42.8 rmi) of the White River from U.S. Highway 79 at Clarendon, Monroe County, Arkansas, downstream to Arkansas Highway 1 near St. Charles, Arkansas County, Arkansas. This unit contains all or some components of all four physical or biological features and contains primary constituent elements 2, 3, 4, and 5. The ACOE maintains a navigation channel, which involves routine dredging and snag removal, from Newport, Arkansas, to its confluence with the Mississippi River. The physical or biological features in this unit may require special management considerations or protection described above except for releases of chemical contaminants from industrial and municipal effluents and including tail water releases from a series of reservoirs on the upper White River; row crop agriculture; increasing demand for instream sand from the White River upstream of Newport, Arkansas, to support natural gas development needs; natural gas development; and channelization. Approximately 84 percent of the riparian lands adjacent to, but not included in, this unit are in Federal ownership and 16 percent are in private ownership (Table 3).

Unit RF9: Black River—Lawrence and Randolph Counties, Arkansas

Unit RF9 includes 51.2 rkm (31.8 rmi) of the Black River from U.S. Highway 67 at Pocahontas, Randolph County, Arkansas, downstream to the Flat Creek confluence southeast of Powhatan, Lawrence County, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and including row crop agriculture. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF10: Spring River—Lawrence, Randolph, and Sharp Counties, Arkansas

Unit RF10 includes 51.5 rkm (32.0 rmi) of the Spring River from the Ott Creek confluence southwest of Hardy in Sharp County, Arkansas, downstream to its confluence with the Black River east of Black Rock, Lawrence and Randolph Counties, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF11: Strawberry River—Independence, Izard, Lawrence, and Sharp Counties, Arkansas

Unit RF11 includes 123.8 rkm (76.9 rmi) of the Strawberry River from Arkansas Highway 56 south of Horseshoe Bend, Izard County, Arkansas, downstream to its confluence with the Black River southeast of Strawberry, Lawrence County, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF12: Buffalo River—Marion, Newton, and Searcy Counties, Arkansas

Unit RF12 includes 113.6 rkm (70.6 rmi) of the Buffalo River from the Cove Creek confluence southeast of Erbie, Newton County, Arkansas, downstream to U.S. Highway 65 west of Gilbert, Searcy County, Arkansas and Arkansas Highway 14 southeast of Mull, Arkansas, downstream to the Leatherwood Creek confluence in the Lower Buffalo Wilderness Area, Arkansas. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. All riparian lands adjacent to, but not included in, this unit are in Federal ownership (Table 3).

Unit RF13: St. Francis River—Madison and Wayne Counties, Missouri

Unit RF13 includes 64.3 rkm (40.0 rmi) of the St. Francis River from the Twelvemile Creek confluence west of Saco, Madison County, Missouri, downstream to Lake Wappepello (where inundation begins), Wayne County, Missouri. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Riparian lands adjacent to, but not included in, this unit are in private (59 percent), Federal (39 percent), and less than 2 percent in State or local ownership (Table 3).

Unit RF14: Big Sunflower River—Sunflower County, Mississippi

Unit RF14 includes 51.5 rkm (32.0 rmi) of the Big Sunflower River from Mississippi Highway 442 west of Doddsville, Mississippi, downstream to the Quiver River confluence east of Indianola, Sunflower County, Mississippi. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and row crop agriculture and channelization. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF15: Bear Creek—Tishomingo County, Mississippi; and Colbert County, Alabama

Unit RF15 includes 49.7 rkm (30.9 rmi) of Bear Creek from the Alabama and Mississippi State line east of Golden, Tishomingo County, Mississippi, downstream to Alabama County Road 4 southwest of Sutton Hill, Colbert County, Alabama (just upstream of Pickwick Lake). Unit RF15 in its entirety is currently designated as critical habitat for the oyster mussel (Duck River dartersnapper) and Cumberlandian combshell. Unit RF15 contains all or some components of all four physical or biological features, except in the Bear Creek Floodway, which has been channelized for flood control and only contains components of physical or biological features associated with the species' nutritional or physiological requirements and contains all five primary constituent elements, except in the Bear Creek Floodway, which has been channelized for flood control and only contains primary constituent elements 3, 4, and 5. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Riparian lands adjacent to, but not included in, this unit are in private (64 percent), Federal (24 percent), and 12 percent in State or local ownership (Table 3).

Unit RF16: Big Black River—Hinds and Warren Counties, Mississippi

Unit RF16 includes 43.3 rkm (26.9 rmi) of Big Black River from Porter Creek confluence west of Lynchburg, Hinds County, Mississippi, downstream to Mississippi Highway 27 west of Newman, Warren County, Mississippi. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above, as well as row crop agriculture and channelization. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF17: Paint Rock River—Jackson, Madison, and Marshall Counties, Alabama

Unit RF17 includes 81.0 rkm (50.3 rmi) of the Paint Rock River from the convergence of Estill Fork and Hurricane Creek north of Skyline, Jackson County, Alabama, downstream to U.S. Highway 431 south of New Hope, Madison and Marshall Counties, Alabama. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture and channelization. Approximately 99 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 1 percent is in Federal ownership (Table 3).

Unit RF18: Duck River—Hickman, Humphreys, Marshall, Maury, and Perry Counties, Tennessee

Unit RF18 includes 235.3 rkm (146.2 rmi) of the Duck River from Lillard Mill (rkm 288; rmi 179) west of Tennessee Highway 272, Marshall County, Tennessee, downstream to Interstate 40 near Bucksnort, Hickman County, Tennessee. Seventy-four rkm (46 rmi) in Unit RF18 from rkm 214 (rmi 133) upstream to Lillards Mill at rkm 288 (rmi 179) is currently designated as critical habitat for the oyster mussel and Cumberlandian combshell (50 CFR 17.95(f)). Unit RF18 contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture and channelization. Approximately 83 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 17 percent are in State or local ownership (Table 3).

Unit RF19a: Tennessee River—Hardin County, Tennessee

Unit RF19a includes 26.7 rkm (16.6 rmi) of Tennessee River from Pickwick Lake Dam downstream to U.S. Highway 64 near Adamsville, Hardin County, Tennessee. This unit contains all or some components of all four physical or biological features and contains primary constituent elements 1, 3, 4, and 5. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture, channelization, and channel stability associated with tail water releases. Approximately 90 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 10 percent are in State or local ownership (Table 3).

Unit RF19b: Tennessee River—Livingston, Marshall, and McCracken Counties, Kentucky

Unit RF19b includes 35.6 rkm (22.1 rmi) of the Tennessee River from Kentucky Lake Dam downstream to its confluence with the Ohio River, McCracken and Livingston Counties, Kentucky. This unit contains all or some components of all four physical or biological features, and in part, contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Approximately 93 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership, 7 percent are in Federal ownership, and less than 1 percent is in State or local ownership (Table 3).

Unit RF20: Ohio River—Ballard and McCracken Counties, Kentucky; Massac and Pulaski Counties, Illinois

Unit RF20 includes 45.9 rkm (28.5 rmi) of the Ohio River from the Tennessee River confluence at the downstream extent of Owens Island downstream to Lock and Dam 53 near Olmstead, Illinois. This unit contains all or some components of all four physical or biological features, and in part, contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above, as well as row crop agriculture, channelization, and channel stability associated with tail water releases. Approximately 72 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 28 percent are in State or local ownership (Table 3).

Unit RF21: Green River—Edmonson, Green, Hart, and Taylor Counties, Kentucky

Unit RF21 includes 175.6 rkm (109.1 rmi) of the Green River from Green River Lake Dam south of Campbellsville, Taylor County, Kentucky, downstream to Mammoth Cave National Park North Entrance Road in Mammoth Cave National Park, Kentucky. This unit contains all or some components of all four physical or biological features, and in part, contains all five primary constituent elements. Releases from Green River Lake dam have altered hydrologic flows and temperature regimes in the tail water reach (Butler 2005, p. 39). The physical or biological features in this unit may require special management

considerations or protection to address changes described above and row crop agriculture, channelization, and channel stability associated with tail water releases. Approximately 90 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 10 percent are in Federal ownership (Table 3).

Unit RF22: French Creek—Crawford, Erie, Mercer, and Venango Counties, Pennsylvania

Unit RF22 includes 120.4 rkm (74.8 rmi) of French Creek from Union City Reservoir Dam northeast of Union City, Erie County, Pennsylvania, downstream to its confluence with the Allegheny River near Franklin, Venango County, Pennsylvania. The Allegheny River rabbitsfoot population (Unit RF23) is likely a single metapopulation with the French Creek population (Unit RF22) (Butler 2005, p. 31). This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture and oil and gas development. Approximately 97 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 3 percent are in Federal ownership (Table 3).

Unit RF23: Allegheny River—Venango County, Pennsylvania

Unit RF23 includes 57.3 rkm (35.6 rmi) of the Allegheny River from the French Creek confluence near Franklin, Venango County, Pennsylvania, downstream to Interstate 80 near Emlenton, Venango County, Pennsylvania. The lower Allegheny River and French Creek (Unit RF22) populations likely represent a single metapopulation because no barriers exist between the streams (Butler 2005, p. 29). This unit contains all or some components of all four physical or biological features and likely functions as a metapopulation to French Creek (Unit RF22). This unit contains primary constituent elements 1, 3, 4, and 5 for the rabbitsfoot. A series of nine locks and dams and Kinzua Dam constructed over the past century has resulted in altered hydrologic flow regimes in the Allegheny River (Butler 2005, p. 29). The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture, oil and gas development, and channelization. Approximately 83 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 17 percent are in State or local ownership (Table 3).

Unit RF24: Muddy Creek—Crawford County, Pennsylvani

Unit RF24 includes 20.1 rkm (12.5 rmi) of Muddy Creek from Pennsylvania Highway 77 near Little Cooley, Crawford County, Pennsylvania, downstream to its confluence with French Creek east of Cambridge Springs, Crawford County, Pennsylvania. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and oil and gas development. Approximately 81 percent of the riparian lands adjacent to, but not included in, this unit are in Federal ownership and 19 percent are in private ownership (Table 3).

Unit RF25: Tippecanoe River—Carroll, Pulaski, Tippecanoe, and White Counties, Indiana

Unit RF25 includes 75.6 rkm (47.0 rmi) of the Tippecanoe River from Indiana Highway 14 near Winamac, Pulaski County, Indiana, downstream to its confluence with the Wabash River northeast of Battle Ground, Tippecanoe County, Indiana, excluding Lakes Shafer and Freeman and the stream reach between the two lakes. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Approximately 97 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 3 percent are in State or local ownership (Table 3).

Unit RF26: Walhonding River—Coshocton County, Ohio

Unit RF26 includes 17.5 rkm (10.9 rmi) of the Walhonding River from the convergence of the Kokosing and Mohican Rivers downstream to Ohio Highway 60 near Warsaw, Coshocton County, Ohio. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above. Approximately 83 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 17 percent are in State or local ownership (Table 3).

Unit RF27: Little Darby Creek—Madison and Union Counties, Ohio

Unit RF27 includes 33.3 rkm (20.7 rmi) of Little Darby Creek from Ohio Highway 161 near Chuckery, Union County, Ohio, downstream to U.S. Highway 40 near West Jefferson, Madison County, Ohio. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and row crop agriculture. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF28: North Fork Vermilion River and Middle Branch North Fork Vermilion River, respectively, Vermilion County, Illinois

Unit RF28 includes a total of 28.5 rkm (17.7 rmi). Unit RF28 includes 21.2 rkm (13.2 rmi) of the North Fork Vermilion River from the confluence of Middle Branch North Fork Vermilion River downstream to Illinois Highway 1 and U.S. Highway 136 upstream of Lake Vermilion, Vermilion County, Illinois. Unit RF28 also includes 7.2 rkm (4.5 rmi) of the Middle Branch North Fork Vermilion River from the Jordan Creek confluence northwest of Alvin, Illinois, downstream to its confluence with North Fork Vermilion River west of Alvin, Vermilion County, Illinois. The rabbitsfoot in the North Fork Vermilion River is considered a metapopulation with the Middle Branch North Fork Vermilion River population (Butler 2005, p. 47). This unit contains all or some components of all four physical or biological features, including connectivity between North Fork Vermilion River and Middle Branch North Fork Vermilion River. This unit contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above and channelization and row crop agriculture. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF29: Fish Creek—Williams County, Ohio

Unit RF29 includes 7.7 rkm (4.8 rmi) of Fish Creek from the Indiana and Ohio

State line northwest of Edgerton, Ohio, downstream to its confluence with the St. Joseph's River north of Edgerton, Williams County, Ohio. This unit contains all or some components of all four physical or biological features and sustains genetic diversity and historical distribution as the only remaining rabbitsfoot population in the Great Lakes sub-basin. This unit contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture and confined animal operations (hogs). Approximately 90 percent of the riparian lands adjacent to, but not included in, this unit are in private ownership and 10 percent are in State or local ownership (Table 3).

Unit RF30: Red River—Logan County, Kentucky; and Montgomery and Robertson Counties, Tennessee

Unit RF30 includes 50.2 rkm (31.2 rmi) of the Red River from the South Fork Red River confluence west of Adairville, Kentucky, downstream to the Sulphur Fork confluence southwest of Adams, Tennessee. This unit contains all or some components of all four physical or biological features and sustains genetic diversity and historical distribution as the largest of two remaining rabbitsfoot populations within the Cumberland River basin. This unit contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protection to address changes described above as well as row crop agriculture and channelization. All riparian lands adjacent to, but not included in, this unit are in private ownership (Table 3).

Unit RF31: Shenango River—Mercer County, Pennsylvania

Unit RF31 includes 24.8 rkm (15.4 rmi) of the Shenango River from Porter Road near Greenville, Pennsylvania, downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania. This unit contains all or some components of all four physical or biological features and contains all five primary constituent elements. The physical or biological features in this unit may require special management considerations or protections to address changes described above as well consumptive water uses. Approximately 54 percent of the riparian lands adjacent to, but not included in, this unit are in Federal ownership and 46 percent are in private ownership (Table 3).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service,* 245 F.3d 434 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the effected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the ACOE under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical

habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for Neosho mucket and the rabbitsfoot. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the Neosho mucket and rabbitsfoot. These activities include, but are not limited to:

(1) Actions that would alter the geomorphology of their stream and river habitats. Such activities may include, but are not limited to, instream excavation or dredging, impoundment, channelization, sand and gravel mining, clearing riparian vegetation, and discharge of fill materials. These activities could cause aggradation or degradation of the channel bed elevation or significant bank erosion, result in entrainment or burial of these mollusks, and cause other direct or cumulative adverse effects to these species and their life cycles.

(2) Actions that would significantly alter the existing flow regime where these species occur. Such activities may include, but are not limited to, impoundment, channelization, urban development, water diversion, water withdrawal, and tail water releases downstream of dams. These activities could eliminate or reduce the habitat necessary for growth and reproduction of these mollusks and their life cycles including fish hosts.

(3) Actions that would significantly alter water chemistry or water quality (for example, temperature, pH, contaminants, conductivity, and excess nutrients). Such activities may include, but are not limited to, tail water releases downstream of dams, or the release of chemicals, biological pollutants, or heated effluents into surface water or connected groundwater at a point source or by dispersed release (nonpoint source). These activities could alter water conditions that are beyond the tolerances of these mussels or their fish hosts or both, and result in direct or cumulative adverse effects to the species and their life cycles.

(4) Actions that would significantly alter stream bed material composition and quality by increasing sediment deposition or filamentous algal growth. Such activities may include, but are not limited to, construction projects, gravel and sand mining, oil and gas development, livestock grazing, timber harvest, off-road vehicle use, and other watershed and floodplain disturbances that release sediments or contaminants into the water. These activities could eliminate or reduce habitats necessary for the survival, growth, and reproduction of these mollusks or their fish hosts or both by causing excessive sedimentation and burial of Neosho mucket and rabbitsfoot or their habitats, sublethal effects from sediment exposure that are not readily apparent, acute and chronic exposure to chemical contaminants resulting in sublethal and lethal effects, and nutrification leading to excessive filamentous algal growth. Excessive filamentous algal growth can cause reduced nighttime dissolved oxygen levels and prevent mussel glochidia from settling into stream sediments.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.'' There are no Department of Defense lands with a completed INRMP within the critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary must designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Consideration of Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts of the proposed designation, we prepared a DEA (Industrial Economics Incorporated (IEc) 2012). The DEA, dated February 6, 2013, was made available for public review from May 9, 2013, through June 10, 2013 (78 FR 27171), from August 27, 2013, through October 28, 2013 (78 FR 52894), and from May 14, 2014, to July 14, 2014 (79 FR 27547). Following the close of the last comment period, an FEA was developed, taking into consideration the public comments and any new information (IEc 2013, entire). By analyzing economic impacts of the proposed designation, which differs from the final designation, the FEA does not capture the exact incremental impacts of the final designation. Therefore, a final summary memorandum has been prepared describing our revised forecast calculations (IEc 2014a and 2014b, entire).

The intent of the FEA is to quantify the economic impacts of all potential conservation efforts for Neosho mucket and rabbitsfoot; some of these costs will likely be incurred regardless of whether we designate critical habitat (baseline). The economic impact of the proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.'' The ''without critical habitat'' scenario represents the baseline for the analysis, considering protections already in place for the species (for example, under the Federal listing and other Federal, State, and local regulations). The baseline, therefore, represents the costs incurred regardless of whether critical habitat is designated. The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the proposed designation of critical habitat for the species. The incremental conservation efforts and associated impacts are those not expected to occur absent the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical

habitat above and beyond the baseline costs; these are the costs we consider in the final designation of critical habitat. The analysis looks retrospectively at baseline impacts incurred since the species was listed, and forecasts both baseline and incremental impacts likely to occur with the designation of critical habitat.

The FEA also addresses how potential economic impacts are likely to be distributed, including an assessment of any local or regional impacts of habitat conservation and the potential effects of conservation activities on government agencies, private businesses, and individuals. The FEA measures lost economic efficiency associated with residential and commercial development and public projects and activities, such as economic impacts on water management and transportation projects, Federal lands, small entities, and the energy industry. Decisionmakers can use this information to assess whether the effects of the proposed designation might unduly burden a particular group or economic sector. Finally, the FEA looks retrospectively at costs that occurred between the publication of the final listing rule and the final rule designating critical habitat, and considers those costs that may occur in the 20 years following the designation of critical habitat, which was determined to be the appropriate period for analysis because limited planning information was available for most activities to forecast activity levels for projects beyond a 20-year timeframe. The FEA quantifies economic impacts of Neosho mucket and rabbitsfoot conservation efforts associated with the following categories of activity:

(1) Water flow management;
(2) Water quality management;
(3) Timber, agriculture, and grazing;
(4) Mining;
(5) Oil and gas;
(6) Transportation and utilities;
(7) Development and recreation; and
(8) Other activities (such as animal and biological control, prescribed burns, land clearing, habitat or shoreline restoration, among others).

Baseline protections for the Neosho mucket and rabbitsfoot address a broad range of threats within a significant portion of the critical habitat area. The key conclusion for the incremental analysis is that critical habitat designation is not expected to generate additional requests for conservation efforts in any of the proposed critical habitat units. All critical habitat units are occupied by at least one of the two mussel species. In addition, incremental economic impacts of the designation will likely be limited to additional administrative costs to the Service, Federal agencies, and third parties. This result is attributed to the following key findings: (1) Baseline protections exist for Neosho mucket and rabbitsfoot, and (2) all designated critical habitat is occupied by at least one of the two mussel species.

In total, the incremental impacts to all economic activities are estimated to be $4,400,000 over the 20-year timeframe, or $290,000 on an annualized basis (assuming a 7 percent discount rate) for the proposed critical habitat. Units RF2 (Verdigris River) and NM1 (Illinois River) are expected to generate the largest incremental impacts, due to section 7 consultations expected to occur in all categories within these units. The majority of incremental impacts across all units are related to transportation and utilities, followed by timber, agriculture, and grazing. Incremental costs associated with transportation are estimated to be $1,400,000 over the 20-year timeframe; $960,000 is associated with timber, agriculture, and grazing over the 20-year timeframe.

Incremental conservation costs of avoiding impacts to mussels and their habitat will vary depending on a variety of factors, including, but not limited to, location, size, and type of project being proposed, as well as the extent to which mussels occur in the project area. These include the costs for mussel surveys, relocation, monitoring and reporting, mussel propagation and population augmentation, best management practices for erosion and sedimentation controls, timing restrictions, and limiting project scope, or in-stream work.

Exclusions Based on Economic Impacts

Our economic analysis did not identify any disproportionate costs that are likely to result from the designation. Consequently, the Secretary is not exercising her discretion to exclude any areas from this designation of critical habitat for the Neosho mucket and rabbitsfoot based on economic impacts.

A copy of the FEA with supporting documents may be obtained by contacting the Arkansas Ecological Services Field Office (see **ADDRESSES**, above) or by downloading from the Internet at *http://www.regulations.gov*.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense or Department of Homeland Security where a national security impact might exist. In preparing this final rule, we have determined that no lands within the designated critical habitat for the Neosho mucket and rabbitsfoot are owned or managed by the Department of Defense or Department of Homeland Security, and, therefore, we anticipate no impact on national security or homeland security. Consequently, the Secretary is not exercising her discretion to exclude any areas from this final designation based on impacts on national security or homeland security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts resulting from the designation of critical habitat. We consider a number of factors, including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this final rule, we have determined that there are currently no permitted HCPs or other approved management plans for Neosho mucket and rabbitsfoot, and the final designation includes only tribal jurisdictional areas, not lands managed by any Tribe or trust resources. We anticipate no effect to tribal lands, partnerships, or HCPs from this critical habitat designation. Accordingly, the Secretary is not exercising her discretion to exclude any areas from this final designation based on other relevant impacts.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that

reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; as well as small businesses. Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts on these small entities are significant, we consider the types of activities that might trigger regulatory impacts under this rule, as well as the types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and therefore, not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7 only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. There is no requirement under RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities are directly regulated by this rulemaking, the Service certifies that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities.

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Based on this information, we affirm our certification that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. OMB has provided guidance for implementing this Executive Order that outlines nine outcomes that may constitute ''a significant adverse effect'' when compared to not taking the regulatory action under consideration. Appendix A of the FEA discusses the potential for critical habitat to affect utilities through the additional cost of considering adverse modification in section 7 consultation. Critical habitat designation for the mussels is anticipated to affect oil and gas activities. The Service does not anticipate consulting with the Federal Energy Regulatory Commission on hydropower operations as a result of the designation. Impacts to oil and gas development are limited to the administrative costs of consultation, and, therefore, reductions in oil and natural gas production are not anticipated. This analysis projects approximately 14 actions each year on oil and gas related activities, totaling approximately $7,000 per year. The magnitude of these consultation costs is not anticipated to increase the cost of energy production or distribution in the United States in excess of one percent.

The economic analysis finds that none of the nine outcomes is relevant to this analysis. Thus, based on information in the economic analysis, energy-related impacts associated with Neosho mucket and rabbitsfoot conservation activities within critical habitat are not expected. As such, the designation of critical habitat is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or

otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect small governments because it would not produce a Federal mandate of $100 million or greater in any year; that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. The FEA concludes incremental impacts may occur due to administrative costs of section 7 consultations for activities related to water flow management; water quality; timber, agriculture, and grazing; mining; oil and gas; transportation and utilities; development and recreation; and other activities; however, these are not expected to significantly affect small government entities. Consequently, we do not believe that the critical habitat designation will significantly or uniquely affect small government entities. As such, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for Neosho mucket and rabbitsfoot in a takings implications assessment. As discussed above, the designation of critical habitat affects only Federal actions. Although private parties that receive Federal funding, assistance, or require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

The majority of the designation occurs in navigable waterways whose stream bottoms are owned by the States. Impacts of this designation could occur on non-Federal riparian lands adjacent to, but not included in, the critical habitat designation where there is Federal involvement (such as Federal funding or permitting) subject to section 7 of the Act, or where a decision on a proposed action on federally owned land could affect economic activity on adjoining non-Federal land. However, in general, we believe that the takings implications associated with this critical habitat designation will be insignificant. Based on the best available information, the takings implications assessment concludes that this designation of critical habitat for the Neosho mucket and rabbitsfoot does not pose significant takings implications.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this rule does not have significant Federalism effects. A Federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this critical habitat designation with appropriate State resource agencies in Alabama, Arkansas, Illinois, Indiana, Kansas, Kentucky, Mississippi, Missouri, Ohio, Oklahoma, Pennsylvania, and Tennessee. We received comments from Kansas, Illinois, Ohio, Oklahoma, and Pennsylvania and have addressed them in the Summary of Comments and Recommendations and Summary of Changes from Proposed Rule sections of this rule. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, this rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (because these local governments no longer have to wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the applicable standards set forth in sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, the rule identifies the elements of physical or biological features essential to the conservation of the Neosho mucket and rabbitsfoot. The designated areas of critical habitat are presented on maps, and the rule provides several options for the

interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to NEPA in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)). However, when the range of the species includes States within the Tenth Circuit, such as that of Neosho mucket and rabbitsfoot, under the Tenth Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service,* 75 F.3d 1429 (10th Cir. 1996), we undertake a NEPA analysis for critical habitat designation and notify the public of the availability of the draft environmental assessment for a proposal when it is finished.

We performed this NEPA analysis and made the draft environmental assessment available for public comment on May 9, 2013 (78 FR 27171), August 27, 2013 (78 FR 52894), and May 14, 2014 (79 FR 27547). The final environmental assessment has been completed and is available with the publication of this final rule. You may obtain a copy of the final environmental assessment online at *http://www.regulations.gov,* by mail from the Arkansas Ecological Services Field Office (see **ADDRESSES**, above), or by visiting the office Web site at *http://www.fws.gov/arkansas-es/.*

The final environmental assessment included a detailed analysis of the potential effects of the proposed critical habitat designation on resource categories, including:

(1) Water flow management;
(2) Water quality management;
(3) Timber, agriculture, and grazing;
(4) Mining;
(5) Oil and gas;
(6) Transportation and utilities;
(7) Development and recreation; and
(8) Other activities (such as animal and biological control, prescribed burns, land clearing, habitat or shoreline restoration, among others, environmental justice, and cumulative effects).

The scope of the effects were primarily limited to those activities involving Federal actions, because critical habitat designation does not have any impact on the environment other than through the Act's section 7 consultation process conducted for Federal actions. Private actions that have no Federal involvement are not affected by critical habitat designation.

Based on the review and evaluation of the information contained in the environmental assessment, we determined that the designation of critical habitat for the Neosho mucket and rabbitsfoot does not constitute a major Federal action having a significant impact on the human environment under the meaning of section 102(2)(c) of NEPA, and so an environmental impact statement is not required.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

We determined that there are no tribal lands occupied by the Neosho mucket and rabbitsfoot at the time of listing that contain the physical or biological features essential to conservation of the species, and no tribal lands unoccupied by the Neosho mucket and rabbitsfoot that are essential for the conservation of the species. Therefore, we are not designating critical habitat for the Neosho mucket and rabbitsfoot on tribal lands.

References Cited

A complete list of all references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Arkansas Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rulemaking are the staff members of the Arkansas Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by revising the entries for ''Mucket, Neosho'' and ''Rabbitsfoot'' under CLAMS in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*	*	
CLAMS							
*	*	*	*	*	*	*	
Mucket, Neosho	*Lampsilis rafinesqueana.*	U.S.A. (AR, KS, MO, OK).	NA	E	816	17.95(f)	NA
*	*	*	*	*	*	*	
Rabbitsfoot	*Quadrula cylindrica cylindrica.*	U.S.A. (AL, AR, GA, IN, IL, KS, KY, LA, MO, MS, OH, OK, PA, TN, WV).	NA	T	816	17.95(f)	NA
*	*	*	*	*	*	*	

* * * * *

■ 3. In § 17.95, amend paragraph (f) by adding entries for ''Neosho Mucket (*Lampsilis rafinesqueana*)'' and ''Rabbitsfoot (*Quadrula cylindrica cylindrica*)'', immediately following the entry for ''Slabside Pearlymussel (*Pleuronaia dolabelloides*),'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(f) *Clams and Snails.*

* * * * *

Neosho Mucket (*Lampsilis rafinesqueana*)

(1) Critical habitat units are depicted for the Neosho mucket on the maps below in the following Counties:

(i) Benton and Washington Counties, Arkansas;

(ii) Allen, Cherokee, Coffey, Elk, Greenwood, Labette, Montgomery, Neosho, Wilson, and Woodson Counties, Kansas;

(iii) Jasper, Lawrence, McDonald, and Newton Counties, Missouri; and

(iv) Adair, Cherokee, and Delaware Counties, Oklahoma.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of the Neosho mucket consist of five components:

(i) Geomorphically stable river channels and banks (channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as stable riffles, sometimes with runs, and mid-channel island habitats that provide flow refuges consisting of gravel and sand substrates with low to moderate amounts of fine sediment and attached filamentous algae).

(ii) A hydrologic flow regime (the severity, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species are found and to maintain connectivity of rivers with the floodplain, allowing the exchange of nutrients and sediment for maintenance of the mussel's and fish host's habitat, food availability, spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats.

(iii) Water and sediment quality (including, but not limited to, conductivity, hardness, turbidity, temperature, pH, ammonia, heavy metals, and chemical constituents) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

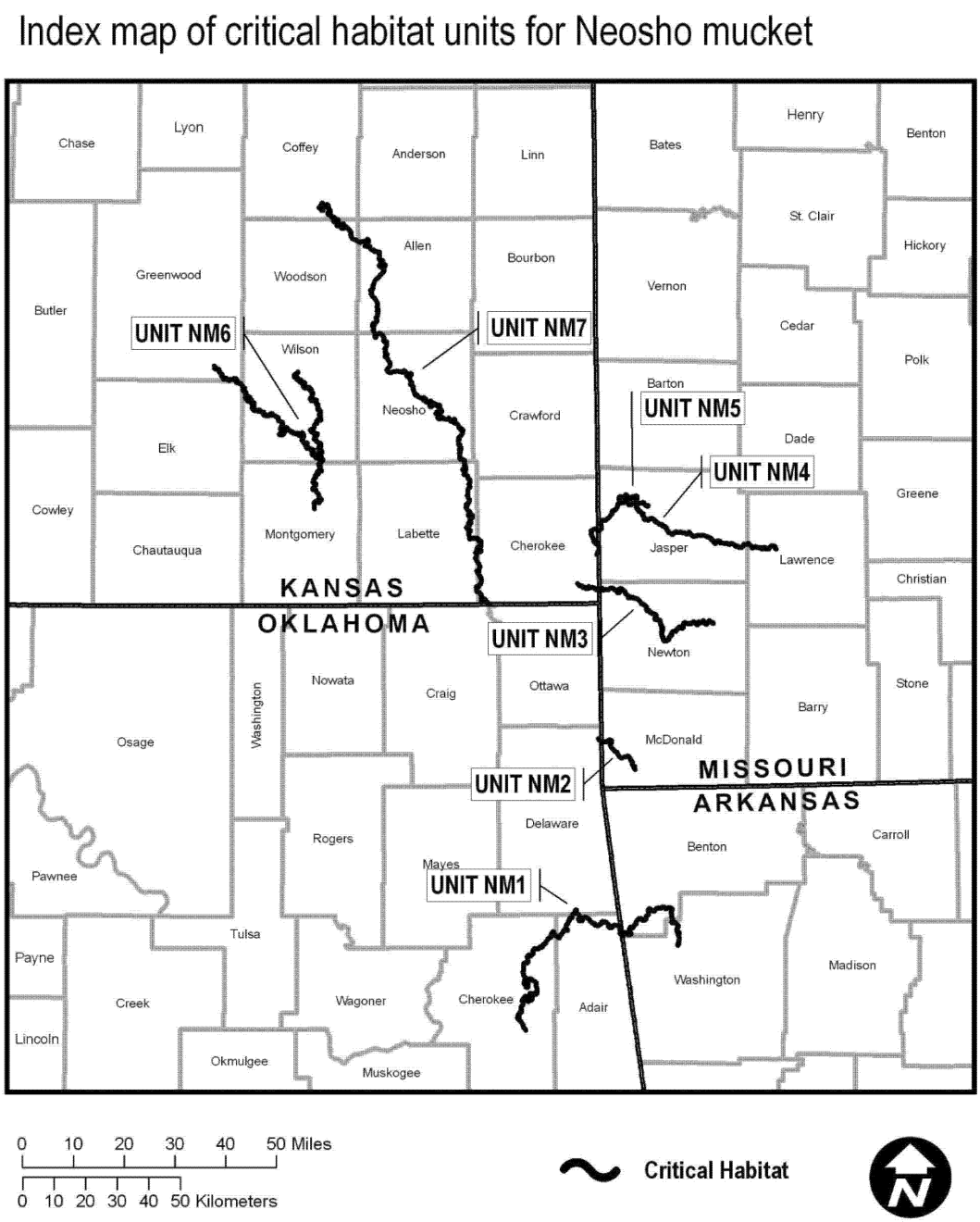
(iv) The occurrence of natural fish assemblages, reflected by fish species richness, relative abundance, and community composition, for each inhabited river or creek that will serve as an indication of appropriate presence and abundance of fish hosts necessary for recruitment of the Neosho mucket. Suitable fish hosts for Neosho mucket glochidia include smallmouth bass (*Micropterus dolomieu*), largemouth bass (*Micropterus salmoides*), and spotted bass (*Micropterus punctulatus*).

(v) Competitive or predaceous invasive (nonnative) species in quantities low enough to have minimal effect on survival of freshwater mussels.

(3) Critical habitat does not include manmade structures (such as dams, piers and docks, bridges, or other similar structures) within the legal boundaries on June 1, 2015.

(4) *Critical habitat map units.* Data layers defining map units were developed using ESRI ArcGIS mapping software along with various spatial data layers. Critical habitat unit upstream and downstream limits were delineated at the nearest road crossing or stream confluence of each occupied reach. Data layers defining map units were created with U.S. Geological Survey National Hydrography Dataset (NHD) Medium Flowline data. ArcGIS was also used to calculate river kilometers (rkm) and river miles (rmi) from the NHD dataset, and it was used to determine longitude and latitude coordinates in decimal degrees. The projection used in mapping and calculating distances and locations within the units was North American Albers Equal Area Conic, NAD 83. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates, plot points, or both on which each map is based are available to the public at the Service's Internet site (*http://www.fws.gov/arkansas-es/te_listing.html*), the Federal eRulemaking Portal (*http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0007), and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Note: Index map of all critical habitat units for the Neosho mucket follows:

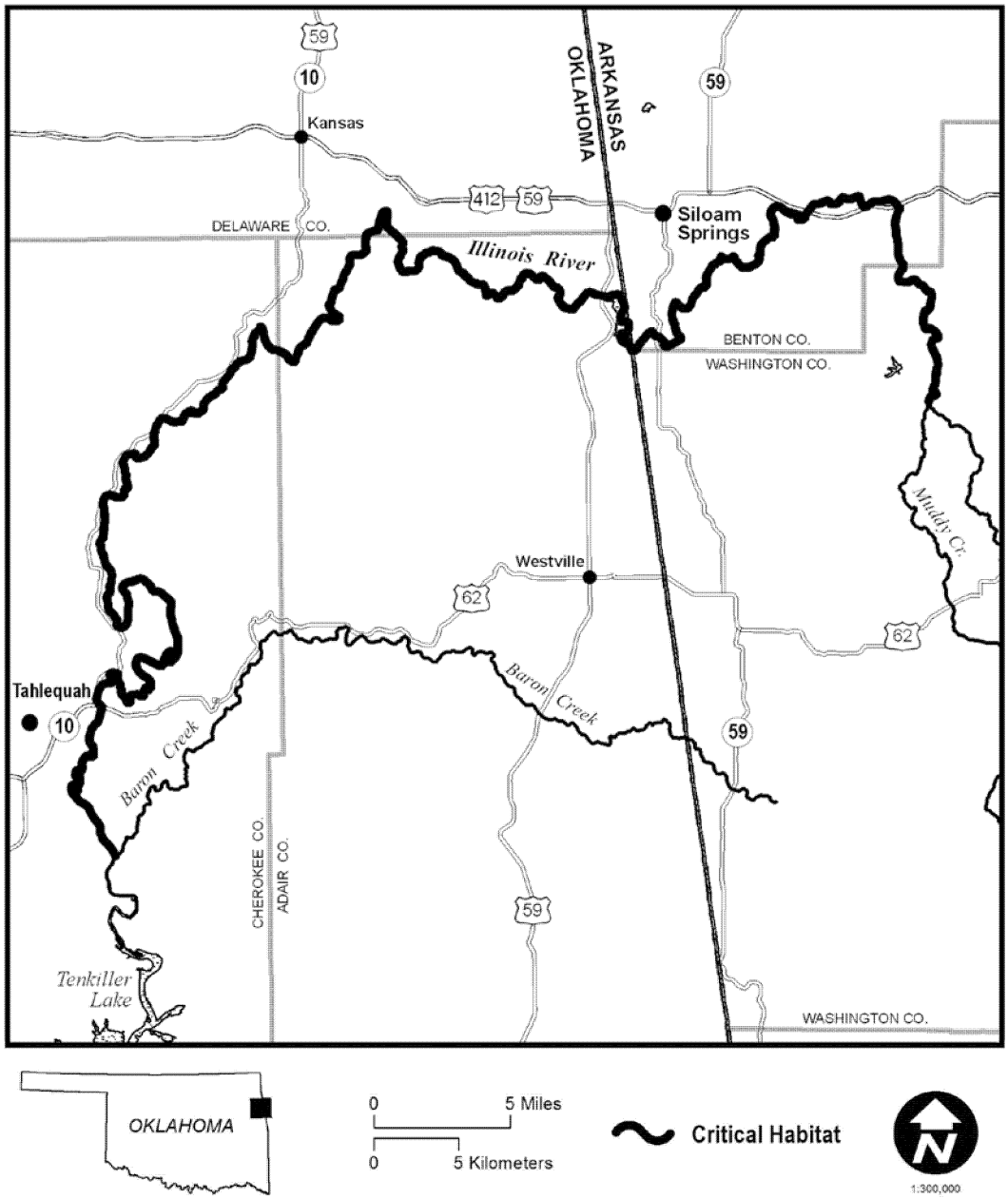


(6) Unit NM1: Illinois River—Benton and Washington Counties, Arkansas; and Adair, Cherokee, and Delaware Counties, Oklahoma.

(i) *General Description:* Unit NM1 includes 146.1 rkm (90.8 rmi) of the Illinois River from the Muddy Fork Illinois River confluence south of Savoy, Washington County, Arkansas, downstream to the Baron Creek confluence southeast of Tahlequah, Cherokee County, Oklahoma.

(ii) Map of Unit NM1 follows:

Map of Unit NM1 (Illinois River) of critical habitat for Neosho mucket

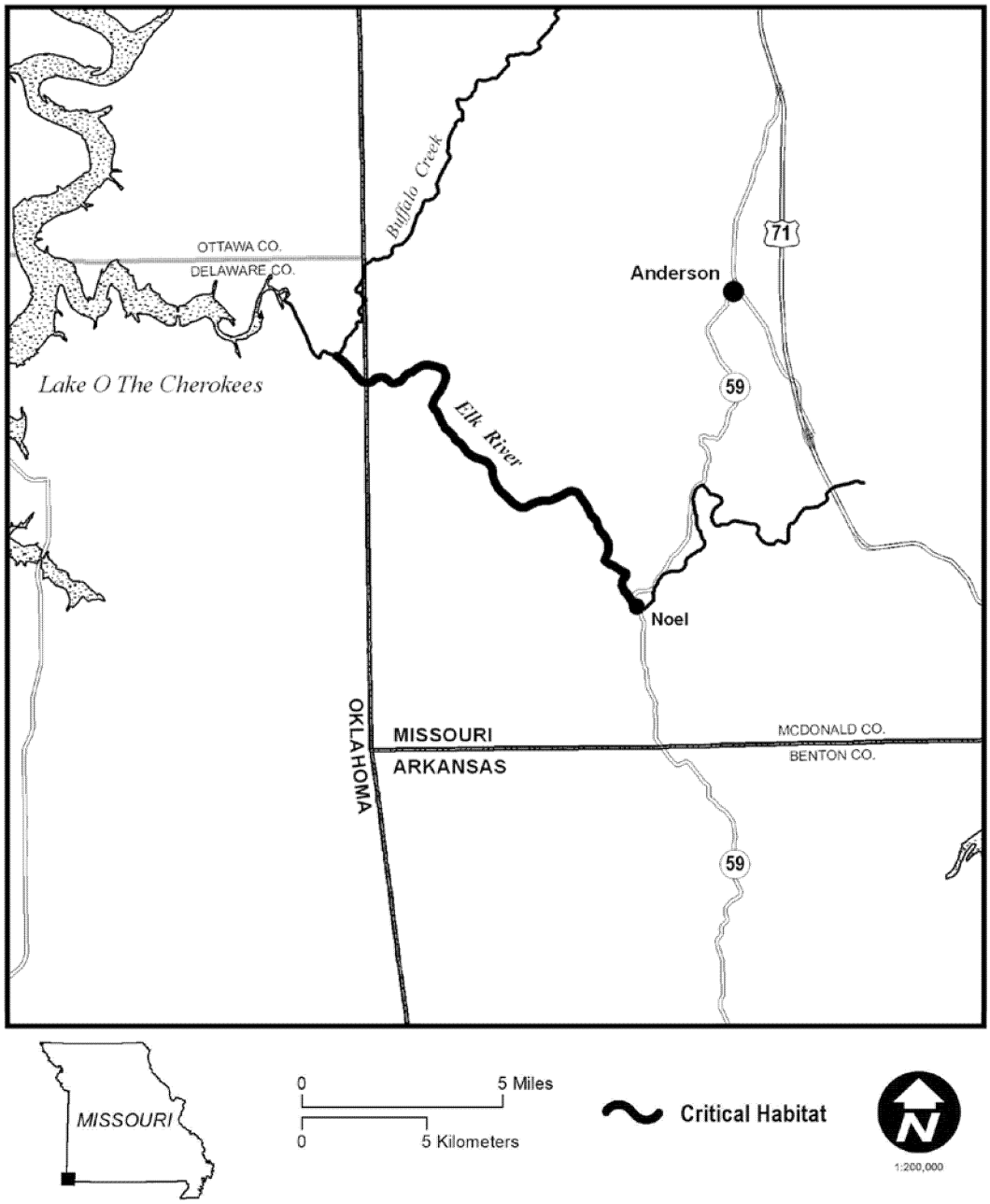


(7) Unit NM2: Elk River—McDonald County, Missouri; and Delaware County, Oklahoma.

(i) *General Description:* Unit NM2 includes 20.3 rkm (12.6 rmi) of the Elk River from Missouri Highway 59 at Noel, McDonald County, Missouri, to the confluence of Buffalo Creek immediately downstream of the Oklahoma and Missouri State line, Delaware County, Oklahoma.

(ii) Map of Unit NM2 follows:

Map of Unit NM2 (Elk River) of critical habitat for Neosho mucket

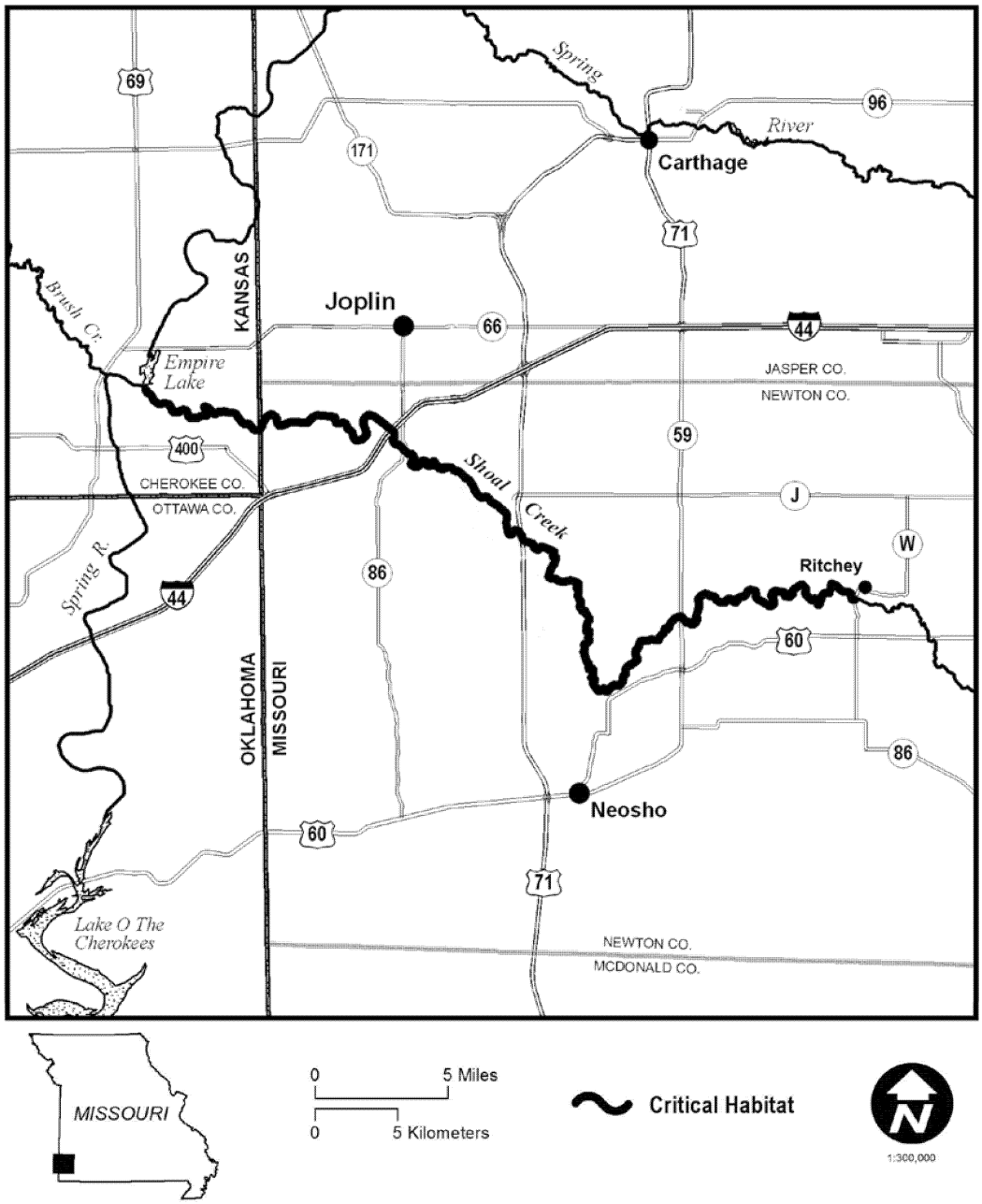


(8) Unit NM3: Shoal Creek—Cherokee County, Kansas; and Newton County, Missouri.

(i) *General Description:* Unit NM3 includes 75.8 rkm (47.1 rmi) of Shoal Creek from Missouri Highway W near Ritchey, Newton County, Missouri, to Empire Lake where inundation begins in Cherokee County, Kansas.

(ii) Map of Unit NM3 follows:

Map of Unit NM3 (Shoal Creek) of critical habitat for Neosho mucket

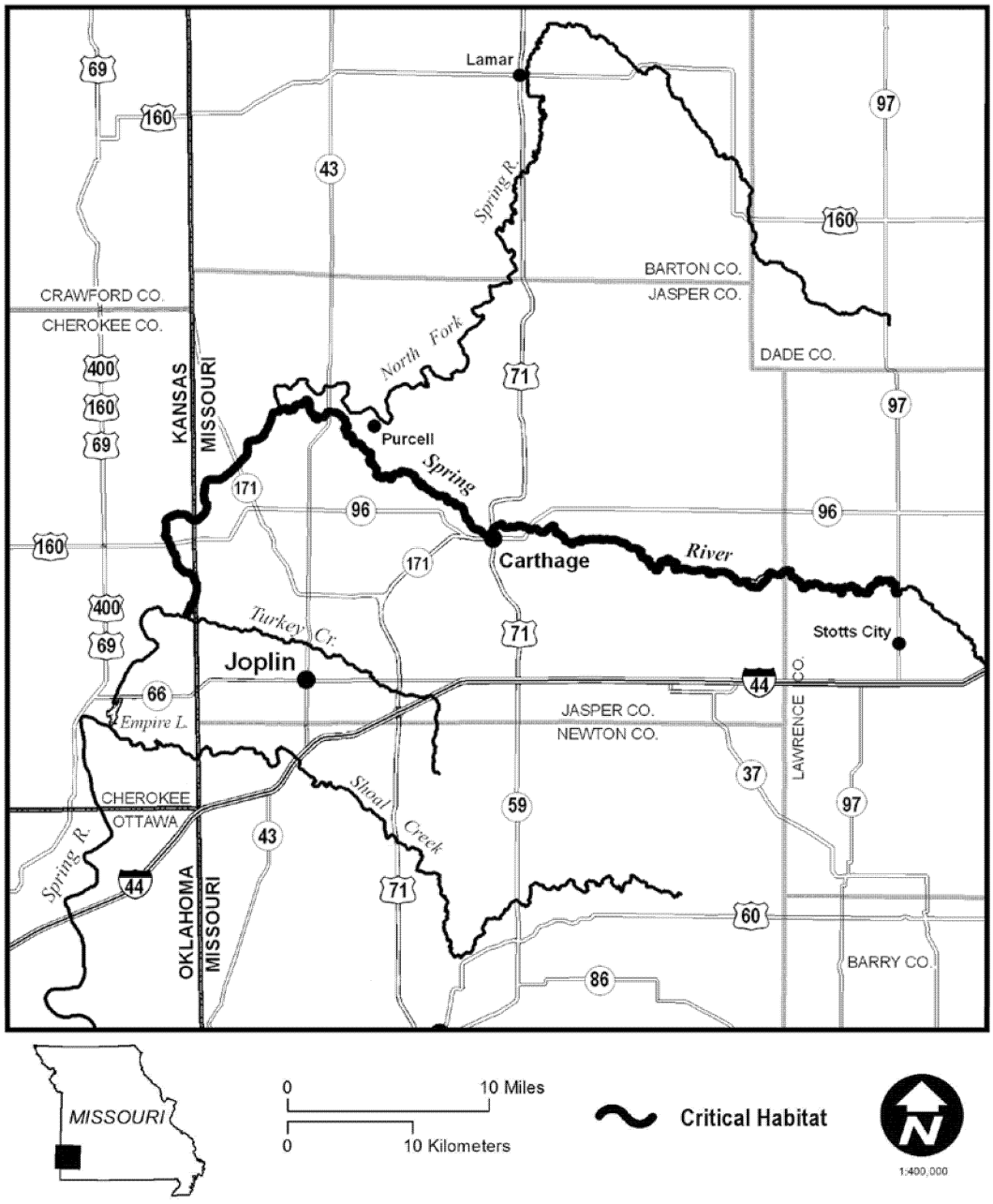


(9) Unit NM4: Spring River—Jasper and Lawrence Counties, Missouri; and Cherokee County, Kansas.

(i) *General Description:* Unit NM4 includes 102.3 rkm (63.6 rmi) of the Spring River from Missouri Highway 97 north of Stotts City, Lawrence County, Missouri, downstream to the confluence of Turkey Creek north of Empire, Cherokee County, Kansas.

(ii) Map of Unit NM4 follows:

Map of Unit NM4 (Spring River) of critical habitat for Neosho mucket

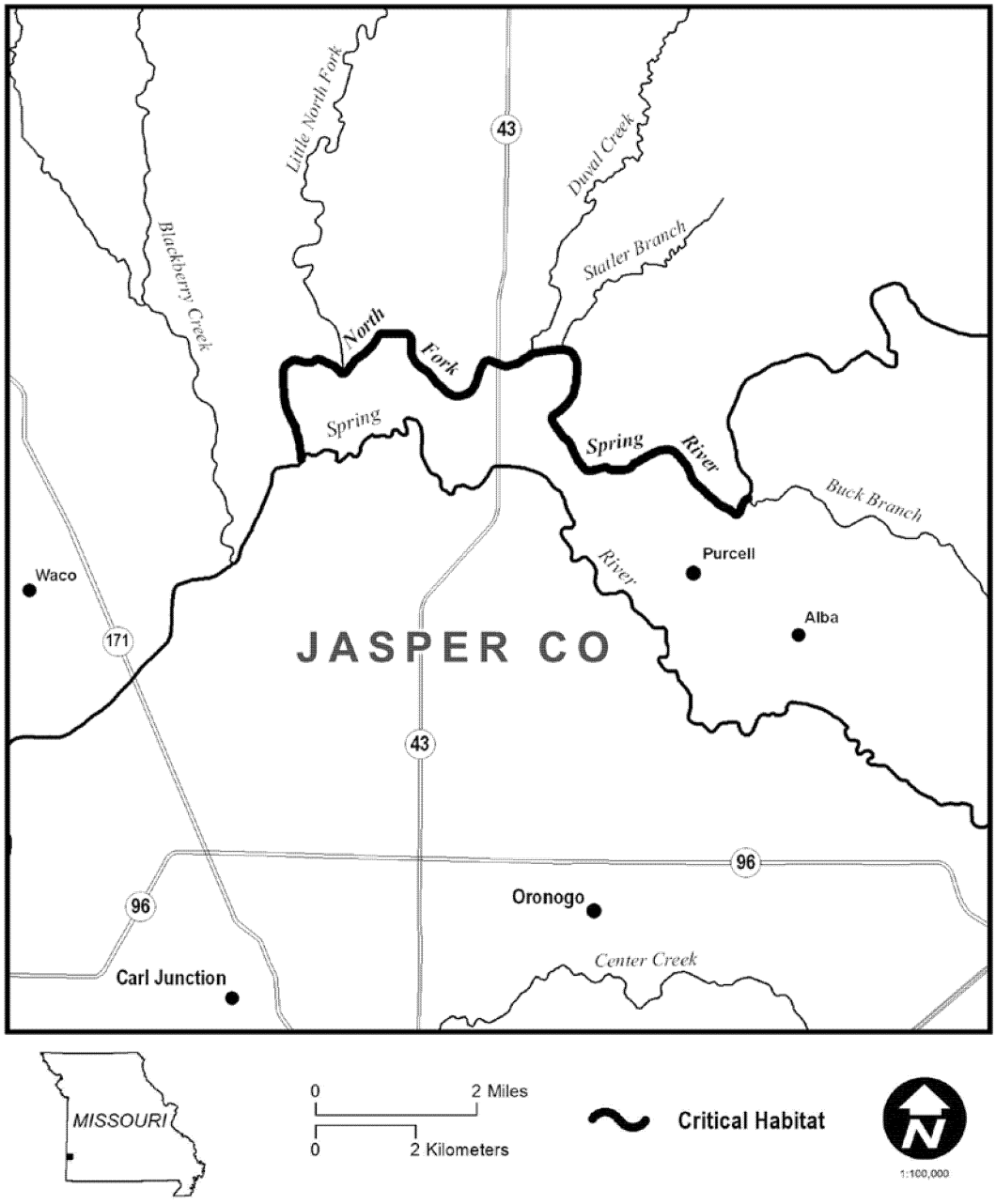


(10) Unit NM5: North Fork Spring River—Jasper County, Missouri.

(i) *General Description:* Unit NM5 includes 16.4 rkm (10.2 rmi) of the North Fork Spring River from the confluence of Buck Branch southwest of Jasper, Missouri, downstream to its confluence with the Spring River near Purcell, Jasper County, Missouri.

(ii) Map of Unit NM5 follows:

Map of Unit NM5 (North Fork Spring River) of critical habitat for Neosho mucket

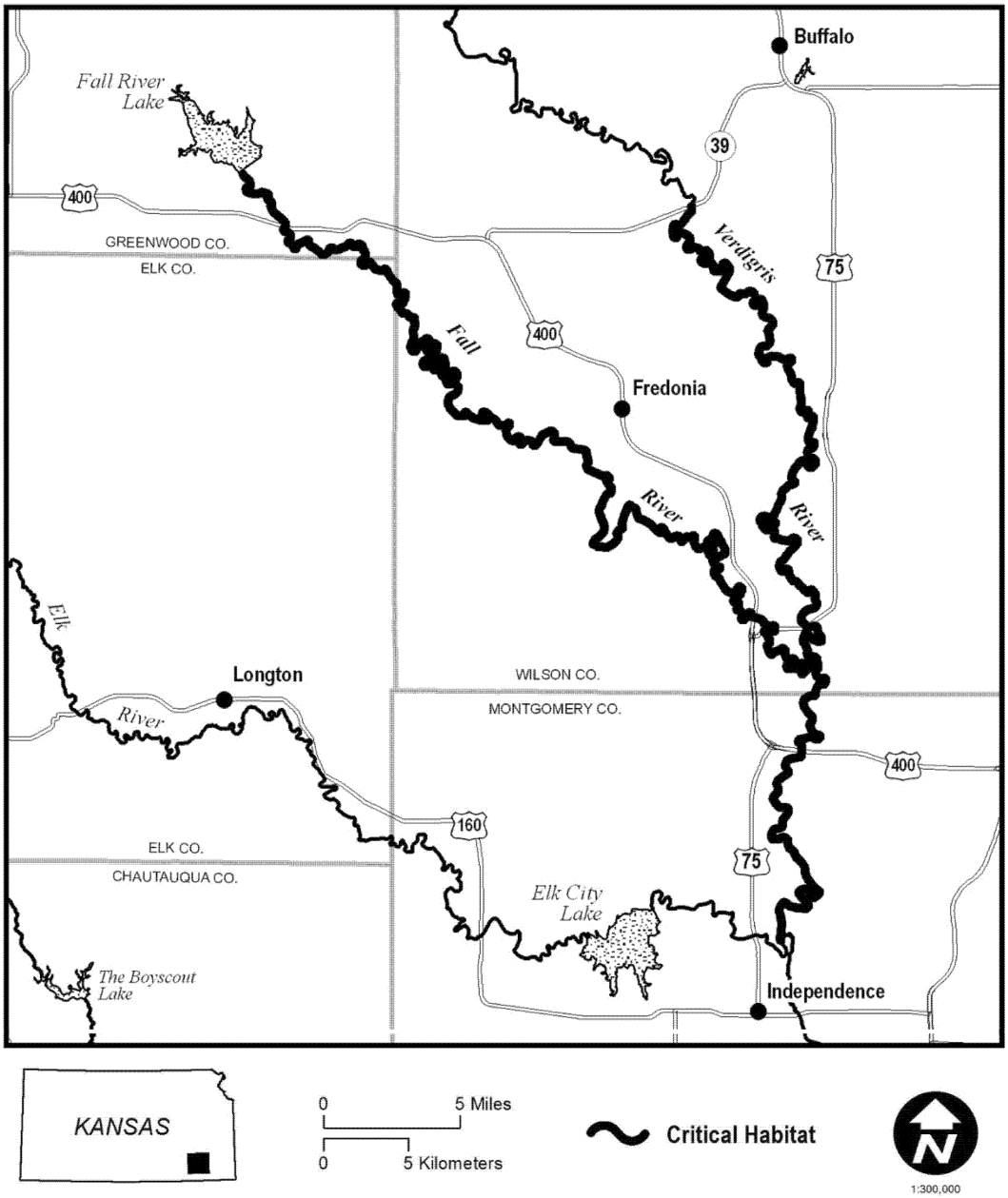


(11) Unit NM6: Fall River—Elk, Greenwood, and Wilson Counties, Kansas; Verdigris River—Montgomery and Wilson Counties, Kansas.

(i) *General Description:* Unit NM6 includes a total of 171.1 rkm (106.3 rmi) including 90.4 rkm (56.2 rmi) of the Fall River from Fall River Lake dam northwest of Fall River, Greenwood County, Kansas, downstream to its confluence with the Verdigris River near Neodesha, Wilson County, Kansas. Unit NM6 also includes 80.6 rkm (50.1 rmi) of the Verdigris River from Kansas Highway 39 near Benedict, Wilson County, Kansas, downstream to the Elk River confluence near Independence, Montgomery County, Kansas.

(ii) Map of Unit NM6 follows:

Map of Unit NM6 (Fall & Verdigris Rivers) of critical habitat for Neosho mucket

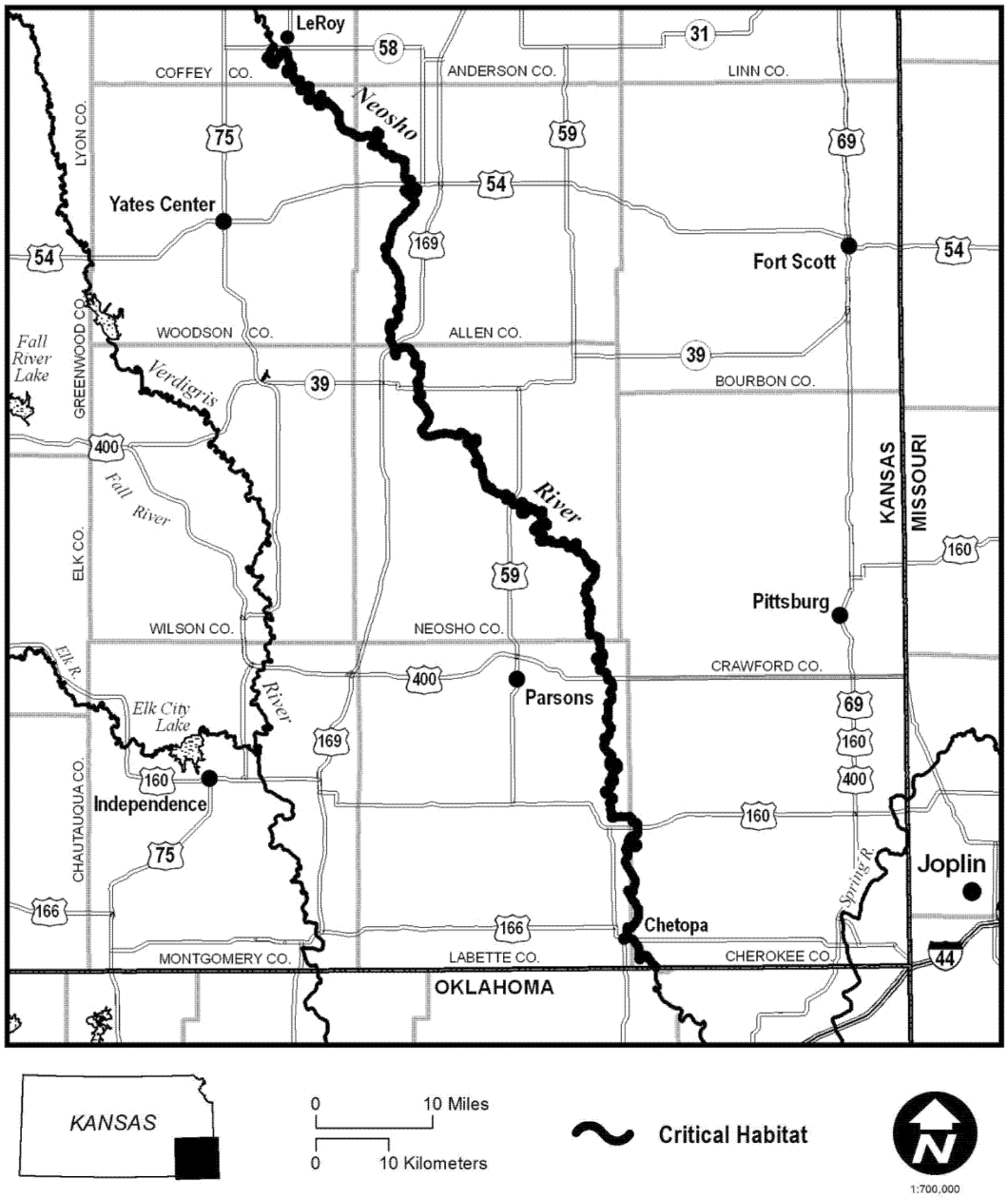


(12) Unit NM7: Neosho River—Allen, Cherokee, Coffey, Labette, Neosho, and Woodson Counties, Kansas.

(i) *General Description:* Unit NM7 includes 244.5 rkm (151.9 rmi) of the Neosho River from Kansas Highway 58 west of LeRoy, Coffey County, Kansas, downstream to the Kansas and Oklahoma State line, Cherokee County, Kansas.

(ii) Map of Unit NM7 follows:

Map of Unit NM7 (Neosho River) of critical habitat for Neosho mucket



Rabbitsfoot *(Quadrula cylindrica cylindrica*)

(1) Critical habitat units are depicted for rabbitsfoot on the maps below in the following Counties:

(i) Colbert, Jackson, Madison, and Marshall Counties, Alabama;

(ii) Arkansas, Ashley, Bradley, Clark, Cleburne, Cleveland, Drew, Hot Spring, Independence, Izard, Jackson, Lawrence, Little River, Marion, Monroe, Newton, Ouachita, Randolph, Searcy, Sevier, Sharp, Van Buren, White, and Woodruff Counties, Arkansas;

(iii) Massac, Pulaski, and Vermilion Counties, Illinois;

(iv) Carroll, Pulaski, Tippecanoe, and White Counties, Indiana;

(v) Allen and Cherokee Counties, Kansas;

(vi) Ballard, Edmonson, Green, Hart, Livingston, Logan, Marshall, McCracken, and Taylor Counties, Kentucky;

(vii) Hinds, Sunflower, Tishomingo, and Warren Counties, Mississippi;

(viii) Jasper, Madison, and Wayne Counties, Missouri;

(ix) Coshocton, Madison, Union, and Williams Counties, Ohio;

(x) McCurtain and Rogers Counties, Oklahoma;

(xi) Crawford, Erie, Mercer, and Venango Counties, Pennsylvania; and

(xii) Hardin, Hickman, Humphreys, Marshall, Maury, Montgomery, Perry, and Robertson Counties, Tennessee.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the

conservation of the rabbitsfoot consist of five components:

(i) Geomorphically stable river channels and banks (channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as stable riffles, sometimes with runs, and mid-channel island habitats that provide flow refuges consisting of gravel and sand substrates with low to moderate amounts of fine sediment and attached filamentous algae).

(ii) A hydrologic flow regime (the severity, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species are found and to maintain connectivity of rivers with the floodplain, allowing the exchange of nutrients and sediment for maintenance of the mussel's and fish host's habitat, food availability, spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats.

(iii) Water and sediment quality (including, but not limited to, conductivity, hardness, turbidity, temperature, pH, ammonia, heavy metals, and chemical constituents) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

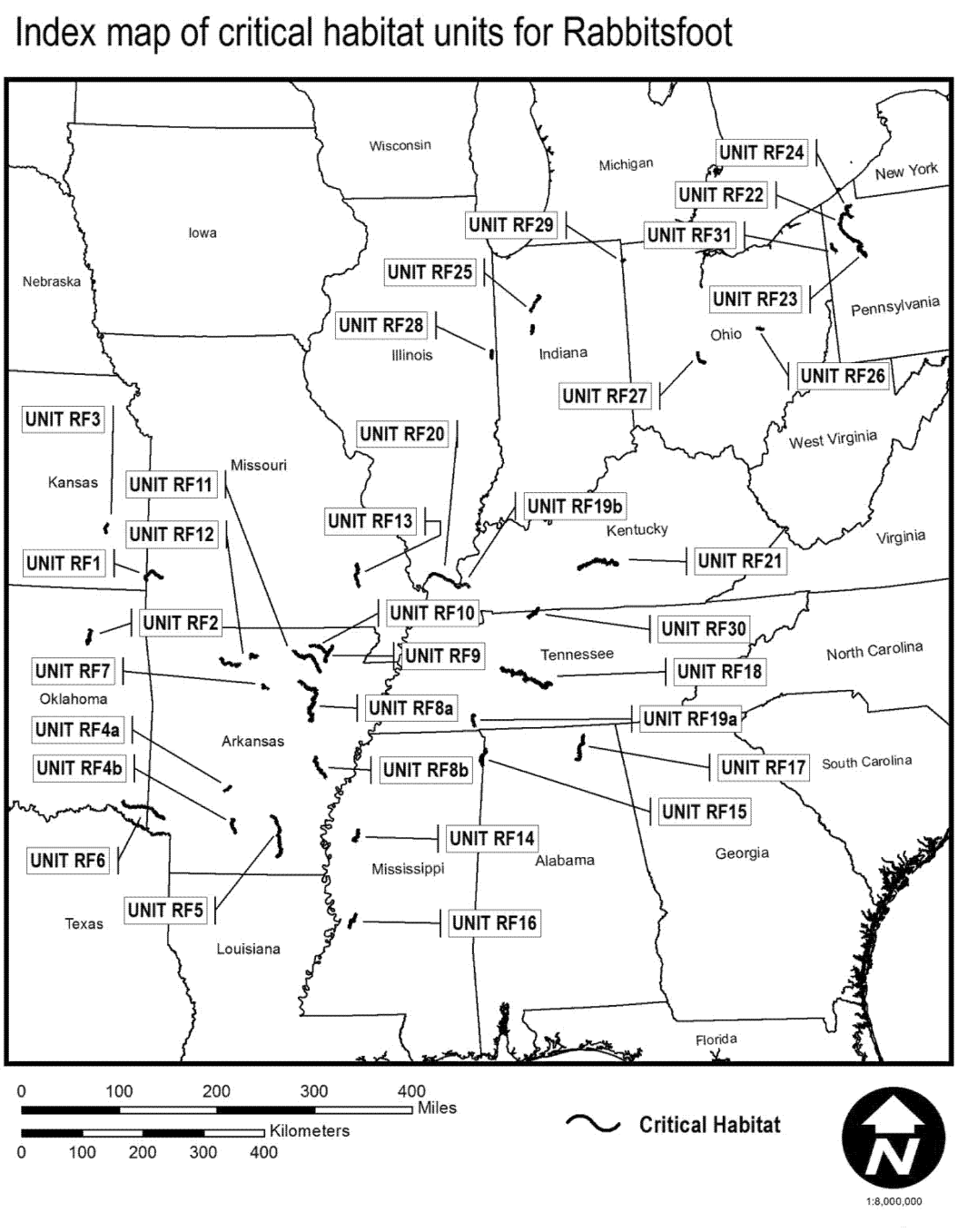
(iv) The occurrence of natural fish assemblages, reflected by fish species richness, relative abundance, and community composition, for each inhabited river or creek that will serve as an indication of appropriate presence and abundance of fish hosts necessary for recruitment of the rabbitsfoot. Suitable fish hosts for rabbitsfoot may include, but are not limited to, blacktail shiner (*Cyprinella venusta*) from the Black and Little River and cardinal shiner (*Luxilus cardinalis*), red shiner (*C. lutrensis*), spotfin shiner (*C. spiloptera*), bluntface shiner (*C. camura*), rainbow darter (*Etheostoma caeruleum*), rosyface shiner (*Notropis rubellus*), striped shiner (*L. chrysocephalus*), and emerald shiner (*N. atherinoides*).

(v) Competitive or predaceous invasive (nonnative) species in quantities low enough to have minimal effect on survival of freshwater mussels.

(3) Critical habitat does not include manmade structures (such as dams, piers and docks, bridges, or other similar structures) within the legal boundaries on June 1, 2015.

(4) *Critical habitat map units.* Data layers defining map units were developed using ESRI ArcGIS mapping software along with various spatial data layers. Critical habitat unit upstream and downstream limits were delineated at the nearest road crossing or stream confluence of each occupied reach. Data layers defining map units were created with U.S. Geological Survey National Hydrography Dataset (NHD) Medium Flowline data. ArcGIS was also used to calculate river kilometers (rkm) and river miles (rmi) from the NHD dataset, and it was used to determine longitude and latitude coordinates in decimal degrees. The projection used in mapping and calculating distances and locations within the units was North American Albers Equal Area Conic, NAD 83. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates, plot points, or both on which each map is based are available to the public at the Service's Internet site (*http://www.fws.gov/arkansas-es/te_listing.html*), the Federal eRulemaking Portal (*http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0007), and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

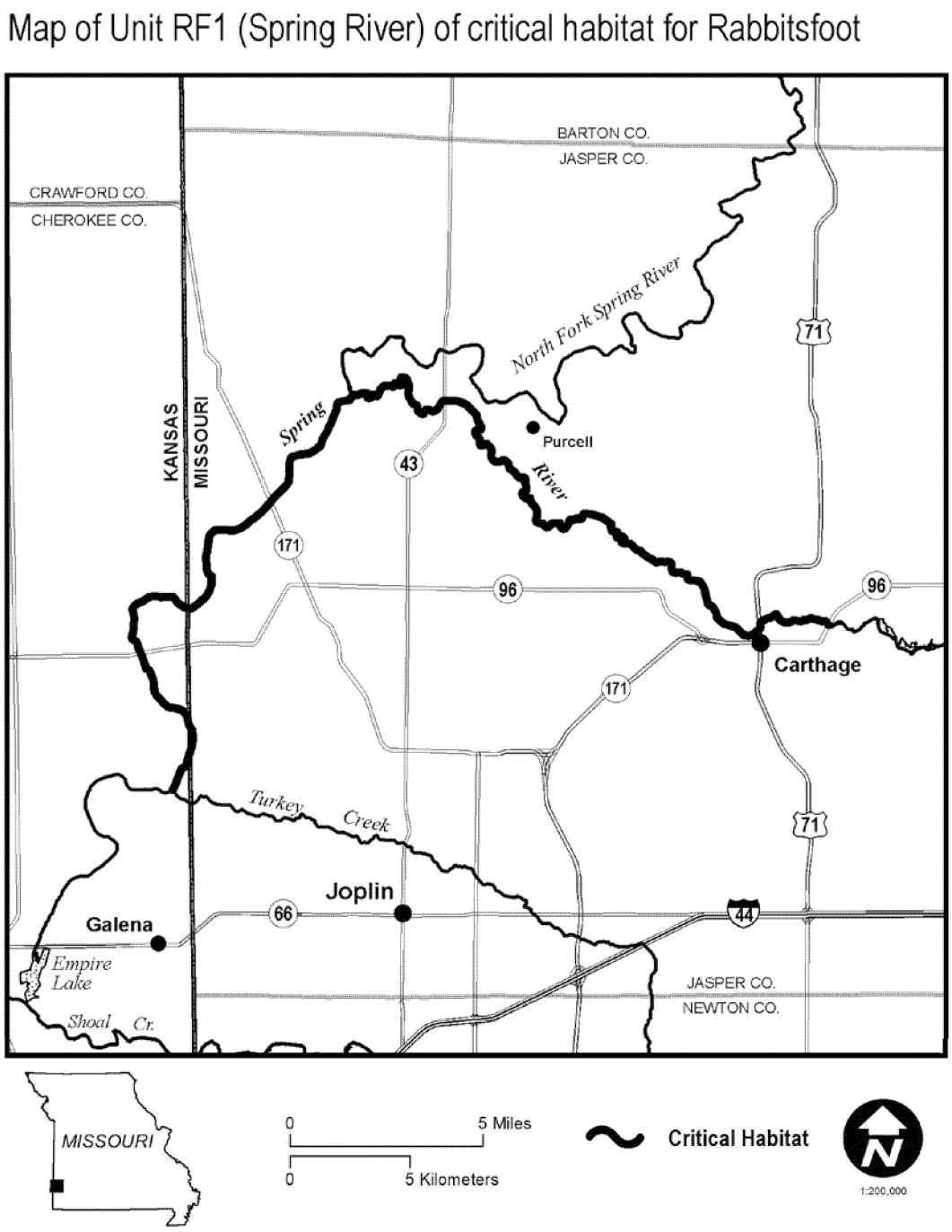
(5) Note: Index map of all critical habitat units for the rabbitsfoot follows:



(6) Unit RF1: Spring River—Jasper County, Missouri; and Cherokee County, Kansas.

(i) *General Description:* Unit RF1 includes 56.5 rkm (35.1 rmi) of the Spring River from Missouri Highway 96 at Carthage, Jasper County, Missouri, downstream to the confluence of Turkey Creek north of Empire, Cherokee County, Kansas.

(ii) Map of Unit RF1 follows:

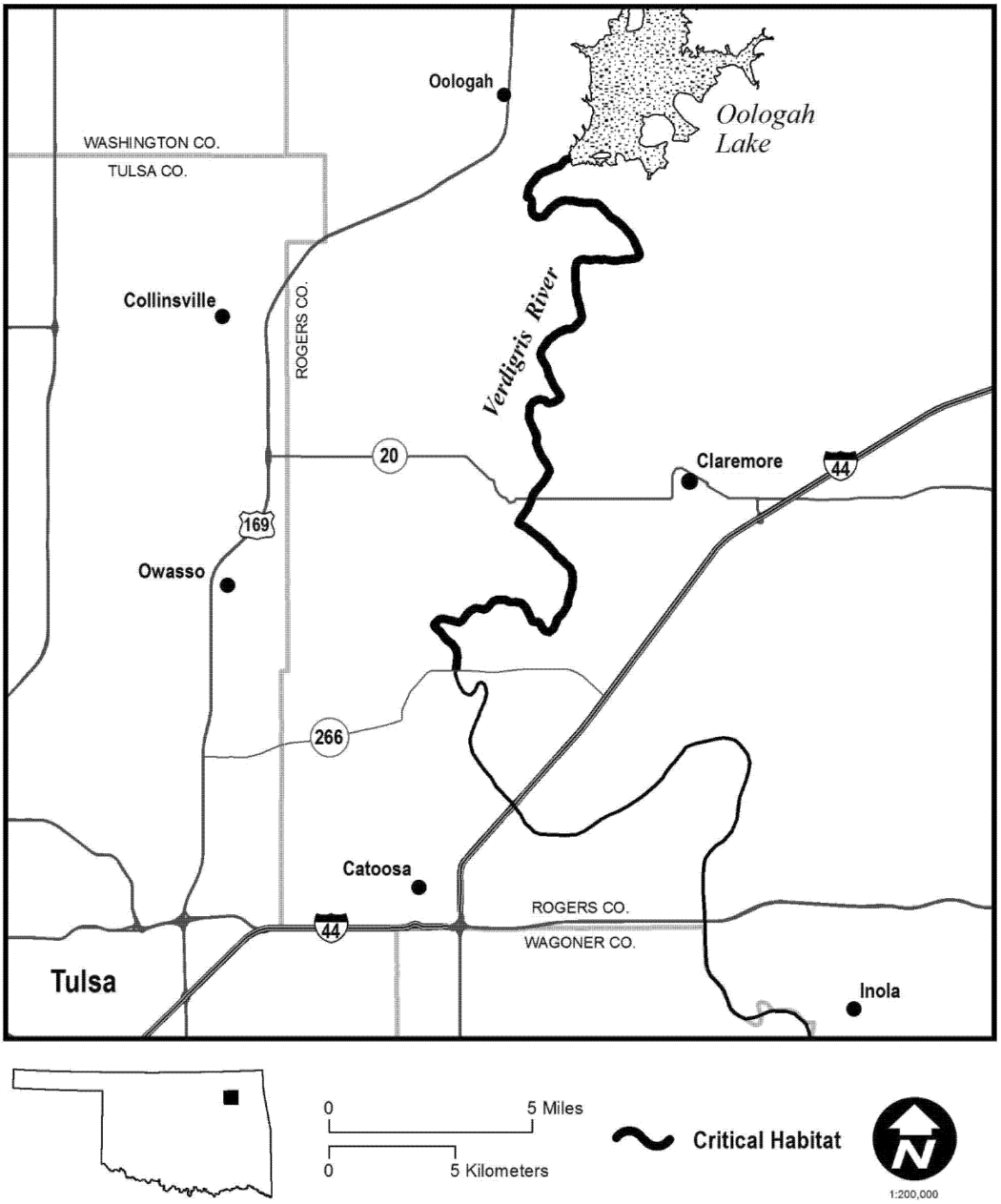


(7) Unit RF2: Verdigris River—Rogers County, Oklahoma.

(i) *General Description:* Unit RF2 includes 38.0 rkm (23.6 rmi) of the Verdigris River from Oologah Lake dam north of Claremore, Oklahoma, downstream to Oklahoma Highway 266 northwest of Catoosa, Rogers County, Oklahoma.

(ii) Map of Unit RF2 follows:

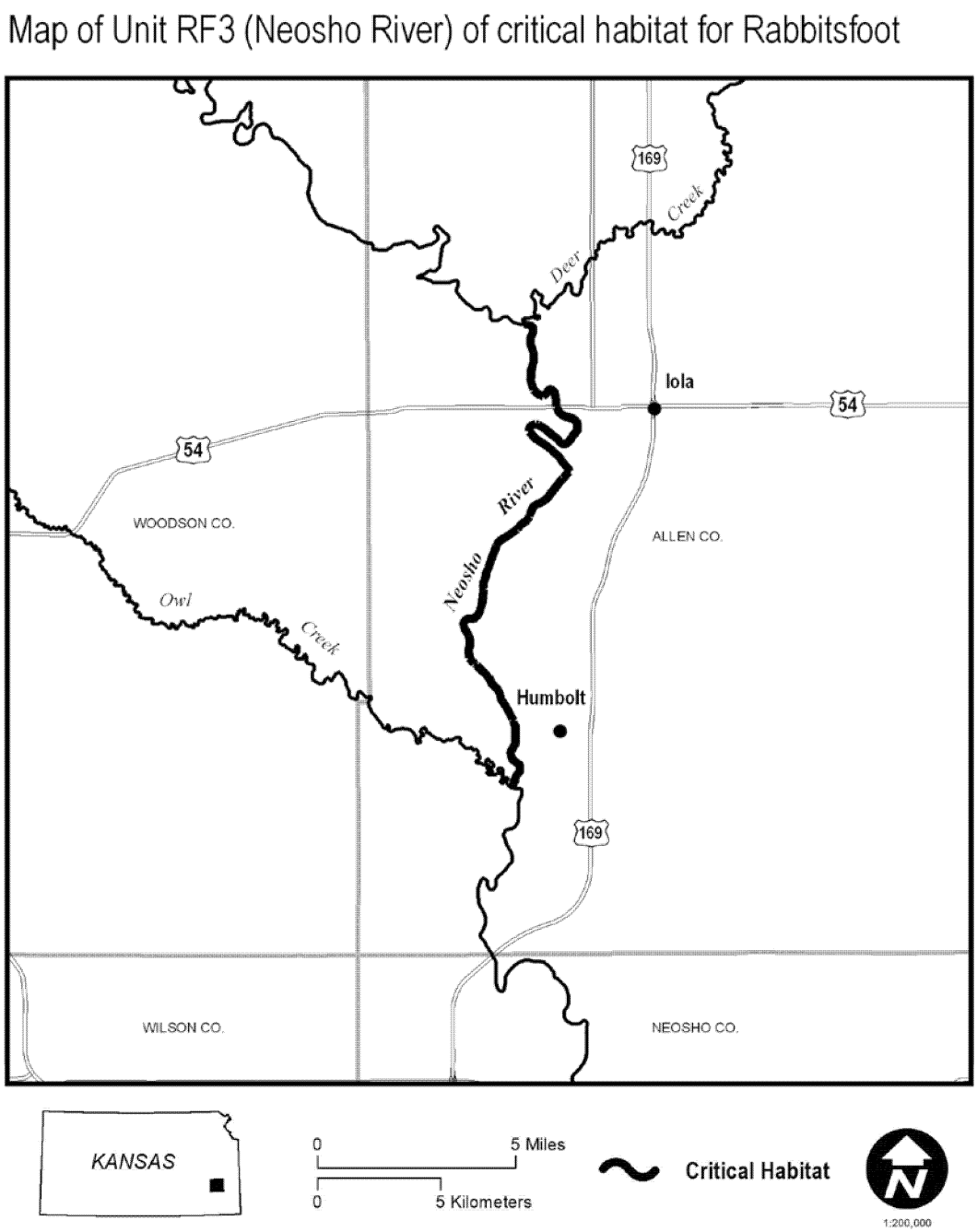
Map of Unit RF2 (Verdigris River) of critical habitat for Rabbitsfoot



(8) Unit RF3: Neosho River—Allen County, Kansas.

(i) *General Description:* Unit RF3 includes 26.6 rkm (16.5 rmi) of the Neosho River from the Deer Creek confluence northwest of Iola, Kansas, downstream to the confluence of Owl Creek southwest of Humboldt, Allen County, Kansas.

(ii) Map of Unit RF3 follows:

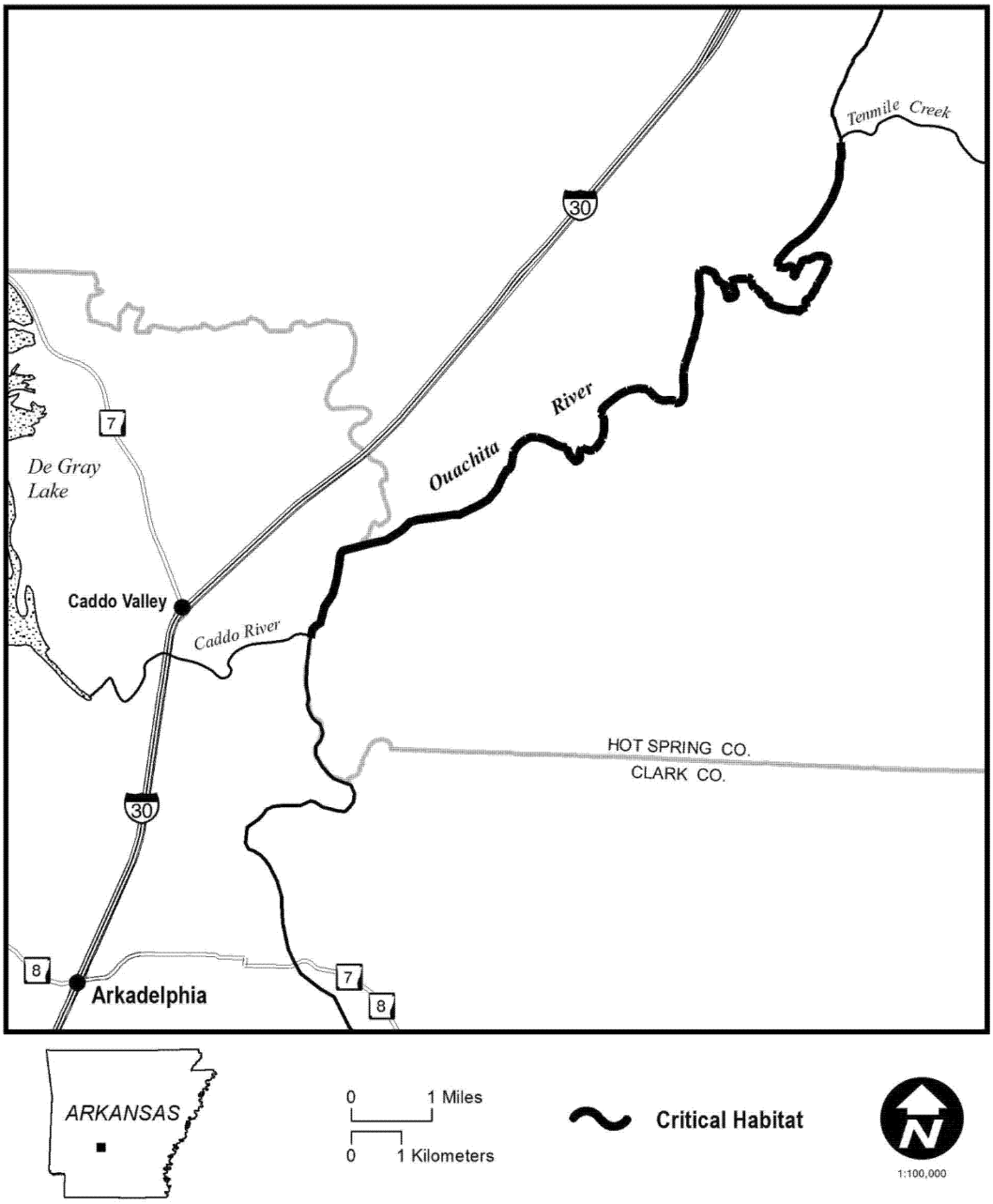


(9) Unit RF4a: Ouachita River—Clark and Hot Spring Counties, Arkansas.

(i) *General Description:* Unit RF4a includes 22.7 rkm (14.1 rmi) of the Ouachita River from the Tenmile Creek confluence north of Donaldson downstream to the Caddo River confluence near Caddo Valley, Hot Spring and Clark Counties, Arkansas.

(ii) Map of Unit RF4a follows:

Map of Unit RF4a (Ouachita River) of critical habitat for Rabbitsfoot

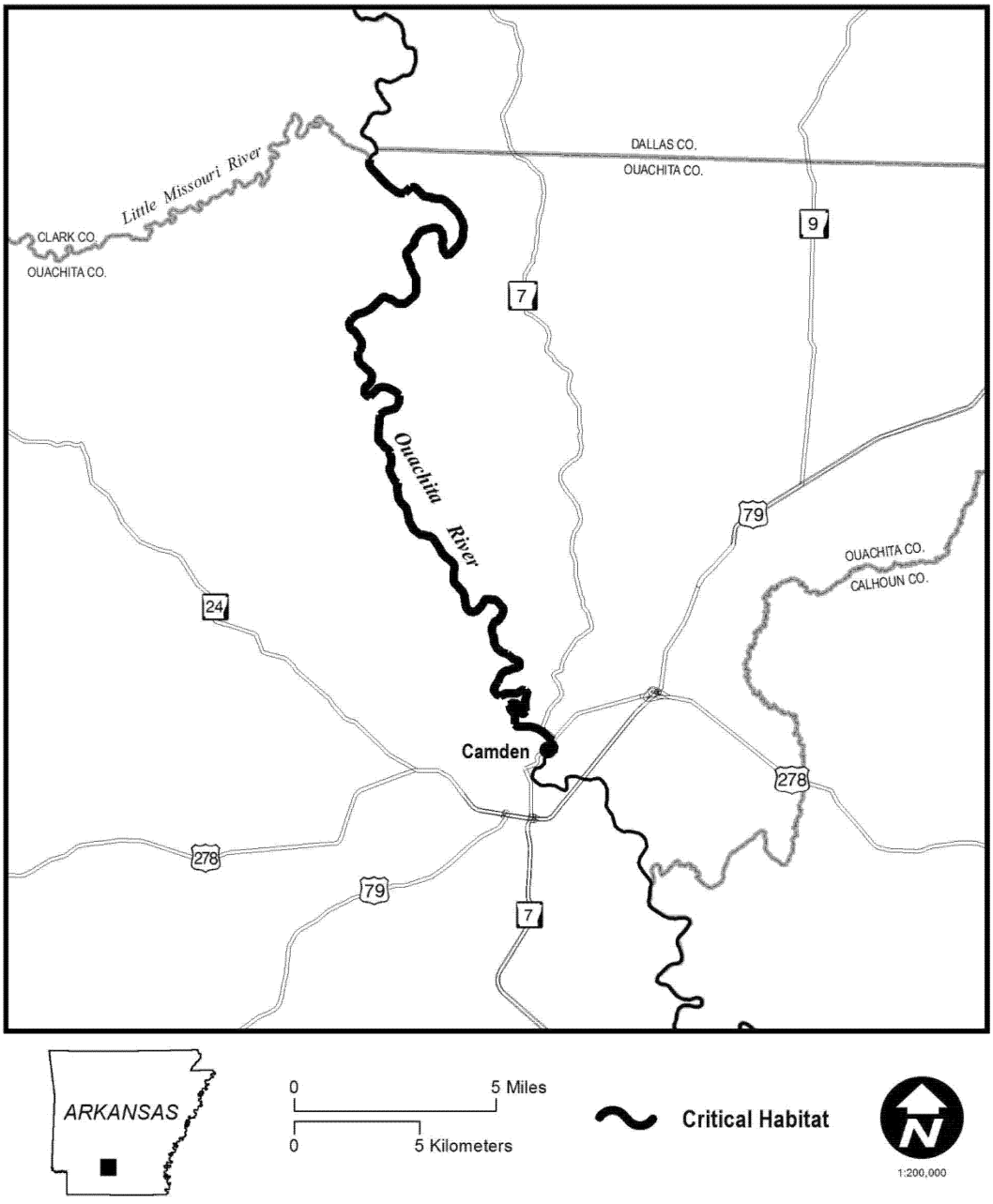


(10) Unit RF4b: Ouachita River—Ouachita County, Arkansas.

(i) *General Description:* Unit RF4b includes 43.0 rkm (26.7 rmi) of the Ouachita River from the Little Missouri River confluence downstream to U.S. Highway 79 at Camden, Ouachita County, Arkansas.

(ii) Map of Unit RF4b follows:

Map of Unit RF4b (Ouachita River) of critical habitat for Rabbitsfoot

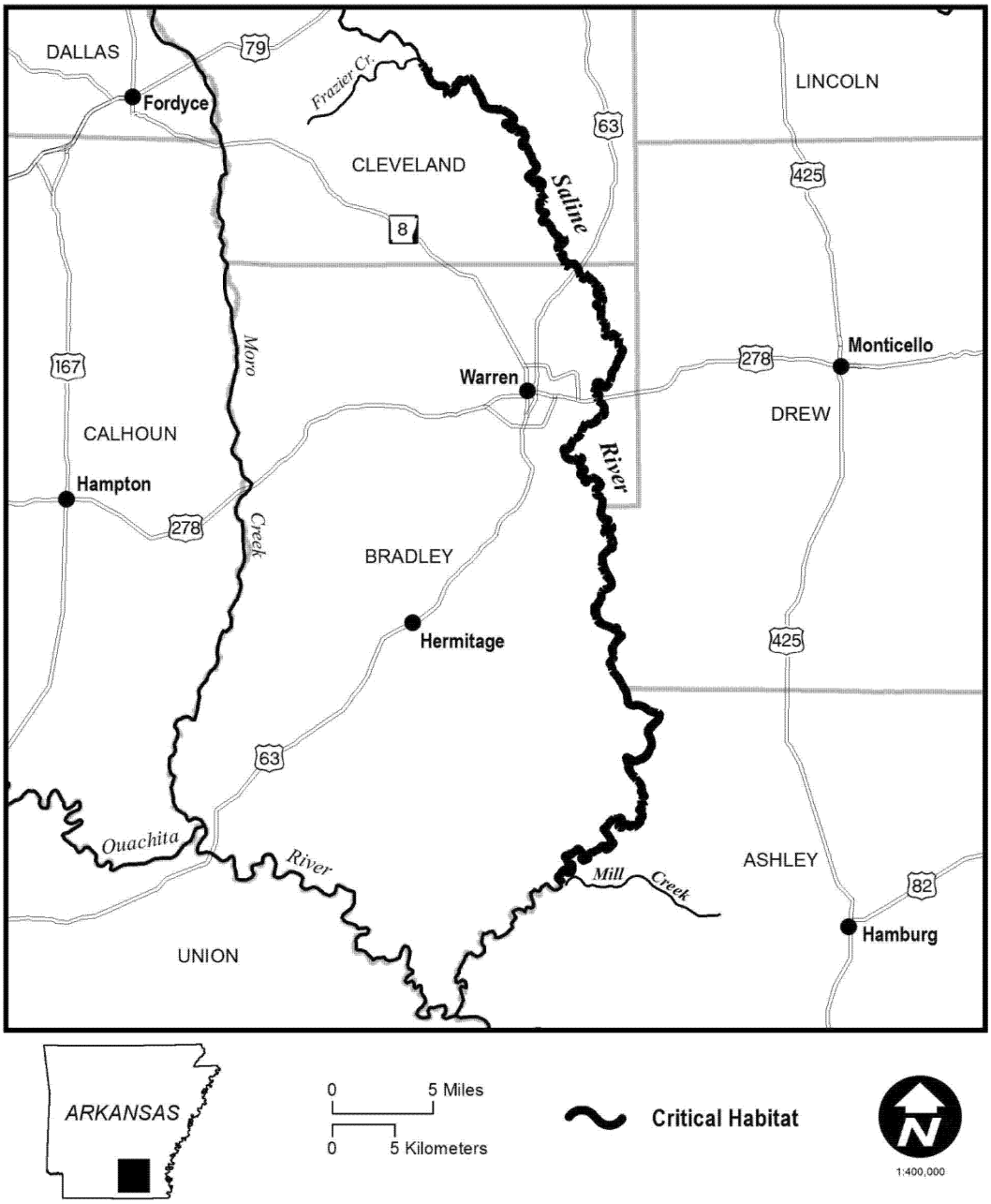


(11) Unit RF5: Saline River—Ashley, Bradley, Cleveland, and Drew Counties, Arkansas.

(i) *General Description:* Unit RF5 includes 119.4 rkm (74.2 rmi) of the Saline River from the Frazier Creek confluence near Mount Elba, Cleveland County, Arkansas, to the Mill Creek confluence near Stillions, Ashley and Bradley Counties, Arkansas.

(ii) Map of Unit RF5 follows:

Map of Unit RF5 (Saline River) of critical habitat for Rabbitsfoot

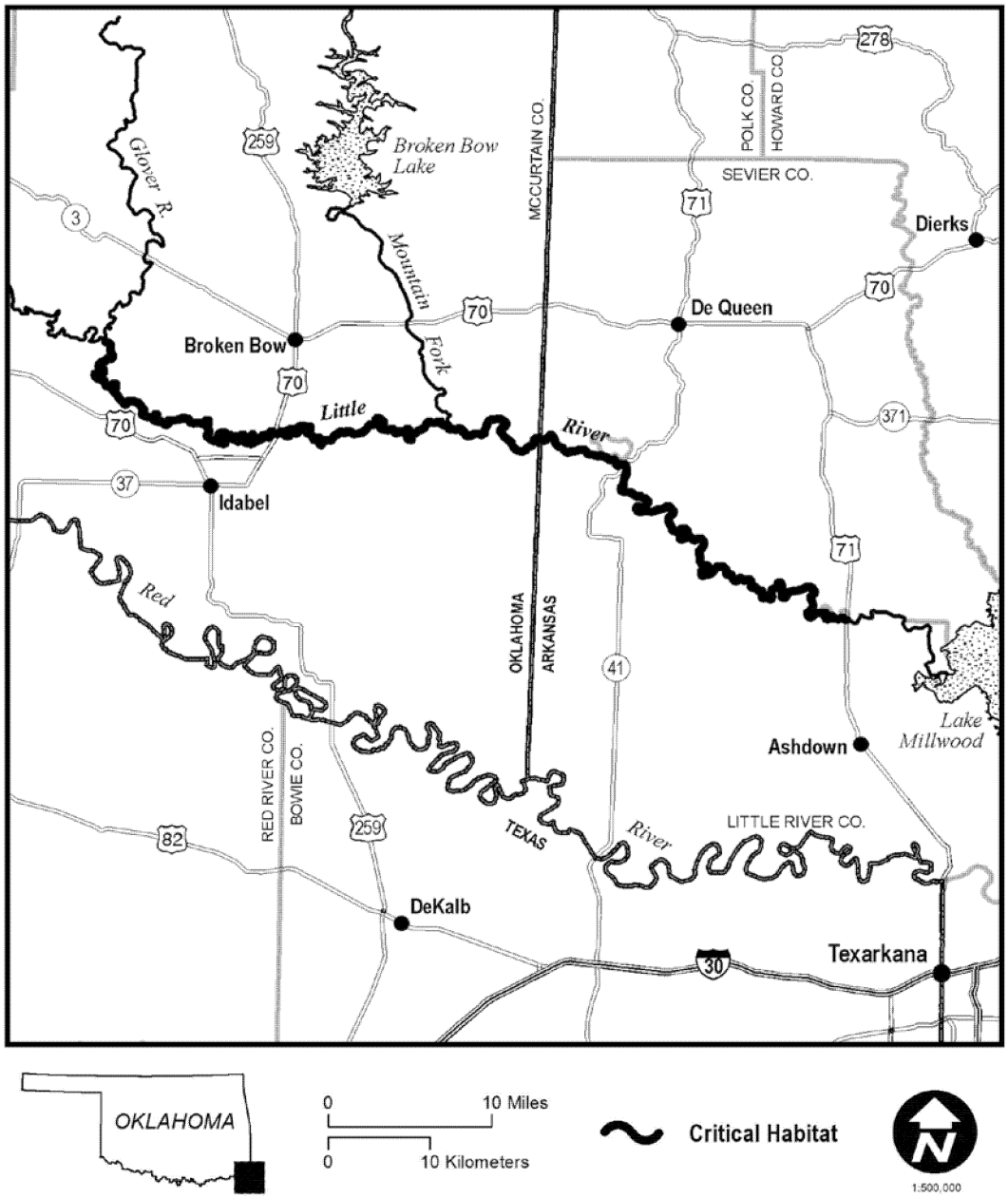


(12) Unit RF6: Little River—McCurtain County, Oklahoma; and Little River and Sevier Counties, Arkansas.

(i) *General Description:* Unit RF6 includes 139.7 rkm (86.8 rmi) of the Little River from the Glover River confluence northwest of Idabel, McCurtain County, Oklahoma, downstream to U.S. Highway 71 north of Wilton, Little River and Sevier Counties, Arkansas.

(ii) Map of Unit RF6 follows:

Map of Unit RF6 (Little River) of critical habitat for Rabbitsfoot

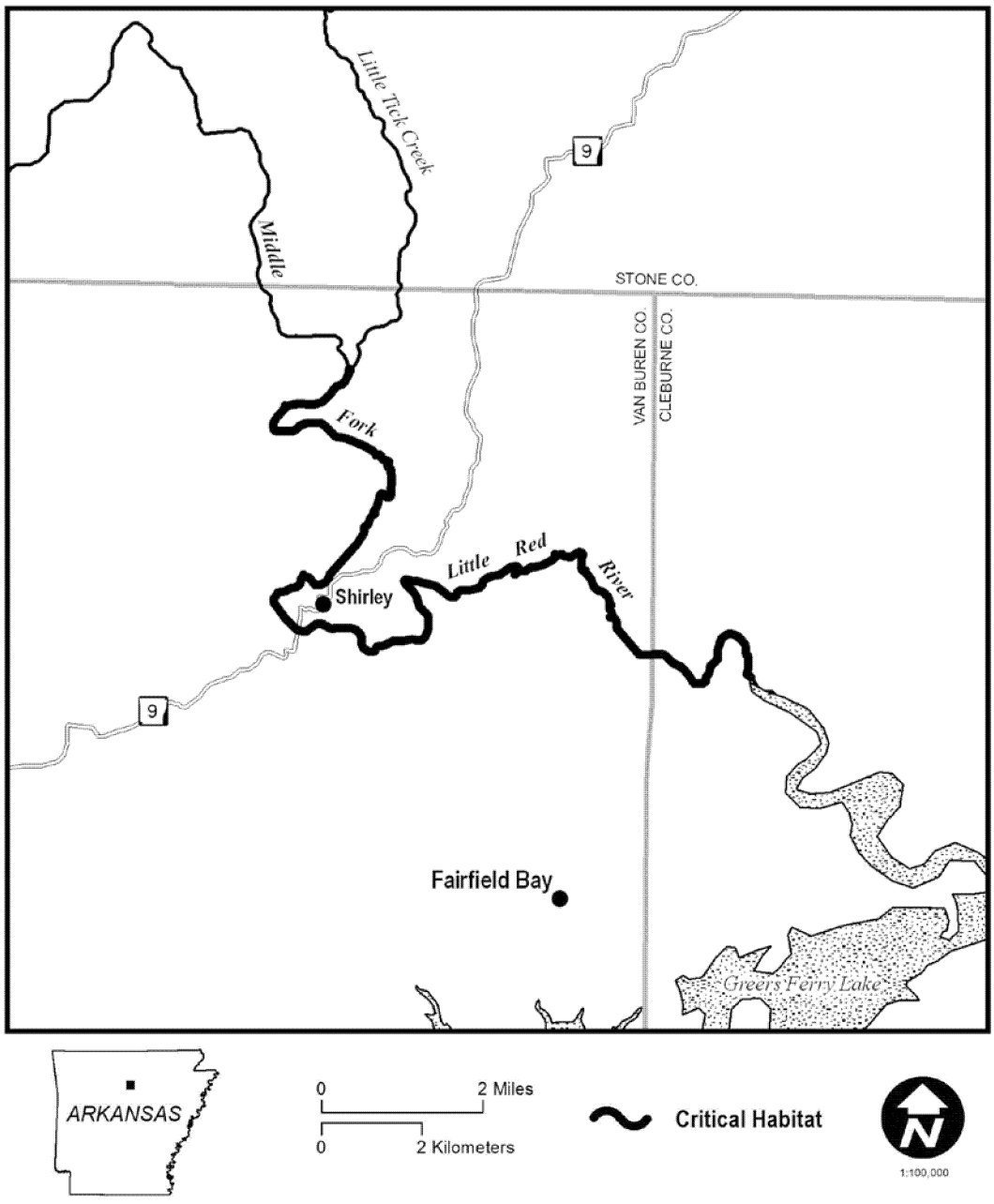


(13) Unit RF7: Middle Fork Little Red River—Cleburne and Van Buren Counties, Arkansas.

(i) *General Description:* Unit RF7 includes 24.8 rkm (15.4 rmi) of the Middle Fork Little Red River from the confluence of Little Tick Creek north of Shirley, Arkansas, downstream to Greers Ferry Reservoir (where inundation begins), Van Buren County, Arkansas.

(ii) Map of Unit RF7 follows:

Map of Unit RF7 (Middle Fork Little Red River) of critical habitat for Rabbitsfoot

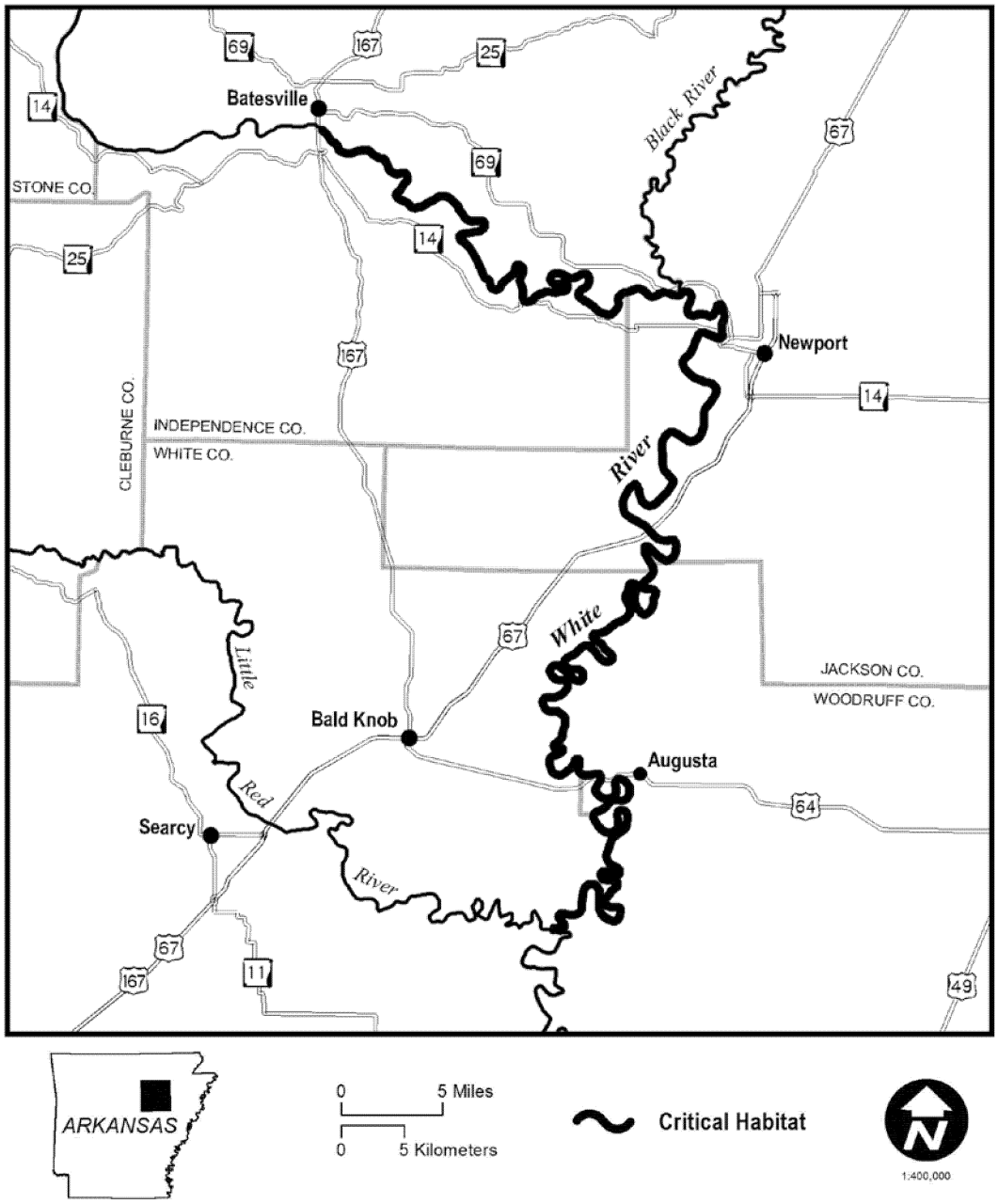


(14) Unit RF8a: White River—Independence, Jackson, White, and Woodruff Counties, Arkansas.

(i) *General Description:* Unit RF8a includes 188.3 rkm (117.0 rmi) of the White River from the Batesville Dam at Batesville, Independence County, Arkansas, downstream to the Little Red River confluence north of Georgetown, White, and Woodruff Counties, Arkansas.

(ii) Map of Unit RF8a follows:

Map of Unit RF8a (White River) of critical habitat for Rabbitsfoot

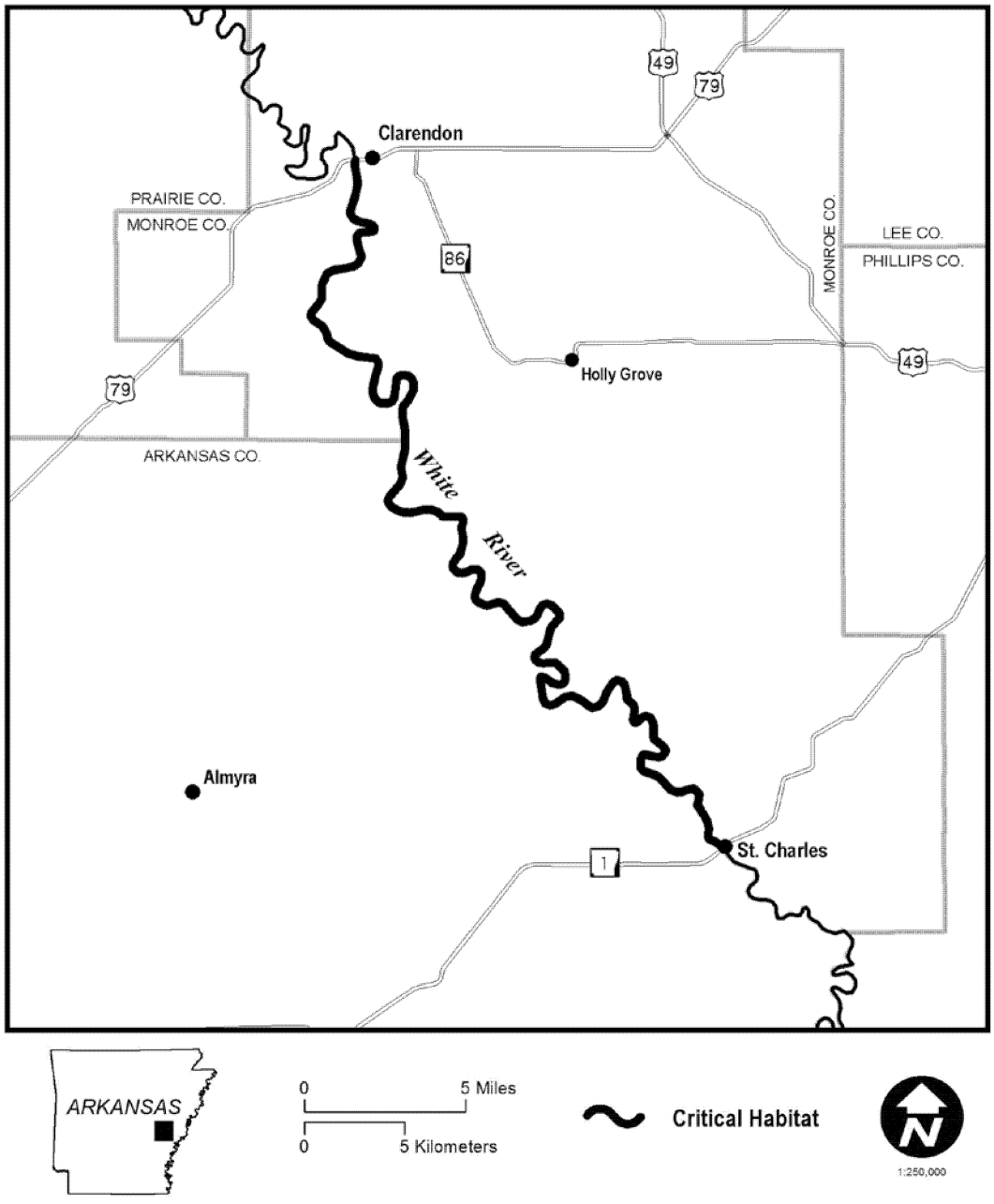


(15) Unit RF8b: White River—Arkansas and Monroe Counties, Arkansas.

(i) *General Description:* Unit RF8b includes 68.9 rkm (42.8 rmi) of the White River from U.S. Highway 79 at Clarendon, Monroe County, Arkansas, downstream to Arkansas Highway 1 near St. Charles, Arkansas County, Arkansas.

(ii) Map of Unit RF8b follows:

Map of Unit RF8b (White River) of critical habitat for Rabbitsfoot

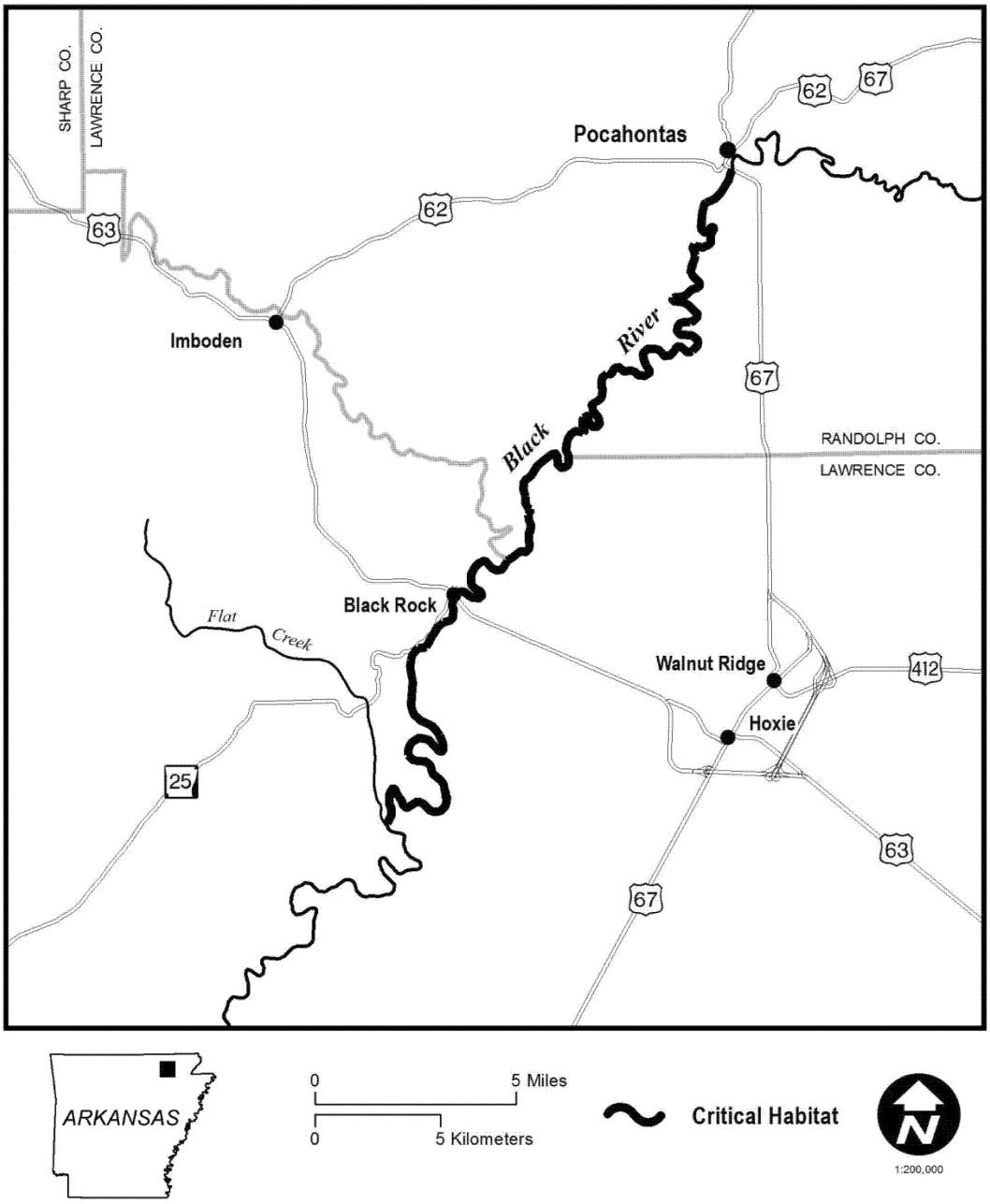


(16) Unit RF9: Black River—Lawrence and Randolph Counties, Arkansas.

(i) *General Description:* Unit RF9 includes 51.2 rkm (31.8 rmi) of the Black River from U.S. Highway 67 at Pocahontas, Randolph County, Arkansas, downstream to the Flat Creek confluence southeast of Powhatan, Lawrence County, Arkansas.

(ii) Map of Unit RF9 follows:

Map of Unit RF9 (Black River) of critical habitat for Rabbitsfoot

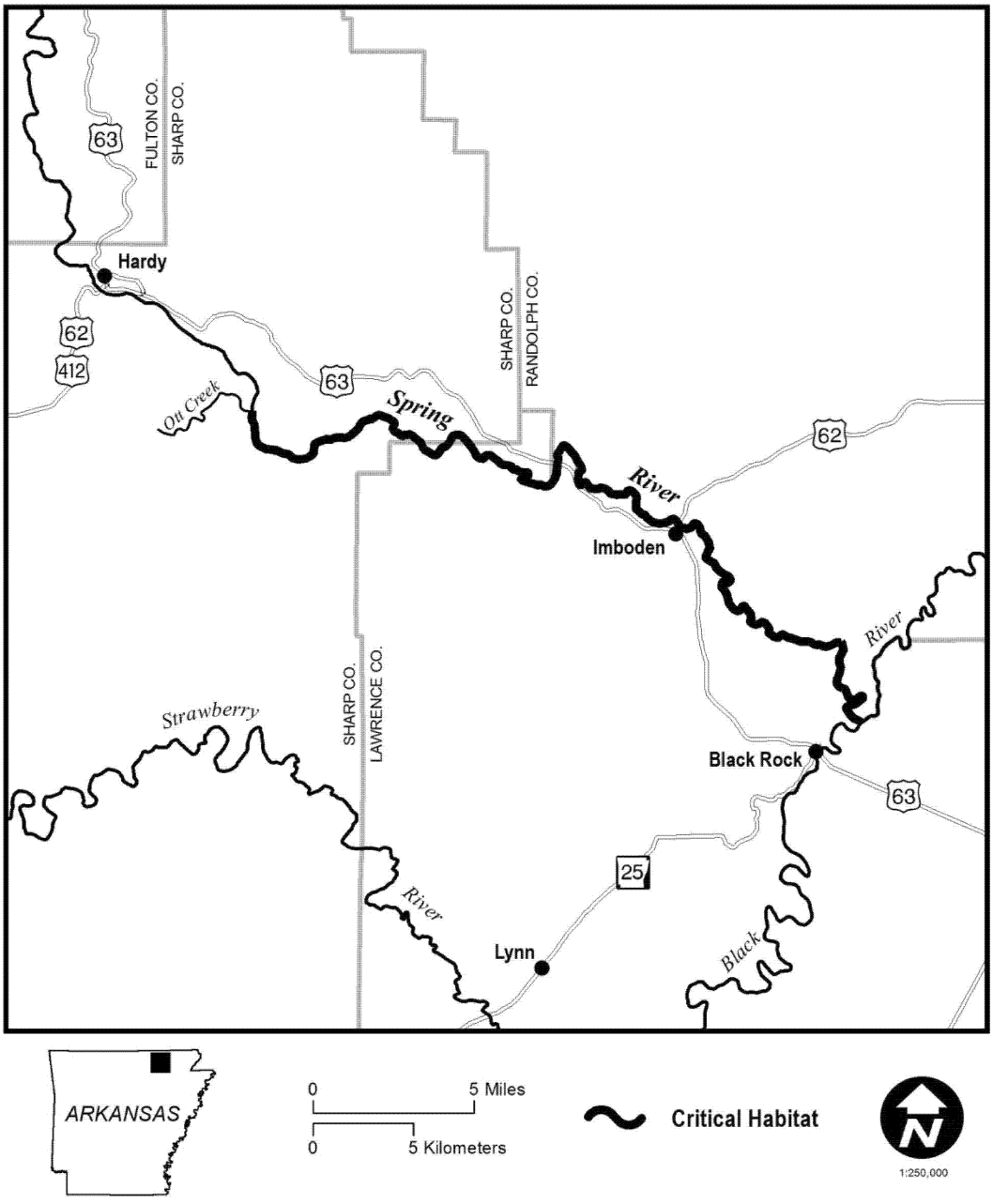


(17) Unit RF10: Spring River—Lawrence, Randolph, and Sharp Counties, Arkansas.

(i) *General Description:* Unit RF10 includes 51.5 rkm (32.0 rmi) of the Spring River from the Ott Creek confluence southwest of Hardy in Sharp County, Arkansas, downstream to its confluence with the Black River east of Black Rock, Lawrence and Randolph Counties, Arkansas.

(ii) Map of Unit RF10 follows:

Map of Unit RF10 (Spring River) of critical habitat for Rabbitsfoot

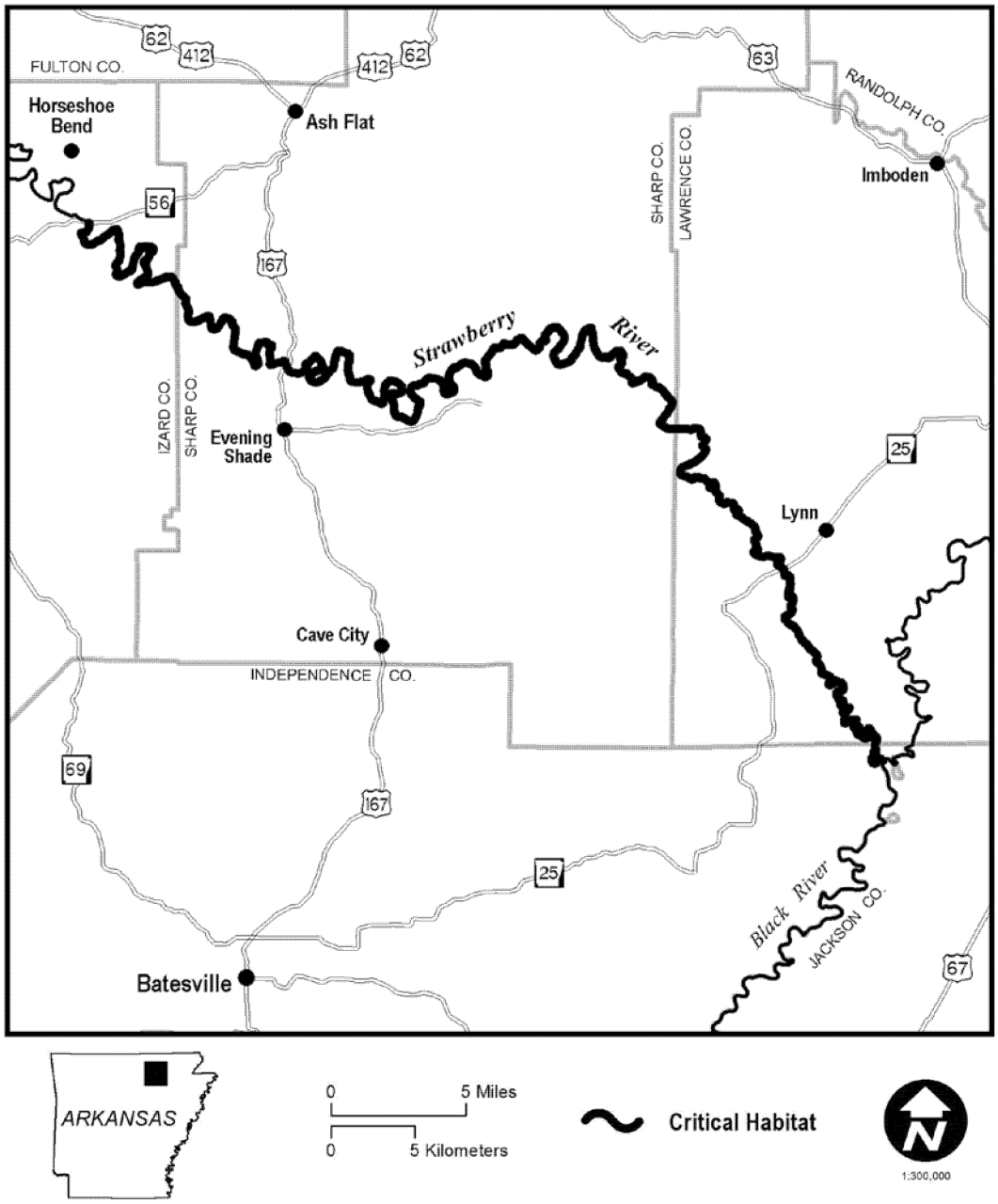


(18) Unit RF11: Strawberry River—Independence, Izard, Lawrence, and Sharp Counties, Arkansas.

(i) *General Description:* Unit RF11 includes 123.8 rkm (76.9 rmi) of the Strawberry River from Arkansas Highway 56 south of Horseshoe Bend, Izard County, Arkansas, downstream to its confluence with the Black River southeast of Strawberry, Lawrence County, Arkansas.

(ii) Map of Unit RF11 follows:

Map of Unit RF11 (Strawberry River) of critical habitat for Rabbitsfoot

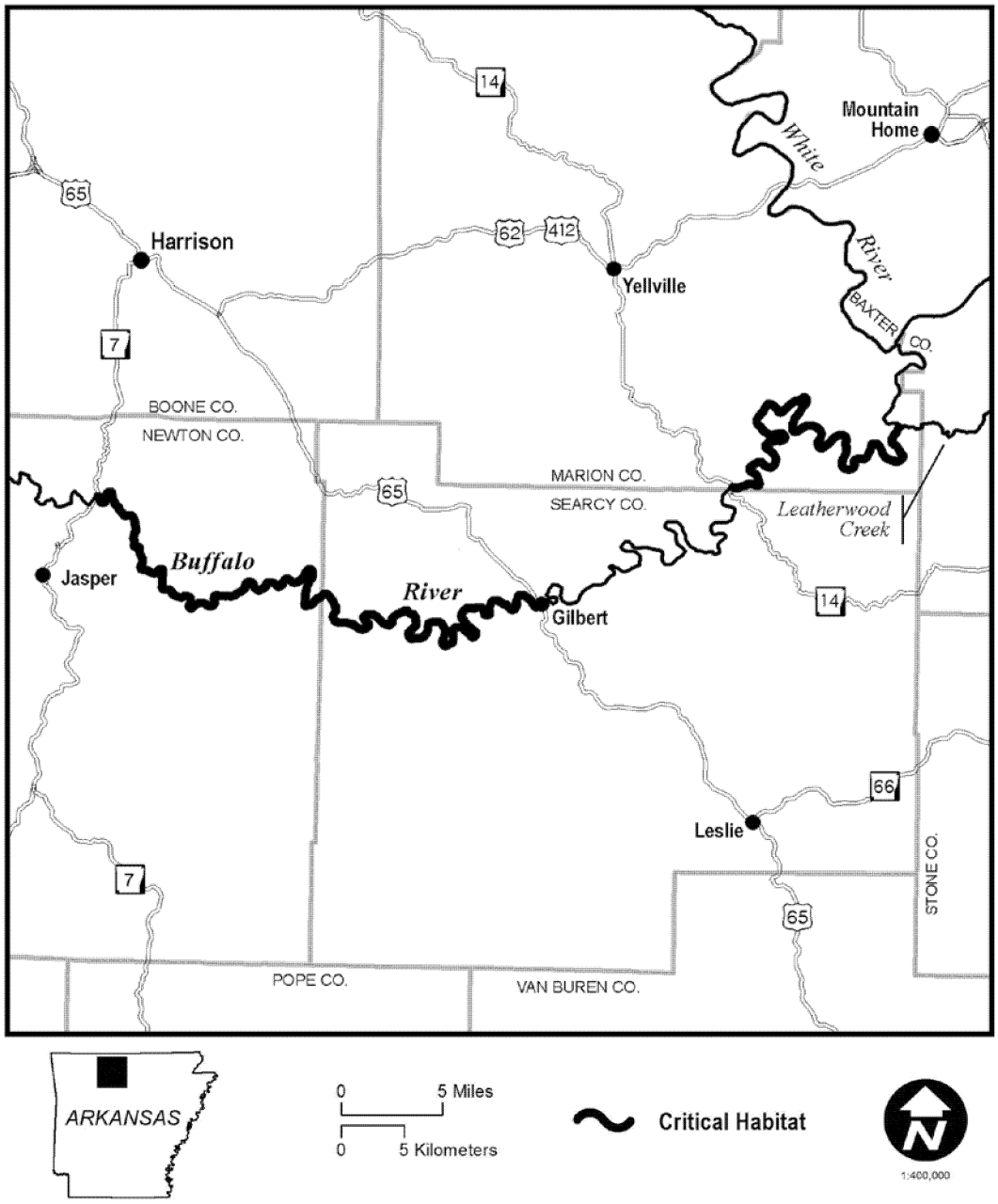


(19) Unit RF12: Buffalo River—Marion, Newton, and Searcy Counties, Arkansas.

(i) *General Description:* Unit RF12 includes 113.6 rkm (70.6 rmi) of the Buffalo River from the Cove Creek confluence southeast of Erbie, Newton County, Arkansas, downstream to U.S. Highway 65 west of Gilbert, Searcy County, Arkansas, and Arkansas Highway 14 southeast of Mull, Arkansas, downstream to the Leatherwood Creek confluence in the Lower Buffalo Wilderness Area, Arkansas.

(ii) Map of Unit RF12 follows:

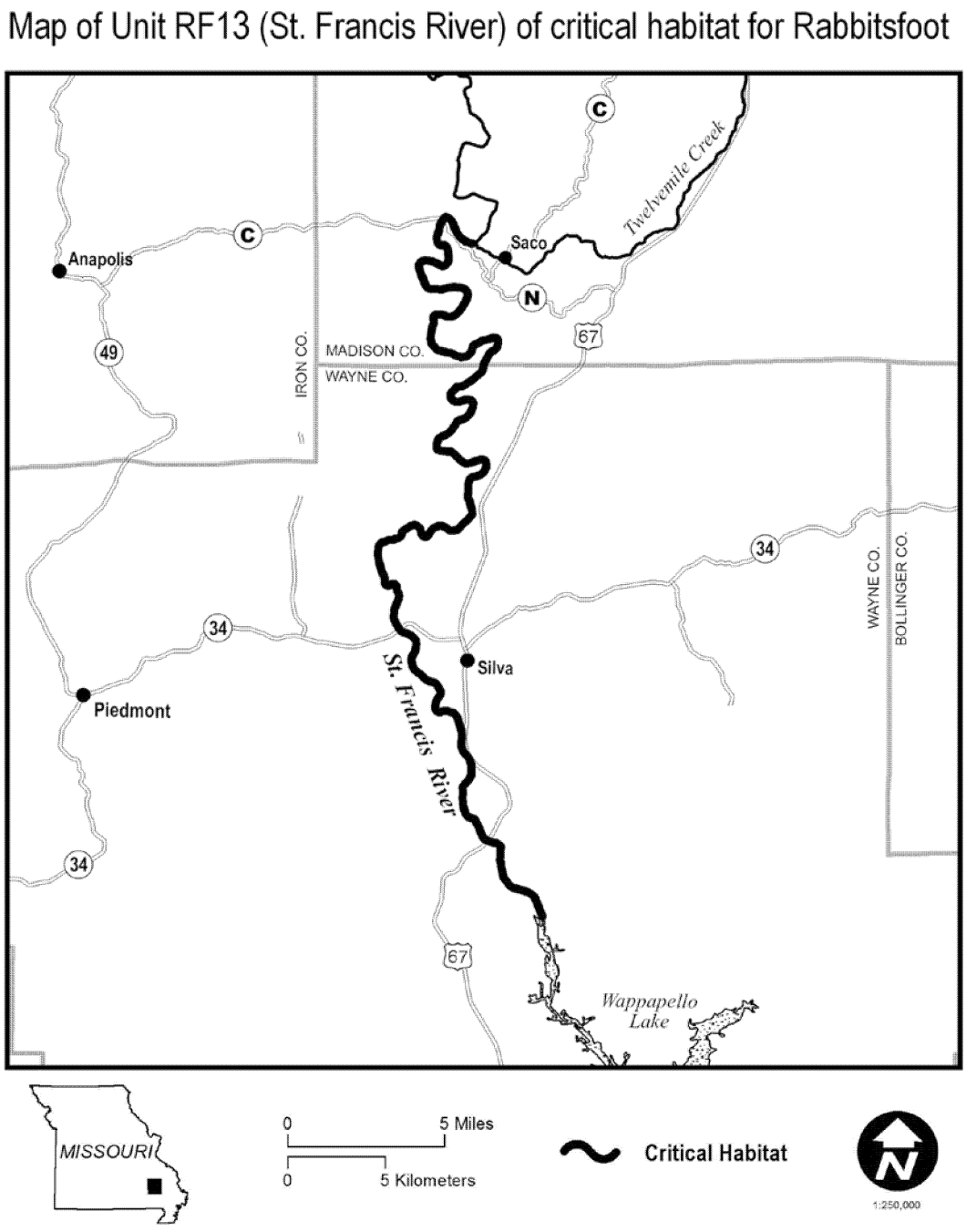
Map of Unit RF12 (Buffalo River) of critical habitat for Rabbitsfoot



(20) Unit RF13: St. Francis River—Madison and Wayne Counties, Missouri.

(i) *General Description:* Unit RF13 includes 64.3 rkm (40.0 rmi) of the St. Francis River from the Twelvemile Creek confluence west of Saco, Madison County, Missouri, downstream to Lake Wappepello (where inundation begins), Wayne County, Missouri.

(ii) Map of Unit RF13 follows:

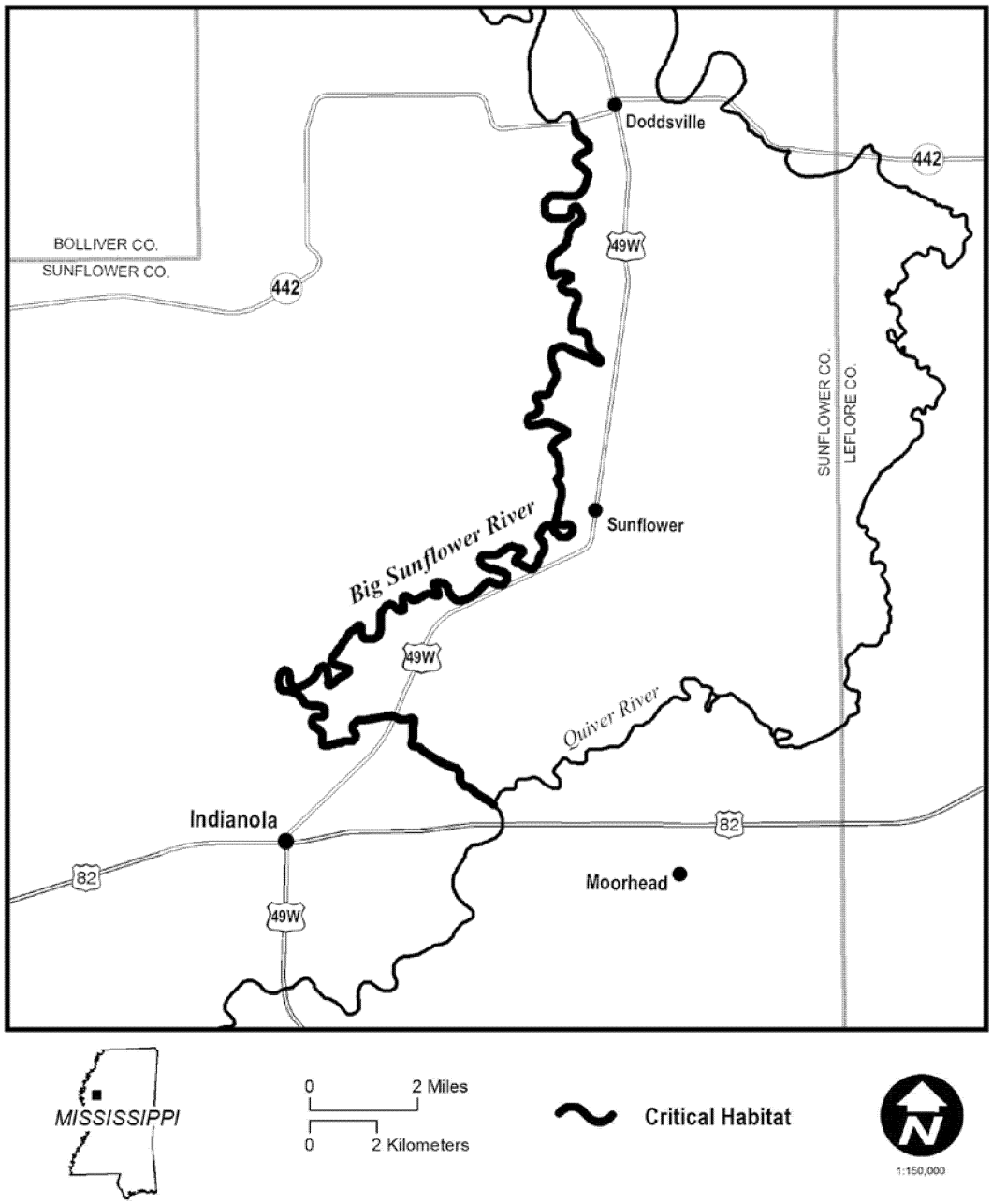


(21) Unit RF14: Big Sunflower River—Sunflower County, Mississippi.

(i) *General Description:* Unit RF14 includes 51.5 rkm (32.0 rmi) of the Big Sunflower River from Mississippi Highway 442 west of Doddsville, Mississippi, downstream to the Quiver River confluence east of Indianola, Sunflower County, Mississippi.

(ii) Map of Unit RF14 follows:

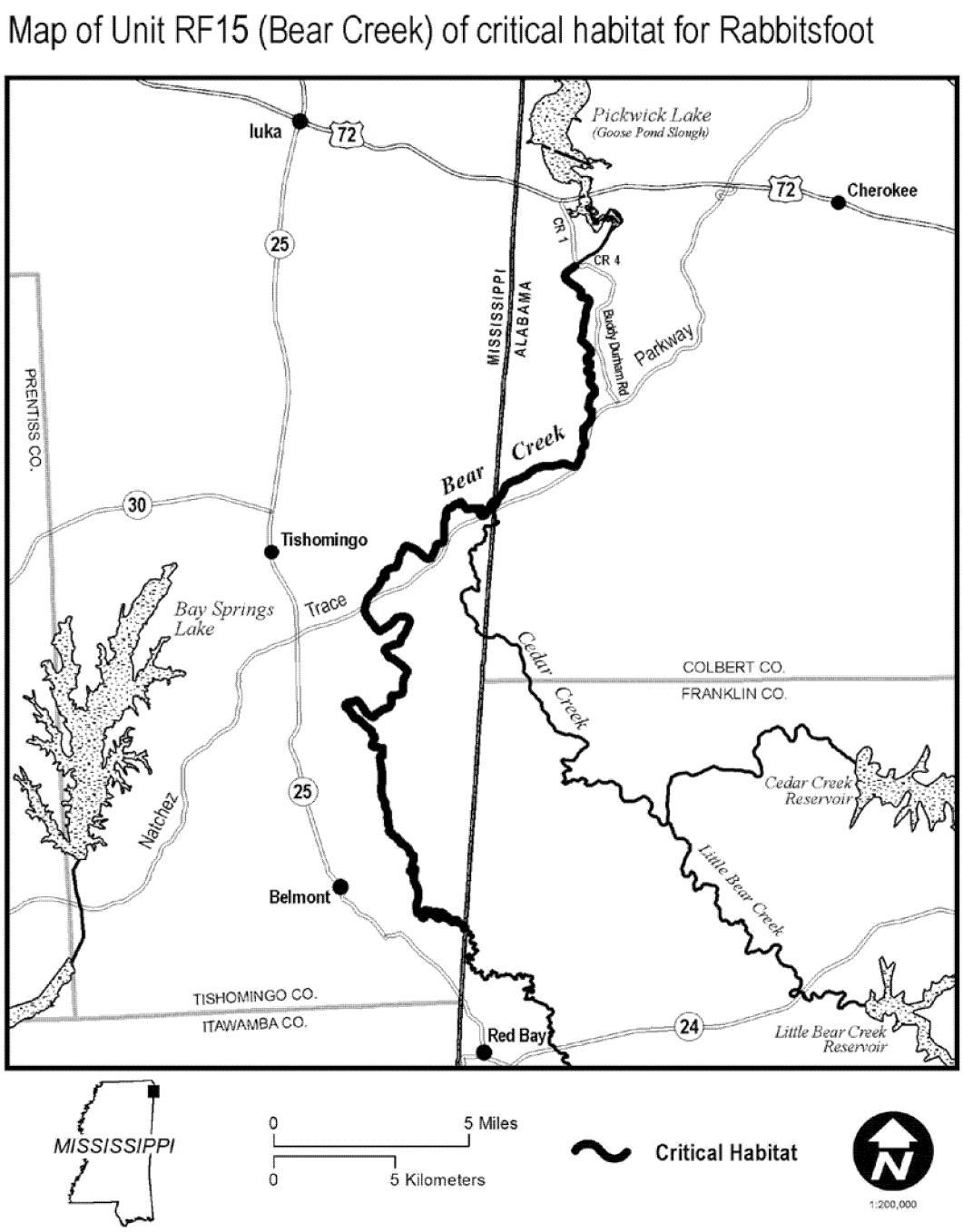
Map of Unit RF14 (Big Sunflower River) of critical habitat for Rabbitsfoot



(22) Unit RF15: Bear Creek—Tishomingo County, Mississippi; and Colbert County, Alabama.

(i) *General Description:* Unit RF15 includes 49.7 rkm (30.9 rmi) of Bear Creek from the Alabama and Mississippi State line east of Golden, Tishomingo County, Mississippi, downstream to Alabama County Road 4 southwest of Sutton Hill, Colbert County, Alabama (just upstream of Pickwick Lake).

(ii) Map of Unit RF15 follows:

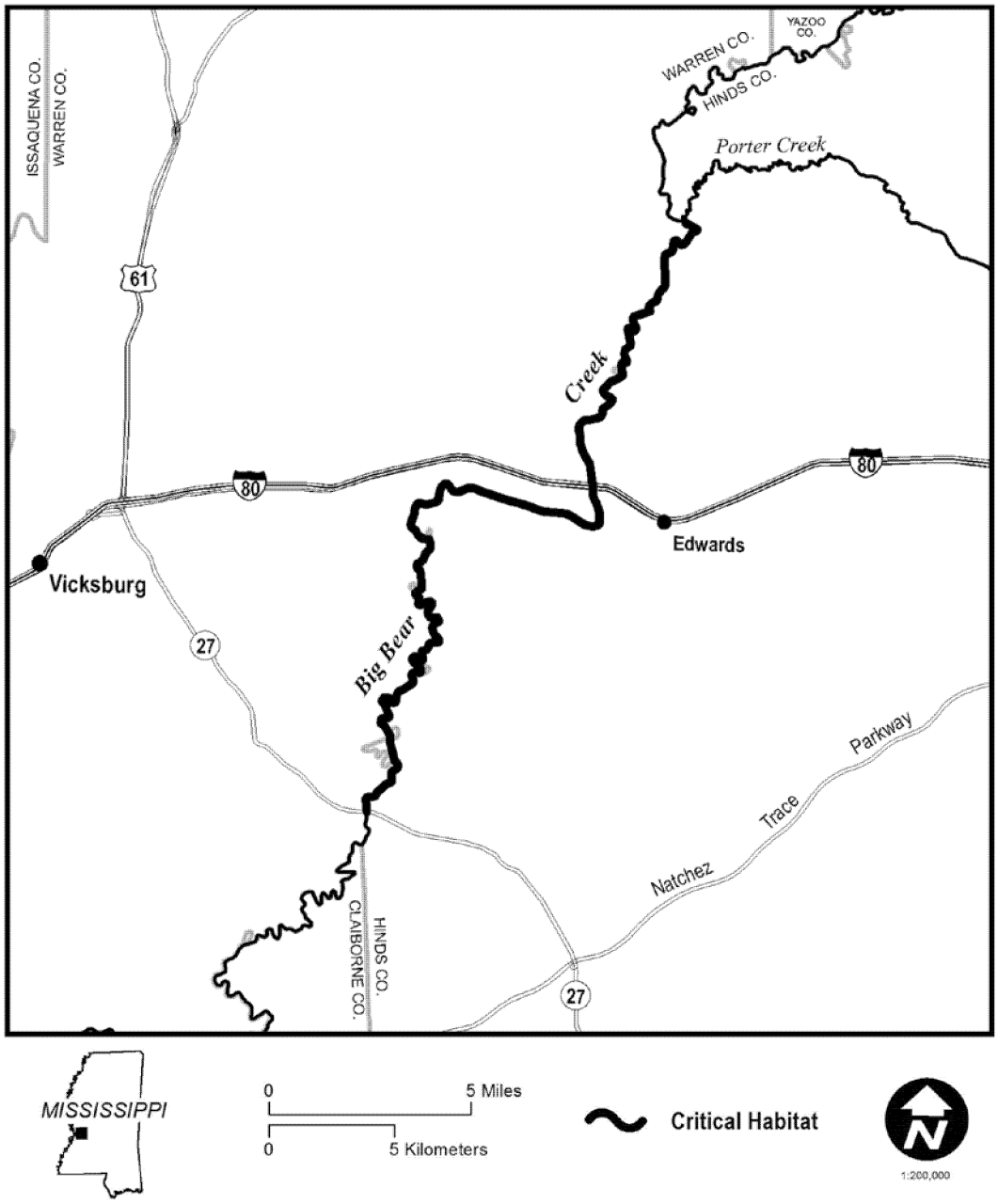


(23) Unit RF16: Big Black River—Hinds and Warren Counties, Mississippi.

(i) *General Description:* Unit RF16 includes 43.3 rkm (26.9 rmi) of the Big Black River from Porter Creek confluence west of Lynchburg, Hinds County, Mississippi, downstream to Mississippi Highway 27 west of Newman, Warren County, Mississippi.

(ii) Map of Unit RF16 follows:

Map of Unit RF16 (Big Black River) of critical habitat for Rabbitsfoot

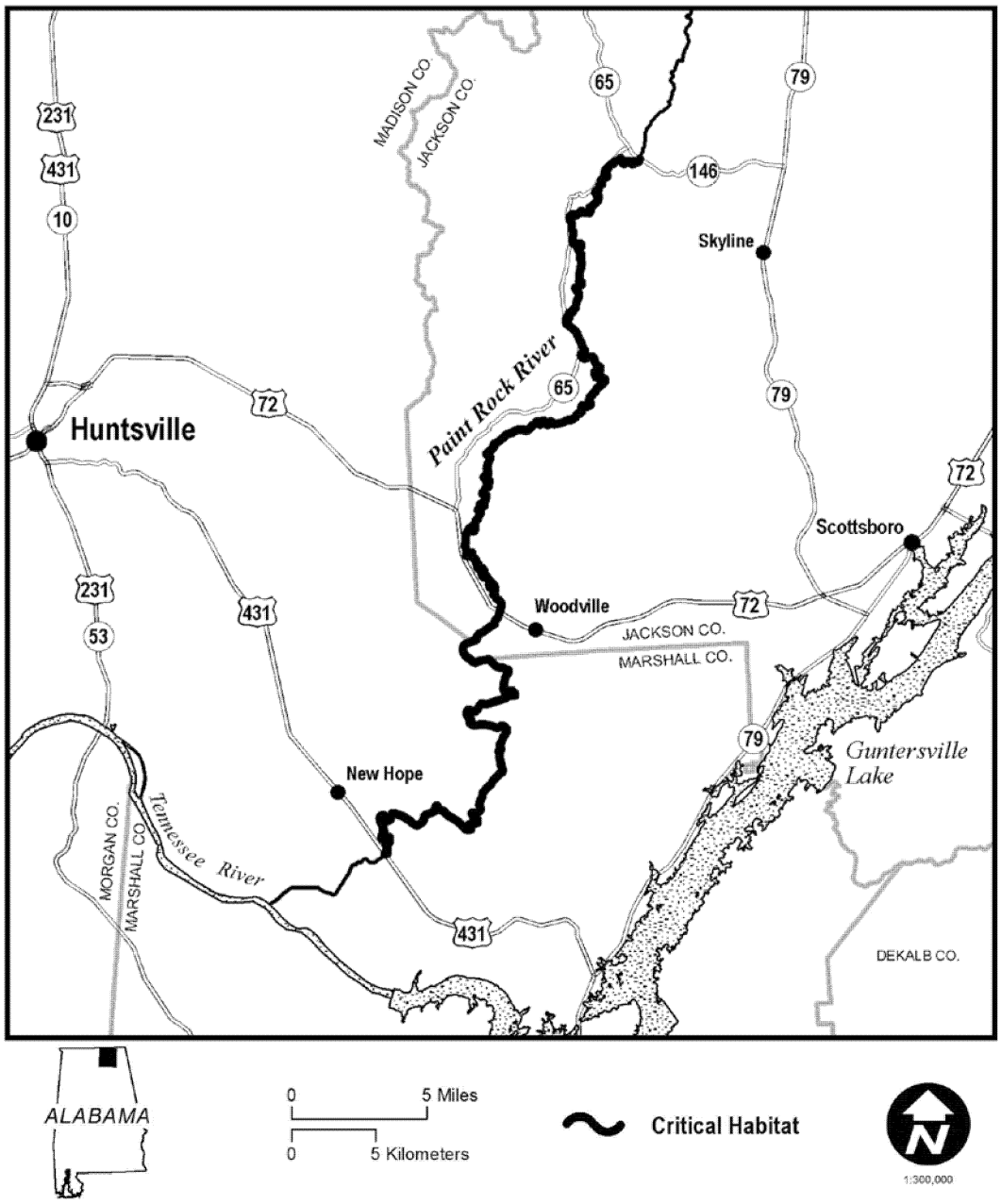


(24) Unit RF17: Paint Rock River—Jackson, Madison, and Marshall Counties, Alabama.

(i) *General Description:* Unit RF17 includes 81.0 rkm (50.3 rmi) of the Paint Rock River from the convergence of Estill Fork and Hurricane Creek north of Skyline, Jackson County, Alabama, downstream to U.S. Highway 431 south of New Hope, Madison and Marshall Counties, Alabama.

(ii) Map of Unit RF17 follows:

Map of Unit RF17 (Paint Rock River) of critical habitat for Rabbitsfoot

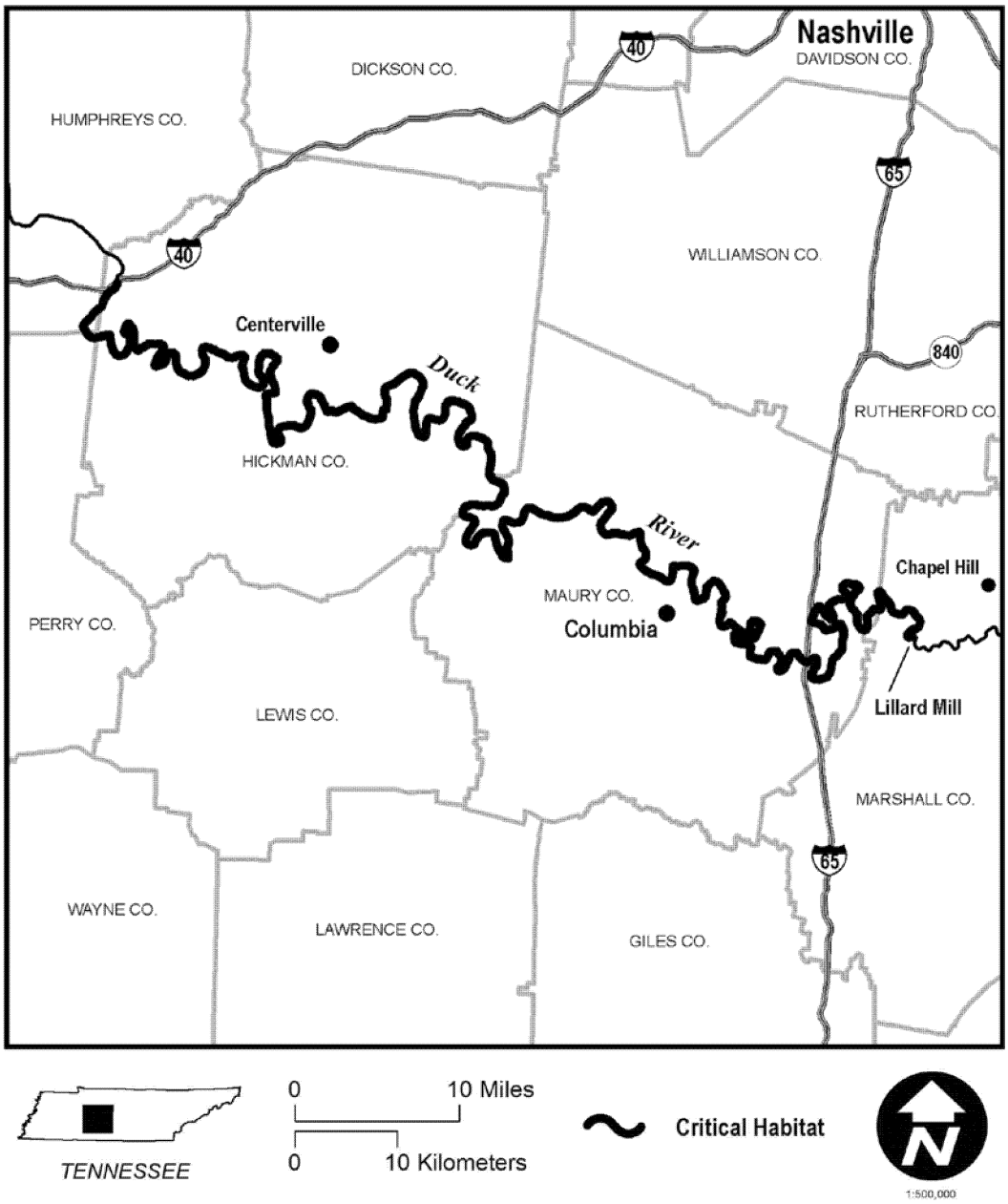


(25) Unit RF18: Duck River—Hickman, Humphreys, Marshall, Maury, and Perry Counties, Tennessee.

(i) *General Description:* Unit RF18 includes 235.3 rkm (146.2 rmi) of the Duck River from Lillard Mill (rkm 288.1; rmi 179) west of Tennessee Highway 272, Marshall County, Tennessee, downstream to Interstate 40 near Bucksnort, Hickman County, Tennessee.

(ii) Map of Unit RF18 follows:

Map for Unit RF18 (Duck River) of critical habitat for Rabbitsfoot

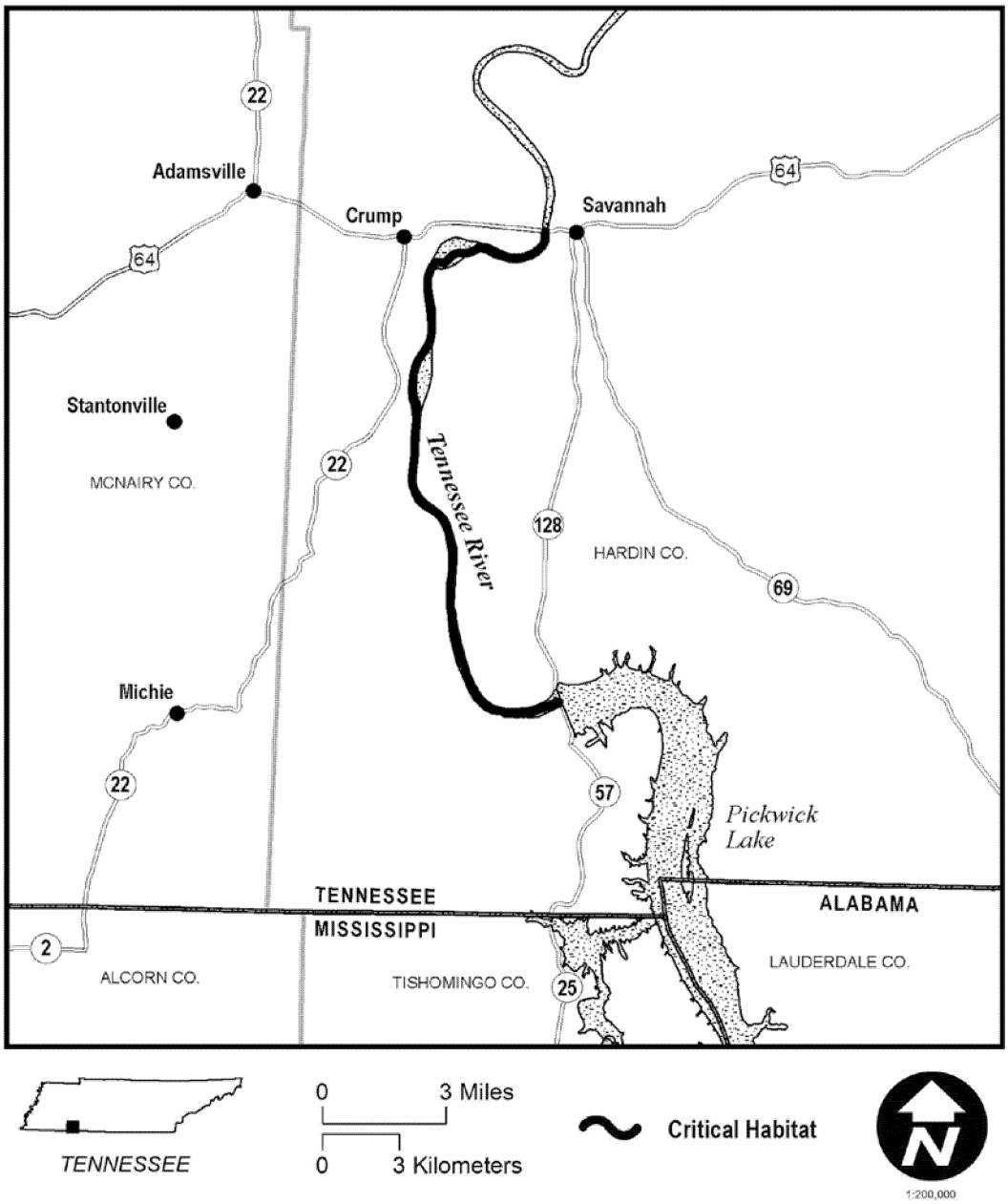


(26) Unit RF19a: Tennessee River—Hardin County, Tennessee.

(i) *General Description:* Unit RF19a includes 26.7 rkm (16.6 rmi) of the Tennessee River from Pickwick Lake Dam downstream to U.S. Highway 64 near Adamsville, Hardin County, Tennessee.

(ii) Map of Unit RF19a follows:

Map for Unit RF19a (Tennessee River) of critical habitat for Rabbitsfoot

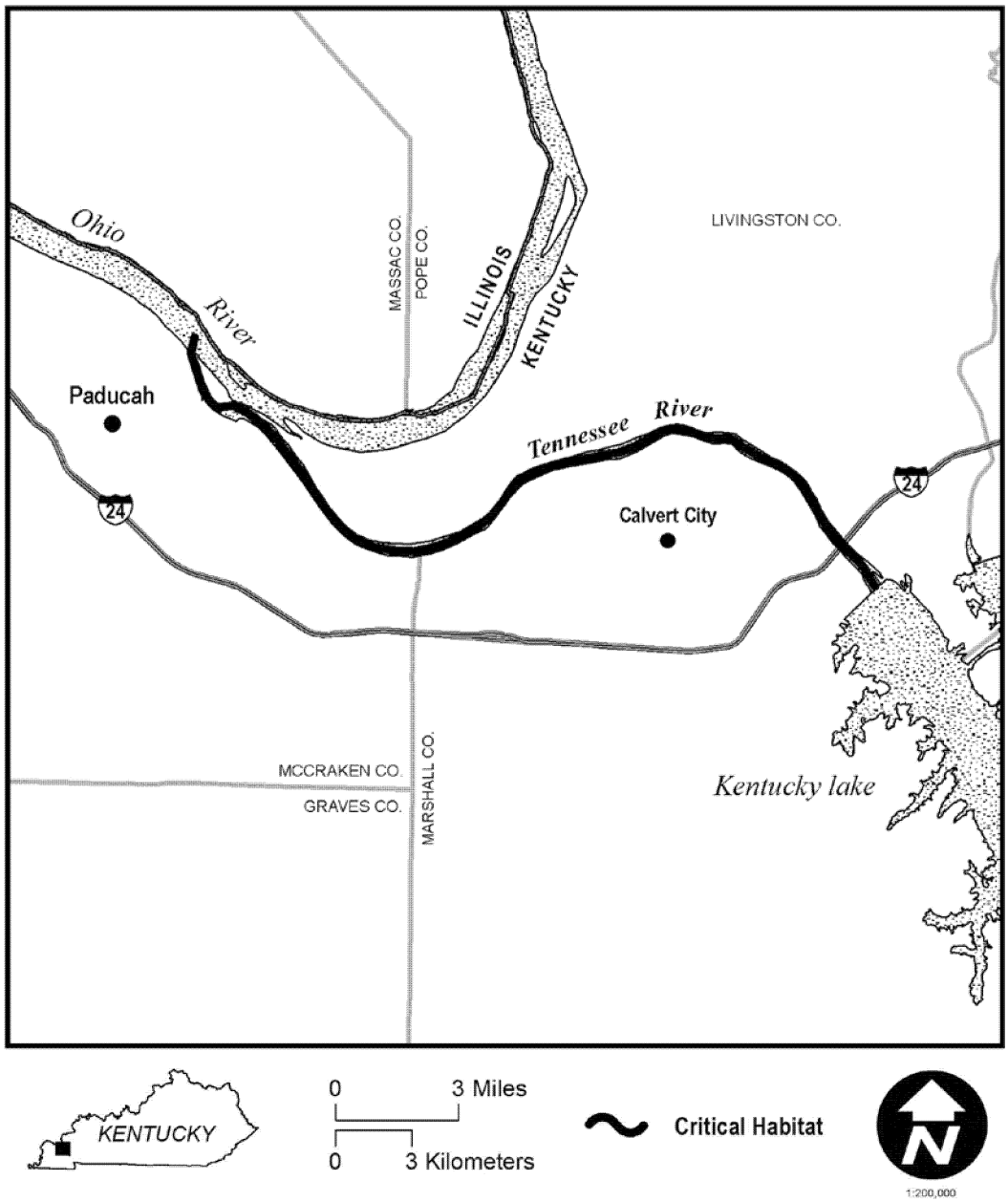


(27) Unit RF19b: Tennessee River—Livingston, Marshall, and McCracken Counties, Kentucky.

(i) *General Description:* Unit RF19b includes 35.6 rkm (22.1 rmi) of the Tennessee River from Kentucky Lake Dam, downstream to its confluence with the Ohio River, McCracken and Livingston Counties, Kentucky.

(ii) Map of Unit RF19b follows:

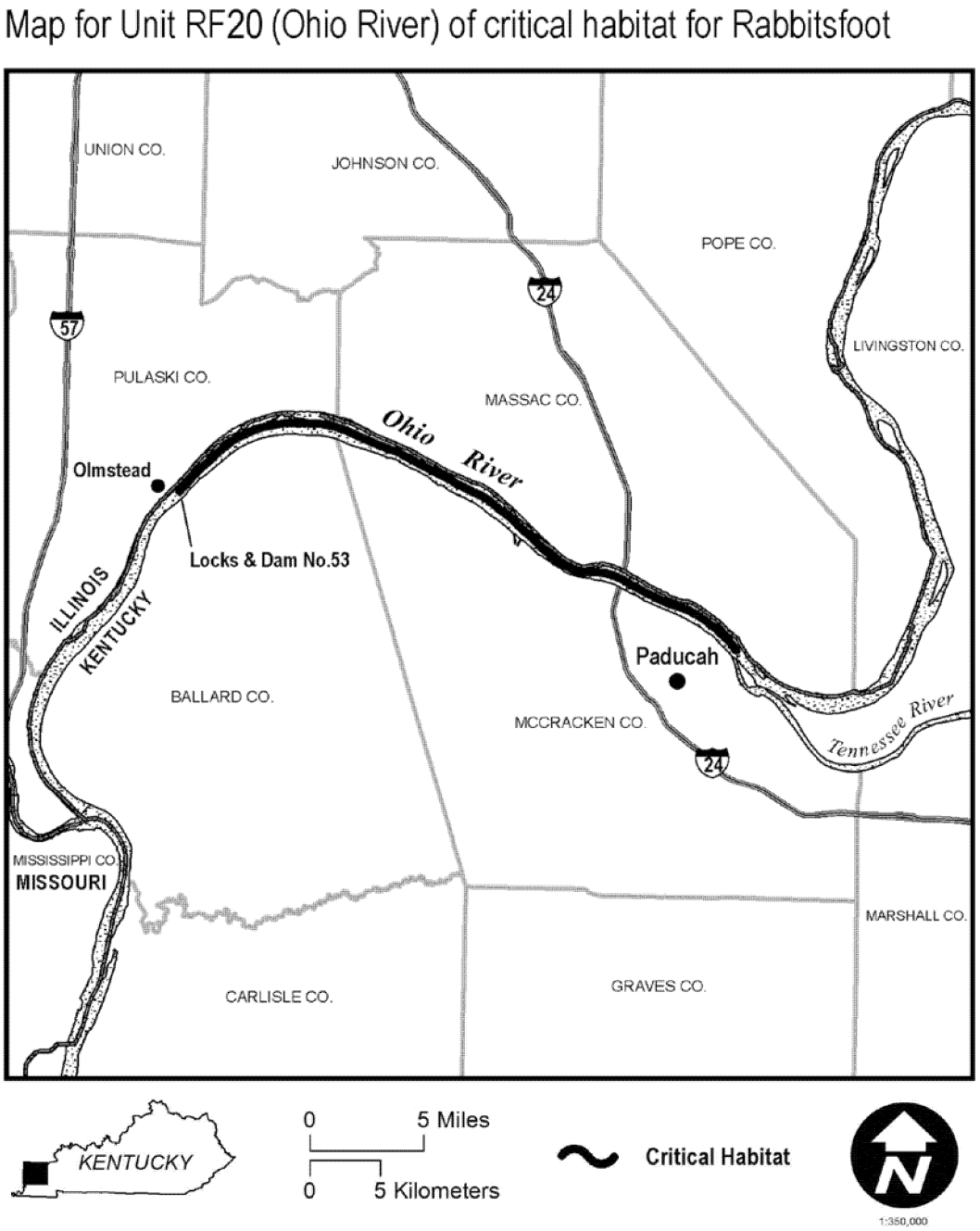
Map for Unit RF19b (Tennessee River) of critical habitat for Rabbitsfoot



(28) Unit RF20: Ohio River—Ballard, and McCracken Counties, Kentucky; Massac and Pulaski Counties, Illinois.

(i) *General Description:* Unit RF20 includes 45.9 rkm (28.5 rmi) of the Ohio River from the Tennessee River confluence at the downstream extent of Owens Island downstream to Lock and Dam 53 near Olmstead, Illinois.

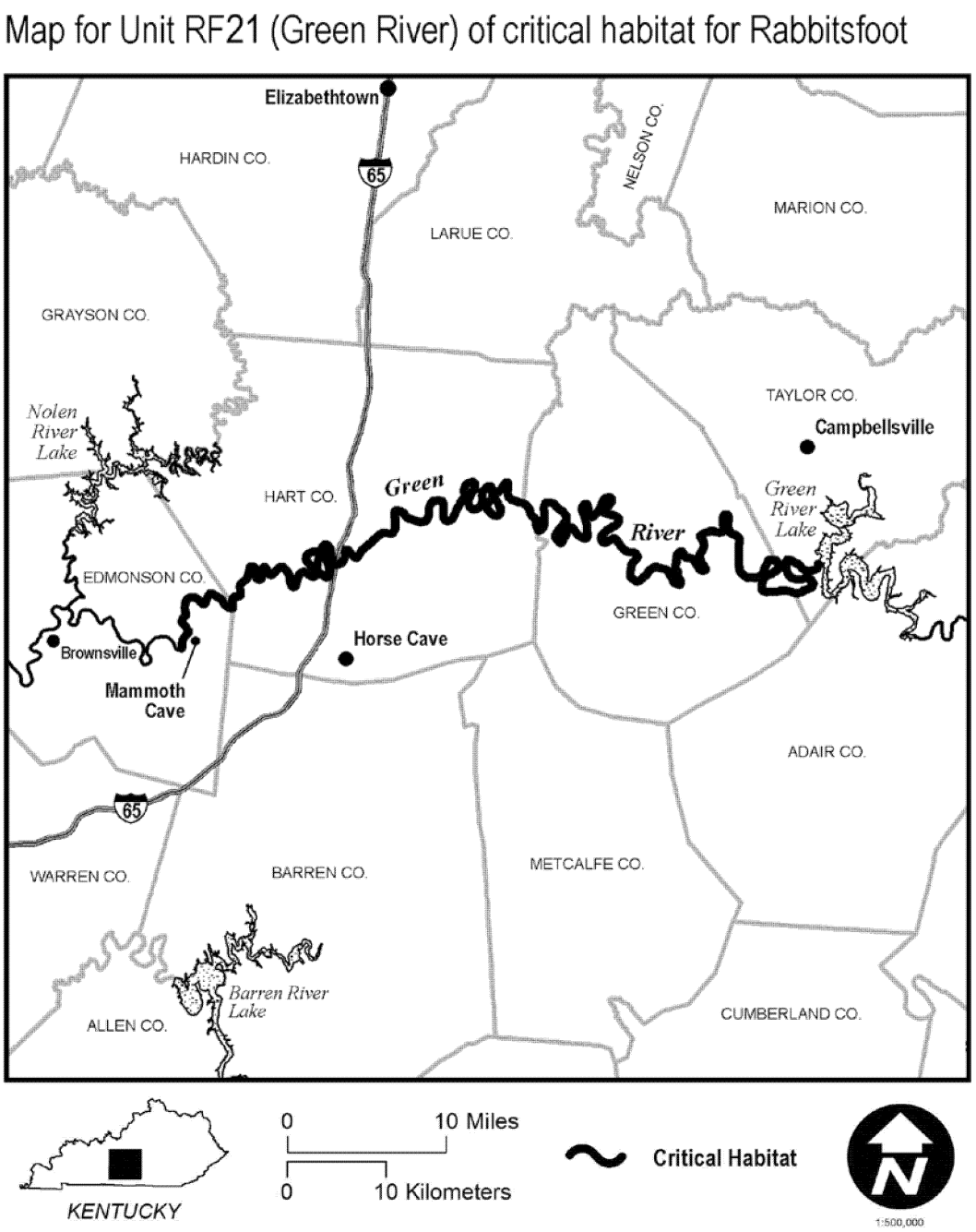
(ii) Map of Unit RF20 follows:



(29) Unit RF21: Green River—Edmonson, Green, Hart, and Taylor Counties, Kentucky.

(i) *General Description:* Unit RF21 includes 175.6 rkm (109.1 rmi) of the Green River from Green River Lake Dam south of Campbellsville, Taylor County, Kentucky, downstream to Mammoth Cave National Park North Entrance Road in Mammoth Cave National Park, Kentucky.

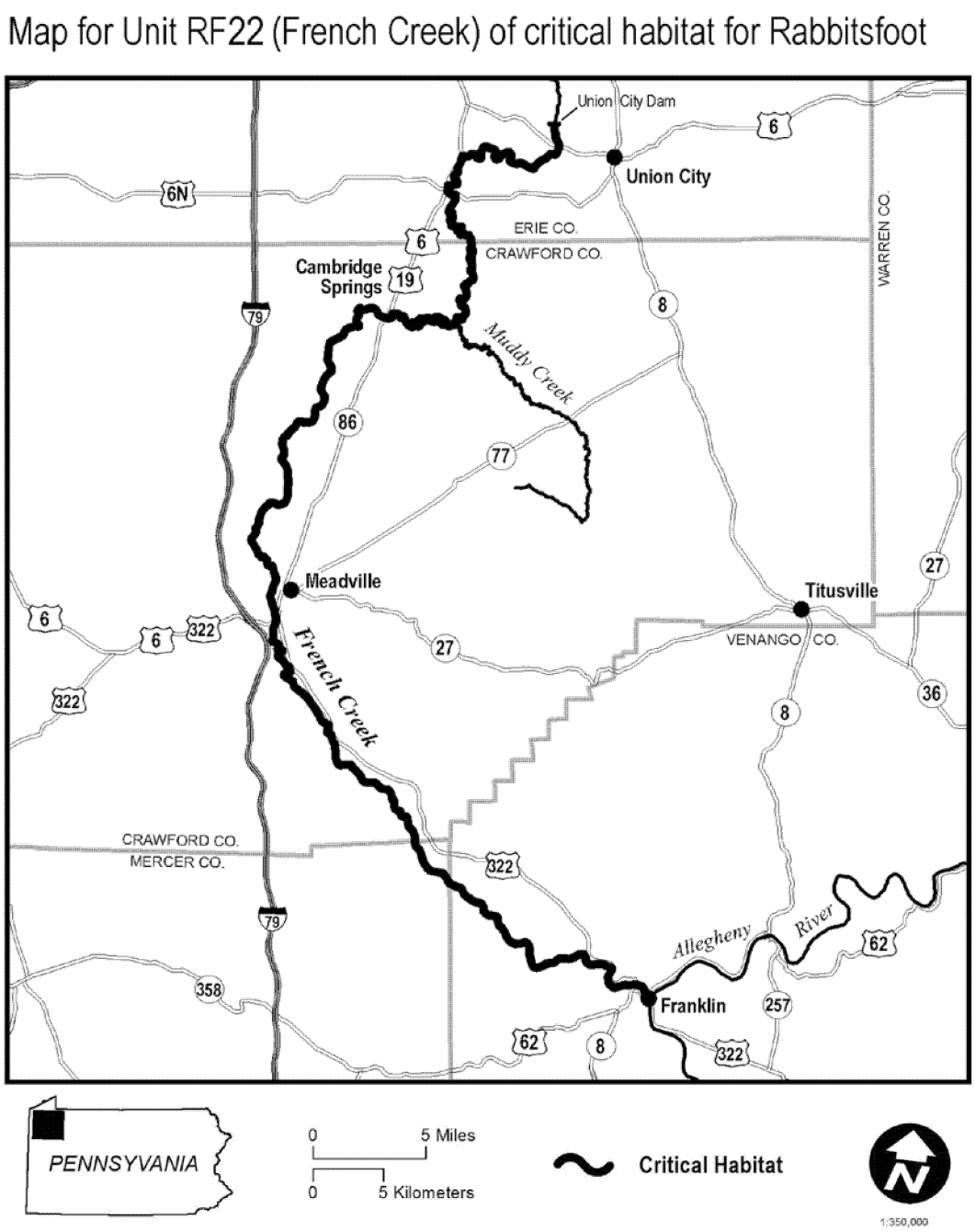
(ii) Map of Unit RF21 follows:



(30) Unit RF22: French Creek—Crawford, Erie, Mercer, and Venango Counties, Pennsylvania.

(i) *General Description:* Unit RF22 includes 120.4 rkm (74.8 rmi) of French Creek from Union City Reservoir Dam northeast of Union City, Erie County, Pennsylvania, downstream to its confluence with the Allegheny River near Franklin, Venango County, Pennsylvania.

(ii) Map of Unit RF22 follows:

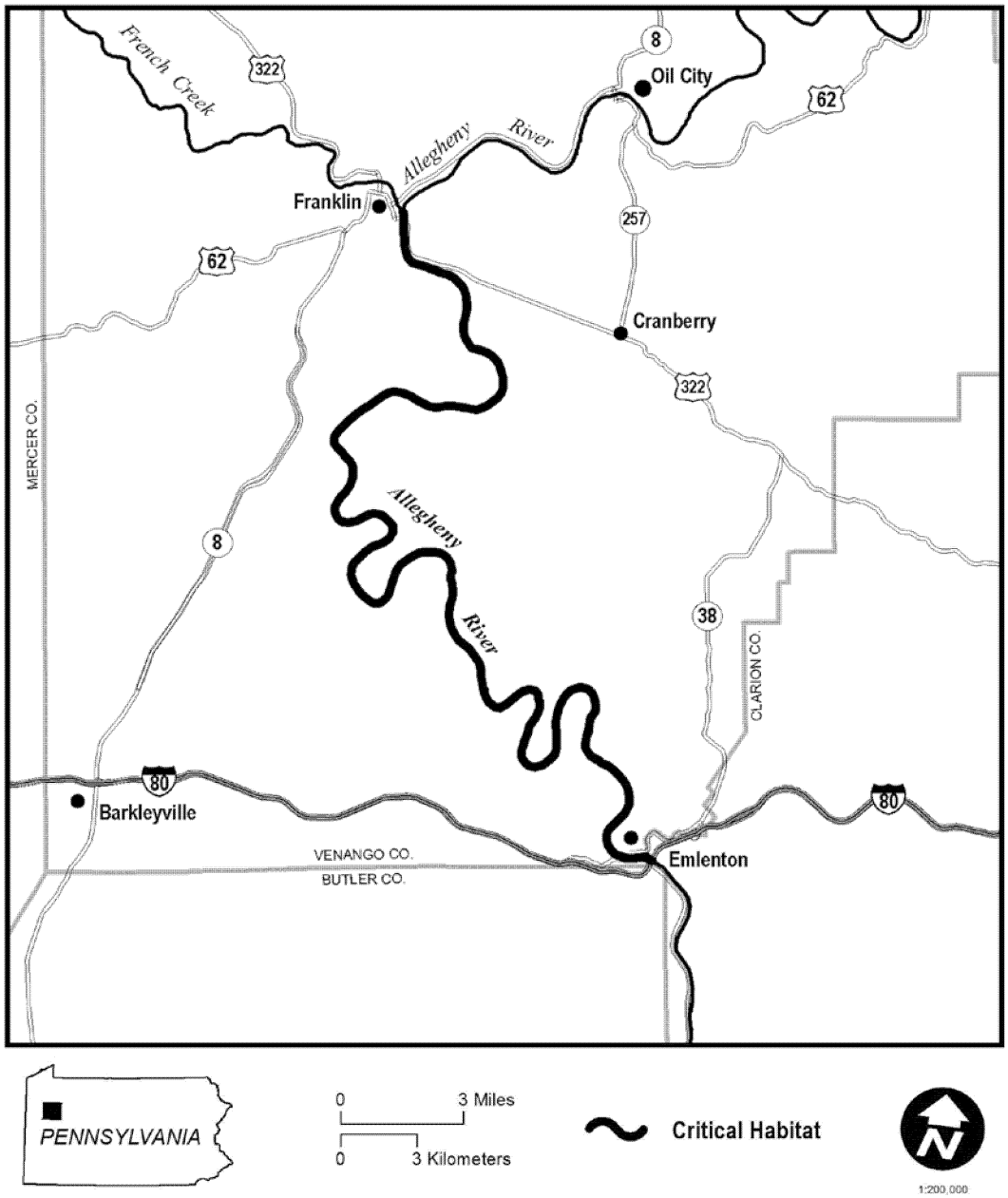


(31) Unit RF23: Allegheny River—Venango County, Pennsylvania.

(i) *General Description:* Unit RF23 includes 57.3 rkm (35.6 rmi) of the Allegheny River from the French Creek confluence near Franklin, Venango County, Pennsylvania, downstream to Interstate 80 near Emlenton, Venango County, Pennsylvania.

(ii) Map of Unit RF23 follows:

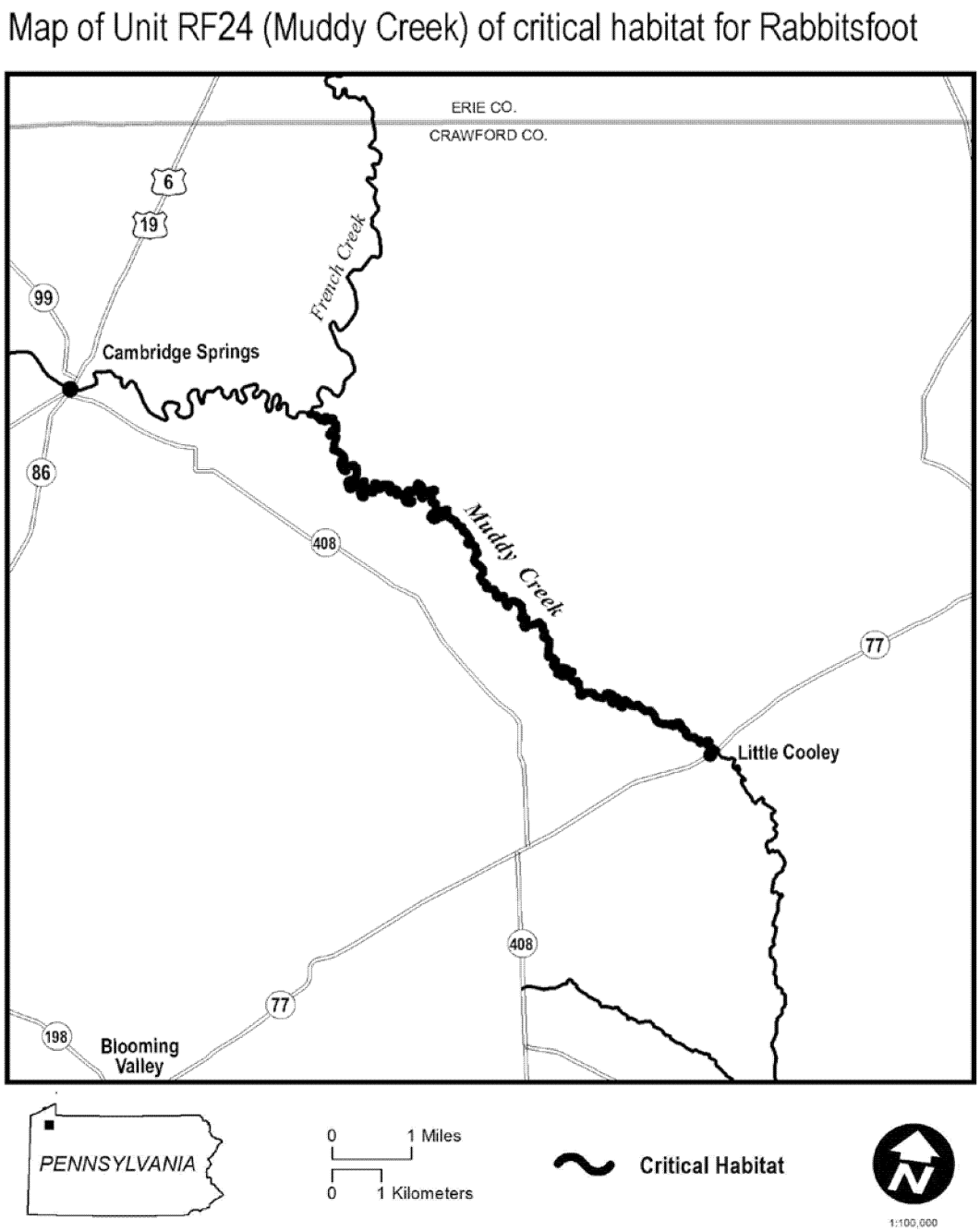
Map of Unit RF23 (Allegheny River) of critical habitat for Rabbitsfoot



(32) Unit RF24: Muddy Creek—Crawford County, Pennsylvania.

(i) *General Description:* Unit RF24 includes 20.1 rkm (12.5 rmi) of Muddy Creek from Pennsylvania Highway 77 near Little Cooley, Crawford County, Pennsylvania, downstream to its confluence with French Creek east of Cambridge Springs, Crawford County, Pennsylvania.

(ii) Map of Unit RF24 follows:

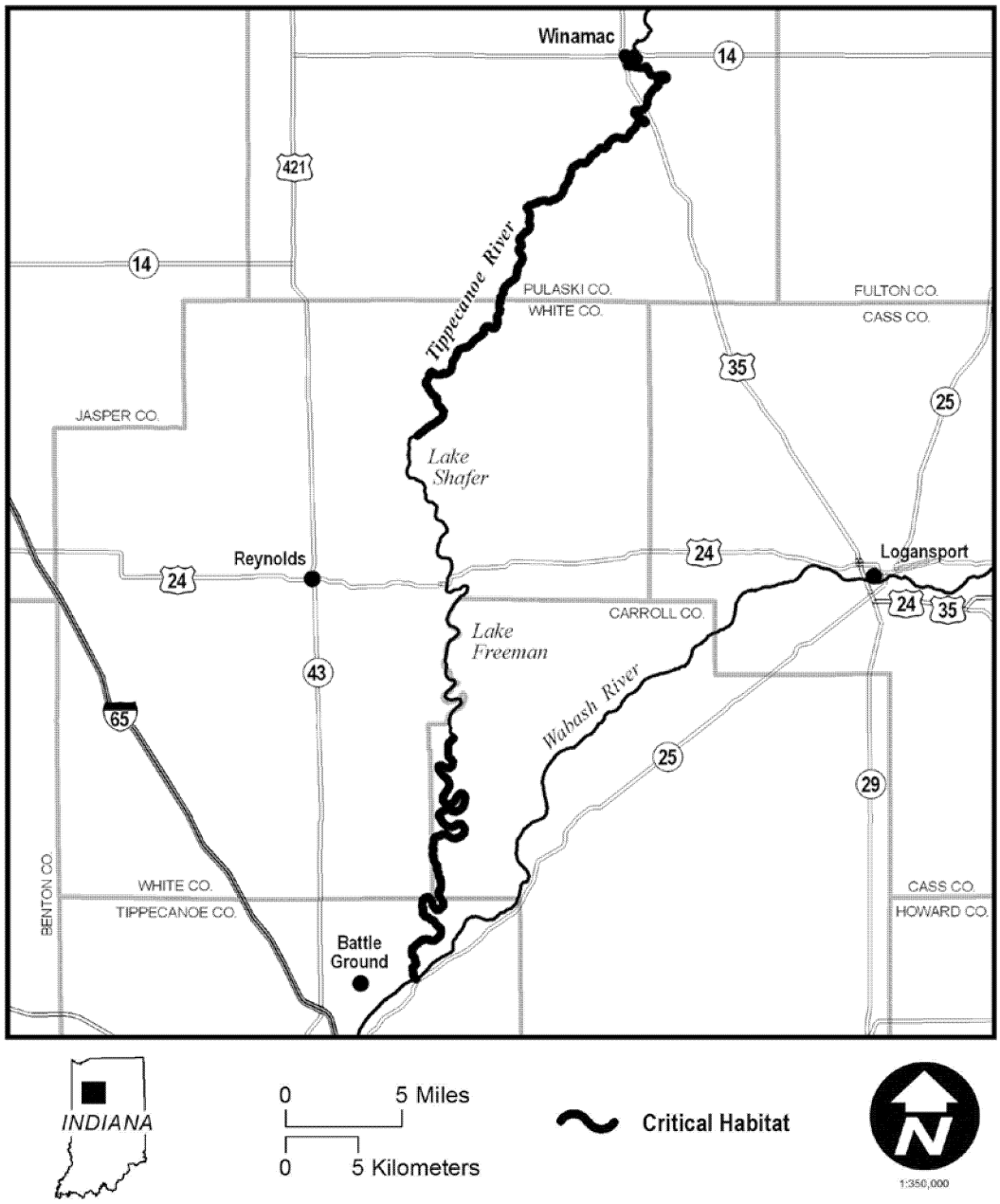


(33) Unit RF25: Tippecanoe River—Carroll, Pulaski, Tippecanoe, and White Counties, Indiana.

(i) *General Description:* Unit RF25 includes 75.6 rkm (47.0 rmi) of the Tippecanoe River from Indiana Highway 14 near Winamac, Pulaski County, Indiana, downstream to its confluence with the Wabash River northeast of Battle Ground, Tippecanoe County, Indiana, excluding Lakes Shafer and Freeman and the stream reach between the two lakes.

(ii) Map of Unit RF25 follows:

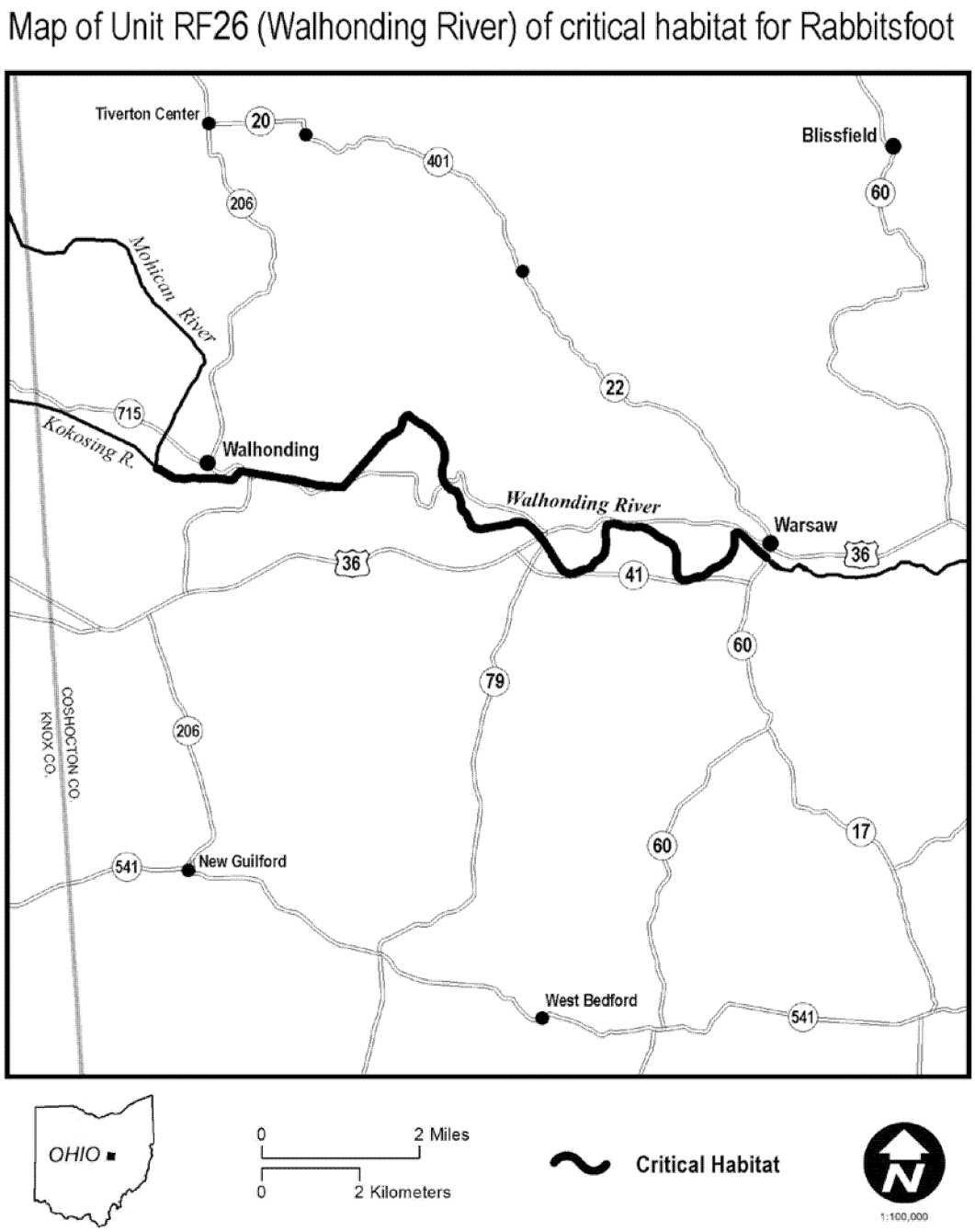
Map of Unit RF25 (Tippecanoe River) of critical habitat for Rabbitsfoot



(34) Unit RF26: Walhonding River—Coshocton County, Ohio.

(i) *General Description:* Unit RF26 includes 17.5 rkm (10.9 rmi) of the Walhonding River from the convergence of the Kokosing and Mohican Rivers downstream to Ohio Highway 60 near Warsaw, Coshocton County, Ohio.

(ii) Map of Unit RF26 follows:

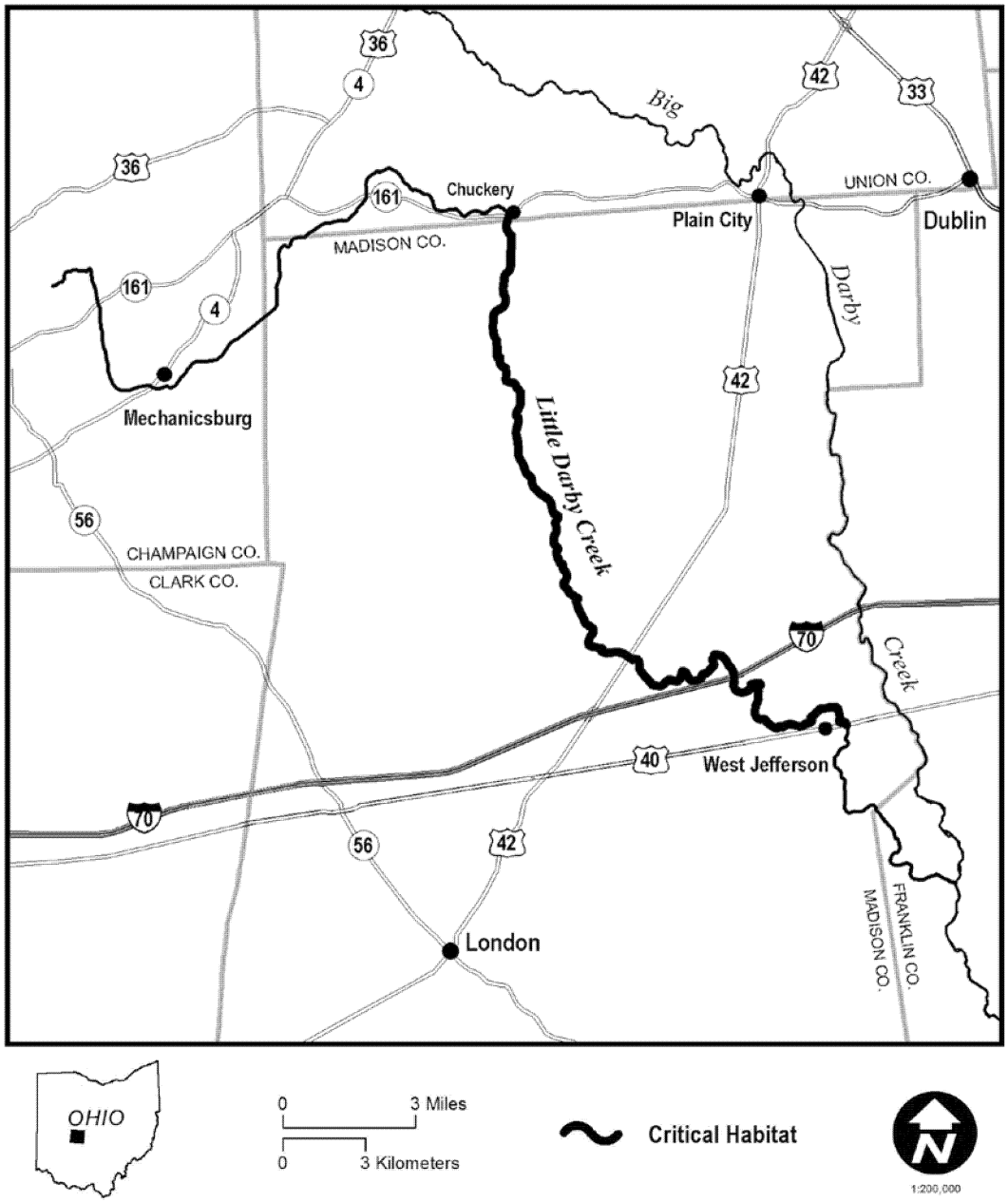


(35) Unit RF27: Little Darby Creek—Madison and Union Counties, Ohio.

(i) *General Description:* Unit RF27 includes 33.3 rkm (20.7 rmi) of Little Darby Creek from Ohio Highway 161 near Chuckery, Union County, Ohio, downstream to U.S. Highway 40 near West Jefferson, Madison County, Ohio.

(ii) Map of Unit RF27 follows:

Map of Unit RF27 (Little Darby Creek) of critical habitat for Rabbitsfoot

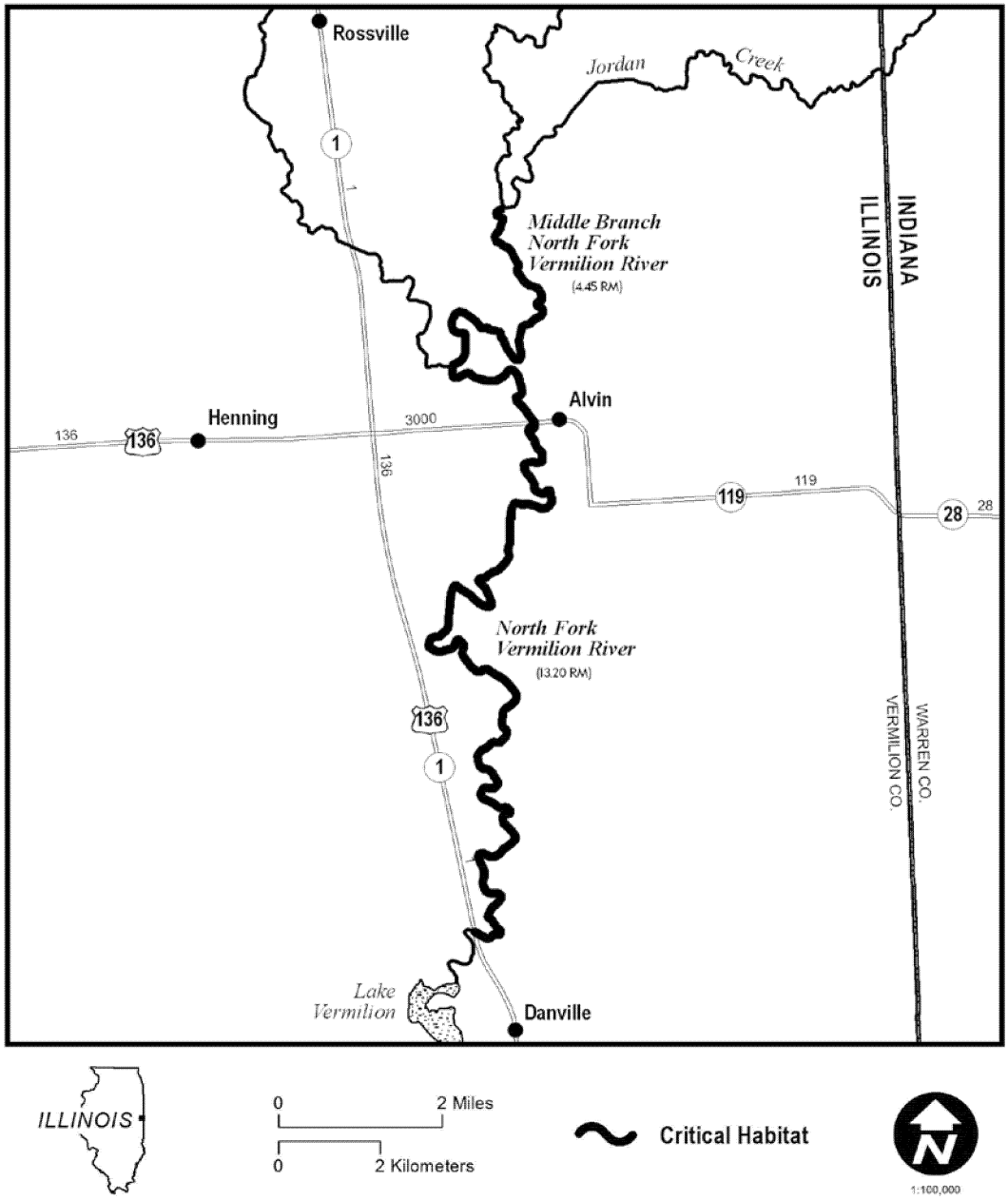


(36) Unit RF28: North Fork Vermilion River and Middle Branch North Fork Vermilion River, respectively—Vermilion County, Illinois.

(i) *General Description:* Unit RF28 includes a total of 28.5 rkm (17.7 rmi). Unit RF28 includes 21.2 rkm (13.2 rmi) of the North Fork Vermilion River from the confluence of Middle Branch North Fork Vermilion River downstream to Illinois Highway 1 and U.S. Highway 136 upstream of Lake Vermilion, Vermilion County, Illinois. Unit RF28 also includes 7.2 rkm (4.5 rmi) of the Middle Branch North Fork Vermilion River from the Jordan Creek confluence northwest of Alvin, Illinois, downstream to its confluence with North Fork Vermilion River west of Alvin, Vermilion County, Illinois.

(ii) Map of Unit RF28 follows:

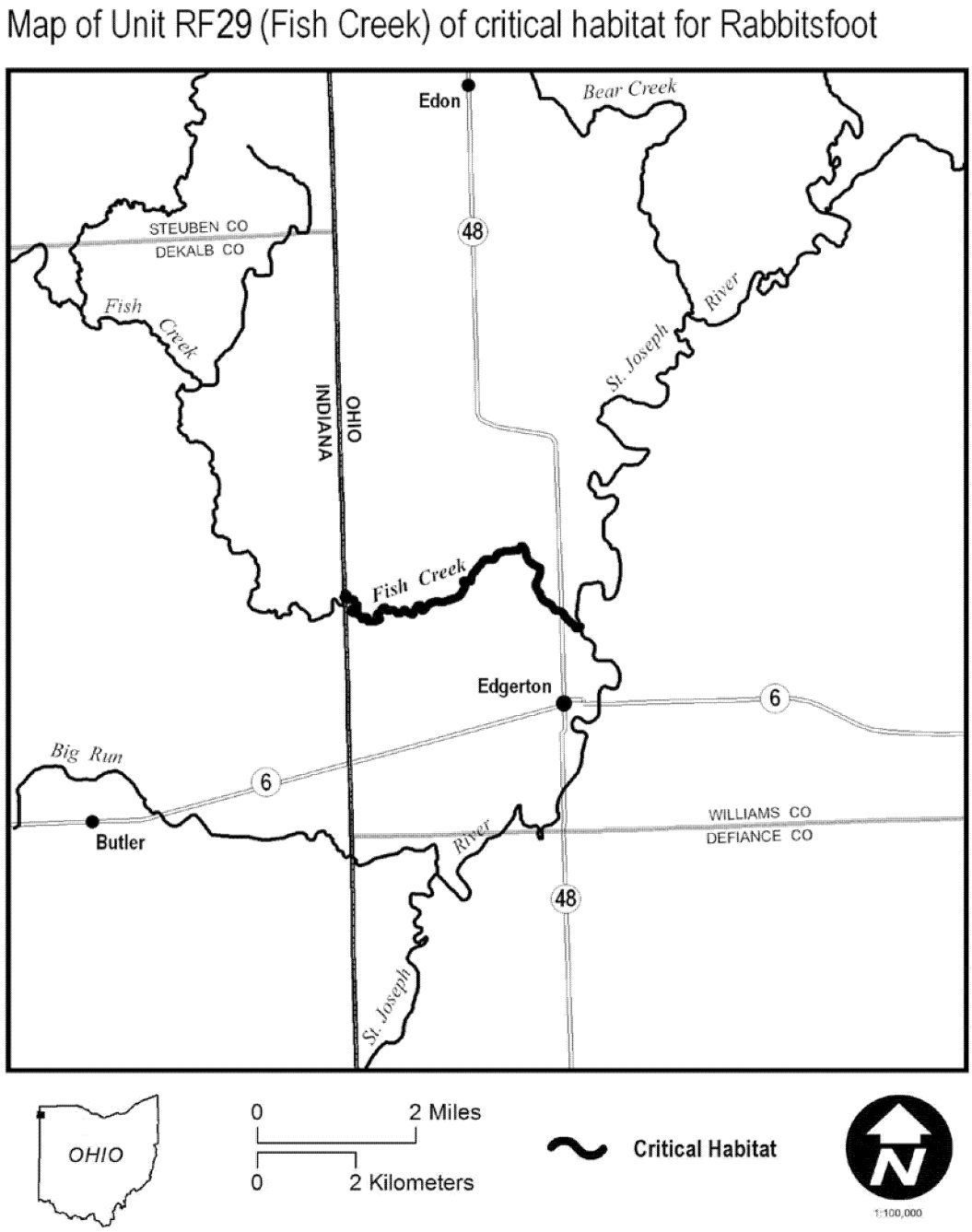
Map for Unit RF28 (North Fork Vermilion River and Middle Branch North Fork Vermilion River) of critical habitat for Rabbitsfoot



(37) Unit RF29: Fish Creek—Williams County, Ohio.

(i) *General Description:* Unit RF29 includes 7.7 rkm (4.8 rmi) of Fish Creek from Indiana and Ohio State line northwest of Edgerton, Ohio, downstream to its confluence with the St. Joseph's River north of Edgerton, Williams County, Ohio.

(ii) Map of Unit RF29 follows:

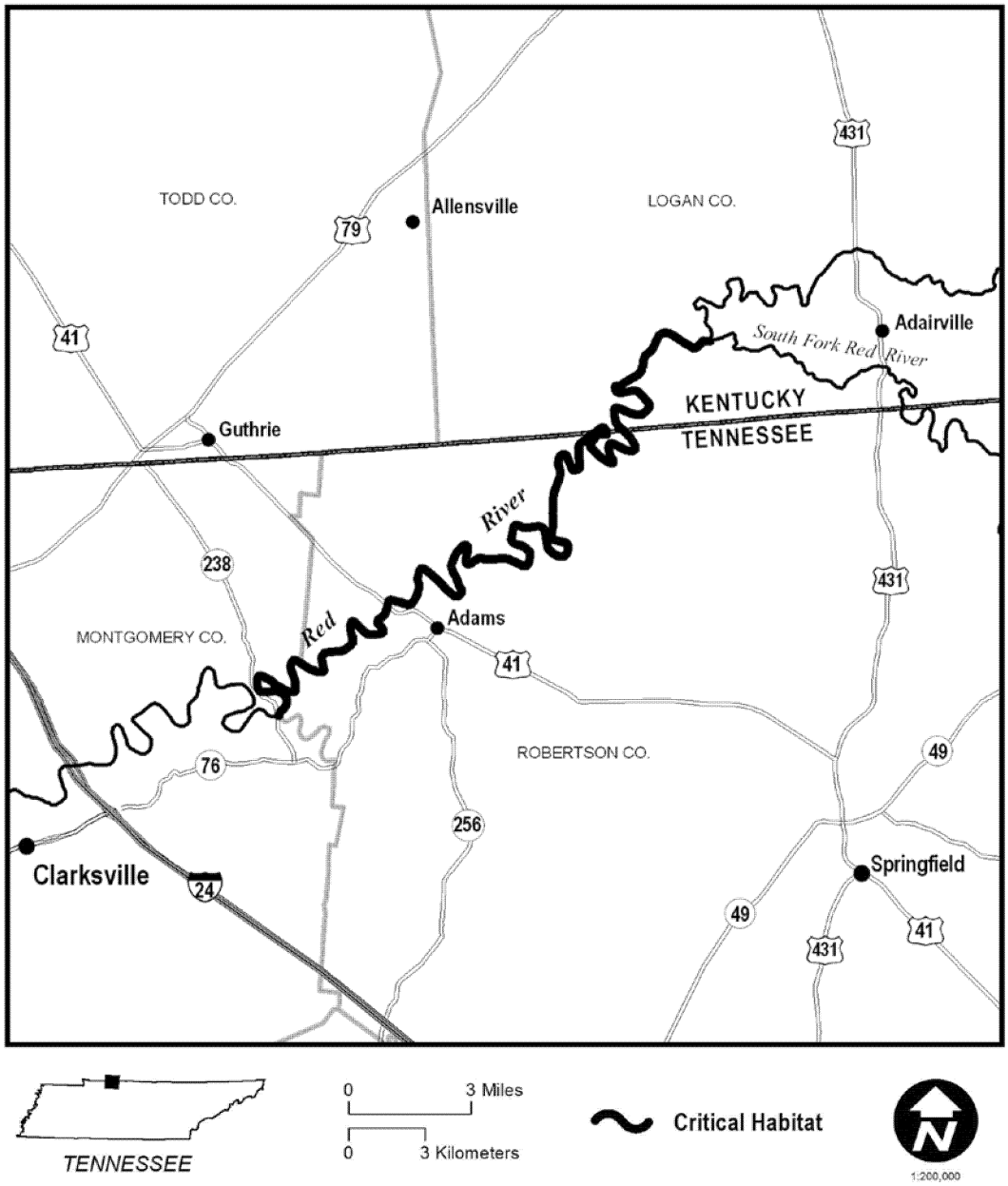


(38) Unit RF30: Red River—Logan County, Kentucky; and Montgomery and Robertson Counties, Tennessee.

(i) *General Description:* Unit RF30 includes 50.2 rkm (31.2 rmi) of the Red River from the South Fork Red River confluence west of Adairville, Kentucky, downstream to the Sulphur Fork confluence southwest of Adams, Tennessee.

(ii) Map of Unit RF30 follows:

Map of Unit RF30 (Red River) of critical habitat for Rabbitsfoot

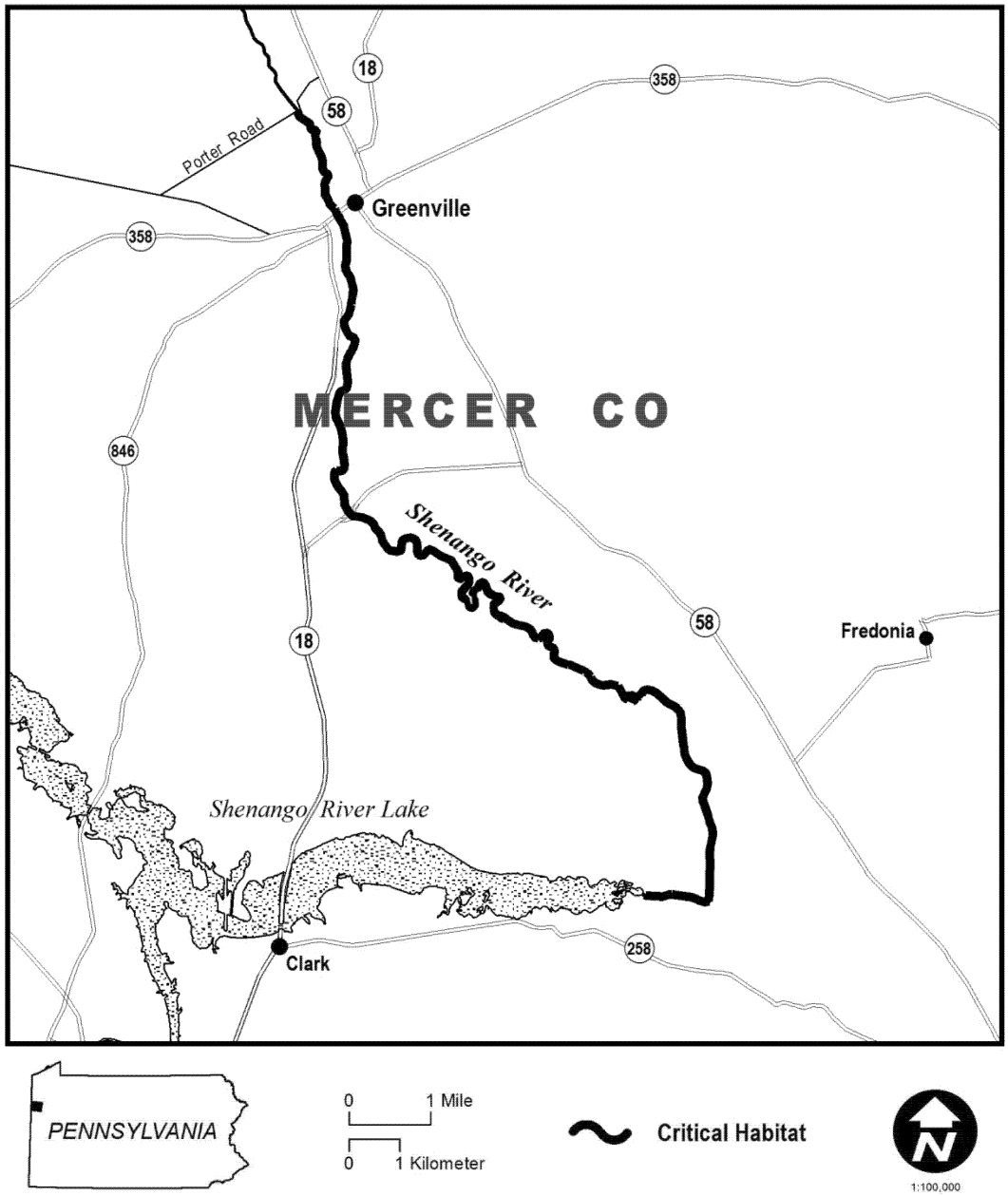


(39) Unit RF31: Shenango River—Mercer County, Pennsylvania.

(i) *General Description:* Unit RF31 includes 24.8 rkm (15.4 rmi) of the Shenango River from Porter Road near Greenville, Pennsylvania, downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania.

(ii) Map of Unit RF31 follows:

Map of Unit RF31 (Shenango River) of critical habitat for Rabbitsfoot



* * * * *

Dated: February 25, 2015.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2015–09200 Filed 4–29–15; 8:45 am]

BILLING CODE 4310–55–P

FEDERAL REGISTER

Vol. 80 Thursday,
No. 83 April 30, 2015

Part IV

The President

Proclamation 9260—Workers Memorial Day, 2015

Federal Register
Vol. 80, No. 83
Thursday, April 30, 2015

Presidential Documents

Title 3—

The President

Proclamation 9260 of April 27, 2015

Workers Memorial Day, 2015

By the President of the United States of America

A Proclamation

Across the United States, as dedicated Americans clock in at factories, walk onto construction sites, put on their hospital uniforms, and report to do the daily work that drives our Nation's progress, they give meaning to the simple yet profound belief that if you work hard and take responsibility, you can get ahead. However, each year millions of people have their shifts cut short by work-related injuries and illnesses, and on average, 12 Americans lose their lives on the job every day. On Workers Memorial Day, we honor those we have lost and recommit to improving conditions for all who work hard to provide for their families and contribute to our country.

Throughout our history, the American worker has labored not only to erect buildings and cities, but also to raise the standards of our Nation's workplaces. Through protests and picket lines, by organizing and raising their voices together, workers have won small and large victories that have pushed our country closer to ensuring safer and healthier jobs for all. Over 40 years ago, the right to a safe workplace was written into law with the Federal Coal Mine Health and Safety Act of 1969 and the Occupational Safety and Health Act of 1970. Since then, job-related deaths, injuries, and illnesses have decreased; but there is more progress to be made, and we cannot grow complacent in the fight for better working conditions.

My Administration continues to bolster workers' rights with millions of dollars in funding targeted at inspecting hazardous workplaces and helping employers understand and comply with safety and health regulations. Additionally, to ensure companies receiving taxpayer money maintain a safe workplace, last year I signed an Executive Order to crack down on Federal contractors who put workers' safety and pay at risk. By creating incentives for better compliance and a process for contractors to follow basic workplace protection laws, we are sending a strong message throughout the economy: if you want to do business with the United States, you must respect our workers.

American laborers form the backbone of our economy—but our economic growth should never come at the cost of their safety or well-being. Those who work every day to put food on the table, provide for their families, or care for their fellow citizens should know their country has their back. Today, as we remember women and men taken from us too soon, we remind ourselves that even one life lost to a preventable job-related incident is one too many, and we focus our efforts on creating a world where success at the workplace is determined only by the strength of our work ethic and the scope of our dreams.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 28, 2015, as Workers Memorial Day. I call upon all Americans to participate in ceremonies and activities in memory of those killed or injured due to unsafe working conditions.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-seventh day of April, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

[FR Doc. 2015–10325
Filed 4–29–15; 11:15 am]
Billing code 3295–F5

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